Siebel Life Sciences Guide

Version 8.0, Rev. D
February 2010

ORACLE®

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1 What's New in This Release

What's New in Siebel Life Sciences Guide, Version 8.0, Rev. D

Table 1 lists changes in Version 8.0, Rev. D of the documentation to support release 8.0 of the software.

Table 1.   What's New in Siebel Life Sciences Guide, Version 8.0, Rev. D

Topic	Description
"Using Signature Control" on page 469	Added a new section about about signature control. With signature control, users can capture signature samples to distribute to qualified contacts.

What's New in Siebel Life Sciences Guide, Version 8.0, Rev. C

Table 2 lists changes in Version 8.0, Rev. C of the documentation to support release 8.0 of the software.

Table 2.   What's New in Siebel Life Sciences Guide, Version 8.0, Rev. C

Topic	Description
"About Features for Call Planning Specific to the Japanese Pharmaceutical Market" on page 122	Added a section that provides an overview about new features that address regulatory restrictions in the Japanese pharmaceutical market.
"Managing the PMS and Pre-Explain PMS Features" on page 123	Added a section about tasks specific to Post Market Surveillance (PMS) and Pre-Explain PMS features. With PMS users can create and track obligatory visits with hospital contacts before and after a new drug is launched.
"Managing the PID Feature" on page 126	Added a section about tasks specific to Product Insert Delivery (PID). With PID users can create and track obligatory visits with hospital contacts when a package insert for a drug is modified.

Table 2.   What's New in Siebel Life Sciences Guide, Version 8.0, Rev. C

Topic	Description
"Marking Package Insert Delivery and Post Market Surveillance Calls as Complete" on page 182	Added a section about marking PMS and PID calls as complete.
Created several new topics in Chapter 12, "Managing Accounts Contacts in Life Sciences," to address new features introduced for call planning specific to the Japanese pharmaceutical market.	Describes functionality that addresses the following tasks: ■ Deleting Multiple Calls in the Accounts Contacts Call Planning Screen ■ Switching to Reporting Mode in the Accounts Contacts Call Planning Screen ■ Displaying Calls Created by Other Representatives

What's New in Siebel Life Sciences Guide, Version 8.0, Rev. B

Table 3 lists changes in Version 8.0, Rev. B of the documentation to support release 8.0 of the software.

Table 3.   What's New in Siebel Life Sciences Guide, Version 8.0, Rev. B

Topic	Description
"Using Personalized Content Delivery" on page 453	Added a chapter about how to use Personalized Content Delivery (PCD). PCD enables sales representatives to convey product messages to customers during face-to-face sales calls.
"Configuring Personalized Content Delivery" on page 493	Added a section about configuring PCD to Appendix A.

What's New in Siebel Life Sciences Guide, Version 8.0, Rev. A

Table 4 lists changes in Version 8.0, Rev. A of the documentation to support release 8.0 of the software.

Table 4.   What's New in Siebel Life Sciences Guide, Version 8.0, Rev. A

Topic	Description
"Regulatory Reporting" on page 409	Added new fields for reporting adverse events on Form 3500A so that it complies with the new FDA mandate.

Table 4. What's New in Siebel Life Sciences Guide, Version 8.0, Rev. A

Topic	Description
"Setting Up MedEd Events (End User)" on page 242	Updated procedures about allocating event costs across team members and across product lines.
Appendix B, "Configuring Data for Oracle Pharma Sales Analytics"	Updated references from Siebel Analytics products to reflect the current Oracle analytics product names in various places throughout the appendix.

What's New in Siebel Life Sciences Guide, Version 8.0

Table 5 lists changes in Version 8.0 of the documentation to support release 8.0 of the software.

Table 5.   What's New in Siebel Life Sciences Guide, Version 8.0

Topic	Description
Created new topic "Viewing Departments and Contacts (End User)" on page 75	Added topic about viewing departments and contacts.
Added support information to the topic "About Electronic Signature Capture" on page 165	Added information about support of Signature capture on tablet PCs using Windows XP on versions 7.7, 7.8, and 8.0.
Created new Chapter 12, "Managing Accounts Contacts in Life Sciences"	Describes the functionality that addresses the following distinctive traits of the Japanese pharmaceutical market: ■ Hospital-Physician relationships ■ Hospital department support ■ Hospital-Physician targeting information ■ Weekly calendar with call-planning capabilities ■ Contact call with account information
Added Accounts Contacts information to Chapter 17, "Importing Data into Life Sciences"	Added Accounts Contacts information to Data and Related Interface Tables.
New functionality added to Chapter 18, "Setting Up and Carrying Out a Clinical Trial"	Added the following new topics: ■ Setting Up a Protocol ■ Tracking and Revising Team Assignment History ■ Creating and Revising Protocol Versions ■ Setting Up Regions ■ Creating a Site (End User)
Added functionality to Chapter 19, "Managing Sites and Clinical Contacts"	Added the following new topics: ■ Capturing Different Types of Addresses for Each Site (End User) ■ Applying Protocol Site Activity Templates ■ Creating CRF Tracking Activities ■ Creating Site Correspondence Activities ■ Adding Notes to a Site
Removed previous Chapter 22 Siebel Advanced Contracts	Moved this chapter to *Siebel Field Service Guide*.

Table 5.   What's New in Siebel Life Sciences Guide, Version 8.0

Topic	Description
Added new topics to Appendix A, "Configuring Siebel Life Sciences"	Added the following new topics to Appendix A: ■ Submitting Contact Details from Third-Party Applications ■ Accounts Contacts Configuration
Created new Appendix B, "Configuring Data for Oracle Pharma Sales Analytics"	Describes how to enter application data in the transactional database, while meeting the requirements of the Siebel Pharma Relationship Management Warehouse (RMW).

2 Overview of Life Sciences

The Siebel Life Sciences product from Oracle comprises Siebel Pharma, Siebel Medical, and Siebel Clinical. Siebel Life Sciences is the only integrated professional and investigator database that captures, tracks, and routes information to other parts of an organization, including the mobile sales force and customer service centers.

This chapter contains the following topics:

- "About Siebel Pharma" on page 25
- "About Siebel Medical" on page 26
- "About Siebel Clinical" on page 28
- "Product Modules and Options" on page 29
- "Business Functions of Screen Tabs in Siebel Life Sciences" on page 29

About Siebel Pharma

Siebel Pharma is a suite of business applications specifically designed for the pharmaceutical industry. Siebel Life Sciences provides the industry's only integrated solution that allows information captured through multiple channels to be shared between sales and marketing, clinical affairs, customer services and other parts of an organization.

Siebel Pharma provides:

- Flexible contact management, supporting a wide range of contact types, both prescribers and nonprescribers, including physicians, pharmacists, nurses, office staff, and business administrators
- Account management, supporting a wide range of account types, such as hospitals, pharmacies, health maintenance organizations (HMOs), clinics, wholesalers, and group purchasing organizations (GPOs)
- Advanced, specific querying and list generation, allowing product promotion to targeted accounts and health care professionals
- Activity management, tightly integrated with the Siebel Calendar, promoting streamlined call planning and call reporting
- Medical education event planning, aiding efficient planning and preparation for many types of medical education events by tracking speakers, invitees, meeting-related activities, and expenses
- Smart Calls, which are call report templates supporting true one-button call reporting
- Comprehensive analysis charts, presenting sales and prescription (Rx) trends by postal code, brick (retail sales analysis territory), territory, plan, and prescriber

■ Dedicated formulary-opportunity management, allowing focused product promotion and opportunity tracking

■ Sales effectiveness tools and methodologies, including Target Account Sales (TAS) and Enterprise Selling Process (ESP), to shorten the sales cycles and increase account revenue and production

■ Contract and pricing management, including contract creation, approval, execution, renewal, and contract-based pricing

■ Enterprise-wide product information for employees, allowing consistent, accurate, and up-to-date information sharing across sales teams and sales forces

■ Simplified sampling workflow for users and administrators, supporting shipments in or out, orders, inventory counts, adjustments, and reconciliation, as well as tracking by lot numbers

■ Support for a full customer service center that handles medical inquiries, adverse events, and other related issues

■ Handling of a large number of inbound telephone calls, faxes, email, and Internet correspondence for customer service, sales, and medical support

■ Support for outbound calling for telesales, telemarketing, and meeting planning

About Siebel Medical

Siebel Medical is a suite of business applications designed specifically for the medical products industry to increase revenue and profitability through strategic customer–partner relationship management, enhanced customer and partner productivity and reduced cost of process inefficiencies.

Siebel Medical provides:

■ Flexible contact management, supporting a wide range of contact types, including physicians, nurses, technicians, office staff, and business administrators

■ Account management, supporting a wide range of account types, such as hospitals, health maintenance organizations (HMOs), clinics, wholesalers, and group purchasing organizations (GPOs)

■ Support for creating and executing complex agreements, which helps make sure correct delivery of benefits and execution of penalties

■ Adverse Event and Complaints management to handle the complete life cycle of a complaint or adverse event, including generation of reports and follow-up reports for submission to regulatory agencies

■ Advanced, specific querying and list generation, allowing product promotion to targeted accounts and health care professionals

■ Activity management, integrated with the Siebel Calendar, promoting streamlined customer support and service

■ Medical education event planning, aiding planning and preparation for many types of medical education events by tracking speakers, invitees, meeting related activities, and expenses

- Comprehensive analysis charts, presenting sales and product usage trend by account, postal code, territory, and plan

- Opportunity management, allowing focused product promotion and opportunity tracking

- Enterprise-wide product information for employees, allowing consistent, accurate, and up-to-date information sharing across sales teams, customer support, and field service

- Simplified workflow to manage assets at customer site, supporting shipments in or out, orders, inventory counts, adjustments and reconciliation

- Support for customer service centers that handle medical inquiries, service requests, and other related issues

- Handling of a large number of inbound telephone calls, faxes, email, and Internet correspondence for customer service, sales, and medical support

- Support for outbound calling for telesales, telemarketing, and meeting planning

- Modeling of products and services that incorporates internal expertise, allowing sales representatives to configure and quote error-free customer solutions

- Field-service functions that provide service center agents, warehouse staff, and field service engineers the tools to respond to service requests

- Functionality to receive service calls, verify service agreements and entitlements, enter a service request, search for solutions, create activities for a service request, and assign and dispatch field service engineers

- Detailed customer configuration, management of trunk inventory, tracking of parts consumption and logistics, management of inventory replenishment, and integration of return materials authorizations and service orders

- Service details, including the required skills, tools, and parts for service activities

- Management of preventive maintenance plans, and repair of defective parts

- Tracking and analysis of service costs, preparation of invoices for service, and tracking of payments

- Definition of asset characteristics and recording of readings from medical equipment (assets) in the field for preventive maintenance, billing, and service

- Audit trail of activities

- Single application to manage partner interactions through the entire partner life cycle, from recruitment, registration, profiling, certification, joint planning, and execution through measurement and analysis of partner performance

- Sharing of opportunities, service requests, accounts, solutions, and other business information with partners in the same way as with employees

- Processes and tools to work collaboratively with partners to develop plans to meet strategic goals; helps analyze partnership effectiveness, forecast revenue, manage market development funds, and analyze partner performance

About Siebel Clinical

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

Siebel Clinical includes:

■ Personalized Internet portal to help site coordinators, clinical investigators, and CRAs better manage clinical trials over the Web

■ 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.

■ Site management tools for CRAs, including a Site Calendar, trip reports, document tracking, and payment generation

■ Investigator and site profiling

■ Activity and calendar management for CRAs and study sites

■ Clinical trial status and management reports for study manager and clinical research associates

■ Integrated payment tracking for sites and investigators

■ Support for multiple contracts associated with a site

■ Visit templates for study staff to better plan subject visits and promote protocol adherence

■ Trip report templates for CRAs to facilitate compliance with good clinical practice (GCP)

■ Project and resource management

■ A flexible audit trail engine

Siebel Clinical was designed to allow pharmaceutical and biotech companies, clinical research organizations, 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

Product Modules and Options

You can purchase many Siebel Business Applications modules and use them with 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, 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, your software interface will differ 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 the application. For introductory information on using the Siebel Life Sciences interface, see *Siebel Fundamentals*, *Online Help*, and Chapter 3, "Getting Started with Life Sciences."

Business Functions of Screen Tabs in Siebel Life Sciences

The Siebel Life Sciences interface provides various task-specific screens and views for administrative and end-user functions.

NOTE: Most administrative tasks are performed from administration screens that are accessed from the Site Map. You cannot access these from the screen tabs.

Table 6 lists the most frequently used Siebel Life Sciences screens and the functions of the views in those screens.

Table 6.   Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Accounts	Manage information about accounts (such as hospitals, HMOs, clinics, wholesalers, GPOs, and pharmacies) and affiliate accounts, contacts, and other information about a particular account.	Chapter 5, "Administering and Managing Accounts in Life Sciences," in this guide
Accounts Contacts	Manage information about account-contact affiliations within dedicated Accounts Contacts List views, and also within an Accounts Contacts Weekly Call Planning screen. The Account-Contact records displayed in these screens are managed within the Siebel Pharma application as a set of separate Targeting records for each Sales Representative Position.	Chapter 12, "Managing Accounts Contacts in Life Sciences," in this guide
Activities	Manage activities with contacts and accounts, and create contact and account calls (with or without Smart Calls).	Chapter 7, "Planning Calls in Pharma," in this guide and *Siebel Applications Administration Guide*

Table 6.   Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Agreements	Manage information about agreements, administrative contracts, and entitlements.	*Siebel Field Service Guide*
Analysis	Display prescriber, account, plan, payer, and territory-level sales and Rx data.	Chapter 13, "Analyzing Syndicated Data," in this guide
Assets	Manage information about products sold to accounts.	*Siebel Field Service Guide*
Business Plans	Create business plans for MCO (Managed Care Organizations) and PBMs (Pharmacy Benefit Managers).	Chapter 11, "Managing Managed Care Accounts," in this guide
Calendar	Create and display activities (including to-do activities) and share calendar information with coworkers.	Chapter 7, "Planning Calls in Pharma," in this guide and *Siebel Fundamentals*
Campaigns	Manage outbound communications with prospects targeted for a particular marketing effort.	*Siebel Marketing Installation and Administration Guide* and *Siebel Marketing User Guide*
Clinical Programs	Manage information about clinical trial programs.	Chapter 18, "Setting Up and Carrying Out a Clinical Trial," in this guide
Contacts	Manage information about health care professionals (such as formulary directors, hospital administrators, pharmacists, and physicians) and their affiliations with other contacts and accounts.	Chapter 4, "Managing Contacts in Life Sciences," in this guide
Corrective Actions	Manage corrective actions for adverse events and complaints.	Chapter 26, "Managing CAPAs," in this guide.
Document Tracking	Track documents at multiple levels (Site, Region, or Protocol) for multiple entities (Contact or Account)	In this guide: Chapter 18, "Setting Up and Carrying Out a Clinical Trial" Chapter 19, "Managing Sites and Clinical Contacts" Chapter 5, "Administering and Managing Accounts in Life Sciences" Chapter 4, "Managing Contacts in Life Sciences"
Expense Reports	Manage expense report information for your expenses, or your team's expenses.	*Siebel Project and Resource Management Administration Guide*

Table 6.   Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Forecasts	Create business forecasts based on opportunities or products.	*Siebel Forecasting Guide*
Home	The first screen you see when you log in to the Siebel Life Sciences application. It is a centralized screen that summarizes contacts, accounts, and activities.	*Siebel Fundamentals*
List Management	Perform queries on profile information (such as best times to call and market ranking), as well as sales and Rx data, in order to generate target lists of contacts or accounts.	Chapter 7, "Planning Calls in Pharma," in this guide
Literature	Display company- and industry-related literature cataloged by the Oracle administrator.	*Siebel Applications Administration Guide*
MedEd	Manage medical education events.	Chapter 15, "Managing MedEd Events," in this guide
Objectives	Define objectives for contacts and accounts and monitor progress made toward meeting goals.	Chapter 16, "Setting and Achieving Objectives," in this guide
Opportunities	Manage formulary opportunities and affiliate contacts, accounts, and other information with a particular opportunity.	*Siebel Applications Administration Guide*
Orders	Manage information about samples ordered by physicians through your company's Web site, as well as all goods and service orders recorded by the service organization.	*Siebel Order Management Guide*
Payments	Keep track of payments pertaining to clinical trial activities at sites.	Chapter 20, "Setting Up and Making Subject Activity Payments," in this guide
Product Issues	Managing adverse events and complaints made against medical products.	Chapter 24, "Investigating Adverse Events and Complaints," Chapter 29, "Communicating with Customers for AECM," and Chapter 29, "Communicating with Customers for AECM," in this guide
Products	Display current product information, including key features and product trends.	Chapter 6, "Managing Products for Life Sciences," in this guide

Table 6.   Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Protocols	Maintain information about clinical trial protocols.	Chapter 18, "Setting Up and Carrying Out a Clinical Trial," in this guide
Quotes	Automatically generate quotes tailored to meet customer requirements.	*Siebel Order Management Guide*
Receiving	Record and review information relating to a physical receipt of material.	*Siebel Field Service Guide*
Regions	Manage region or country level information about clinical trial protocols.	Chapter 18, "Setting Up and Carrying Out a Clinical Trial," in this guide
Regulatory Reports	Create Managing complaints made against medical products.	Chapter 27, "Regulatory Reporting," in this guide
Repairs	Track defective products returned to a service center for repair.	Chapter 13, "Analyzing Syndicated Data," in this guide and *Siebel Field Service Guide*
Routes	Create routes to schedule regular visits to groups of accounts.	Chapter 7, "Planning Calls in Pharma," in this guide
Samples	Organize phases of samples workflow: shipments, orders, adjustments, inventory counts, and reconciliation.	Chapter 8, "Managing Pharma Samples," in this guide
Service Requests	Manage requests for medical or product information, adverse events, complaints, and related activities and attachments.	Chapter 23, "Capturing Adverse Events and Complaints," in this guide and *Siebel Field Service Guide*
Shipping	Record and review information relating to a physical shipment of material.	*Siebel Field Service Guide*
Site Management	Manage information about a particular clinical trial site, including associated contacts, subjects, activities, payments, and site visits.	Chapter 19, "Managing Sites and Clinical Contacts," in this guide
Site Visits	Manage site visits to a clinical site, and also monitor follow-up activities associated with these visits.	Chapter 18, "Setting Up and Carrying Out a Clinical Trial"
Smart Calls	Create and edit Smart Call templates that are applied in the Contact Call Detail and Account Call Detail views.	Chapter 10, "Creating Smart Calls," in this guide

Table 6.   Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
SmartScripts	Define the application workflow for an interactive situation in a script. These interactive situations could include inbound communications (such as customer service) and outbound contacts (such as telemarketing).	*Siebel SmartScript Administration Guide*
Solutions	Enter and display resolutions successfully used for reported problems.	*Siebel Field Service Guide*
Subjects	Manage information about clinical trial subjects.	Chapter 18, "Setting Up and Carrying Out a Clinical Trial," in this guide
Time Off Territory	Manage information about time when sales representatives and field personnel are out of their territories, not working on activities directly associated with accounts, contacts, or opportunities.	Chapter 14, "Tracking Time Off Territory," in this guide
Time Sheets	Track employee time, by project, for compensation and billing purposes.	*Siebel Project and Resource Management Administration Guide*

3 Getting Started with Life Sciences

This chapter covers the following topics:

- "About Getting Started with Life Sciences" on page 35
- "Administrative Setup Tasks for Life Sciences" on page 36
- "About the My Team's Filter" on page 41
- "Using Assignment Manager in Siebel Life Sciences" on page 41
- "Setting Up Mobile Web Clients for Position Rollup" on page 44

About Getting Started with Life Sciences

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

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 you will 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 those in the administration guide whereas others might be additional tasks. Make sure you review Table 7 on page 36 before following the procedures in *Siebel Applications Administration Guide*.

This guide assumes that you have already installed Siebel Life Sciences or completed an upgrade from another Siebel application. If you have not, 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.

NOTE: The Siebel Bookshelf is available on Oracle Technology Network (OTN) and Oracle E-Delivery. It might also be installed locally on your intranet or on a network location.

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 for the operating system you are using, and *Siebel System Administration Guide*.

CAUTION: Do not perform system administration functions on your local database. Although there is nothing to prevent you from doing this, it can have serious results, such as data conflicts, an overly large local database, or a large number of additional transactions to route.

Administrative Setup Tasks for Life Sciences

Table 7 lists the administrative setup procedures that are specific to Siebel Life Sciences 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 your application, use Table 7 in combination with the main resource, *Siebel Applications Administration Guide*.

Table 7.   Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Define sales territories	■ Define sales territories and set up the territory assignment process	*Siebel Assignment Manager Administration Guide* and *Siebel Territory Management Guide*
Define medical specialties	■ Defining medical specialties ■ Defining account specialties ■ Specifying a contact's primary specialty	Chapter 4, "Managing Contacts in Life Sciences"
Set up bricks	■ Defining bricks ■ Associating a brick with a contact address	Chapter 4, "Managing Contacts in Life Sciences"
Define decision issues	■ Defining decision issues	Chapter 4, "Managing Contacts in Life Sciences" Chapter 6, "Managing Products for Life Sciences"

Table 7.   Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Managing Samples	■ Establishing and reconciling initial master inventory ■ Transferring inventory to end users ■ Monitoring samples activities (disbursements, orders, transfers between employees, user inventory counts, and inventory adjustments) ■ Setting up and maintaining a home-office master inventory (optional) ■ Defining lot numbers (optional) ■ Managing electronic signatures ■ Identifying sample locations in the event of recalls ■ Determine the number of open (unreconciled) inventory periods allowed ■ Disabling samples tracking by lot number ■ Allowing sample product reconciliation without lot numbers (optional)	Chapter 8, "Managing Pharma Samples" Appendix A, "Configuring Siebel Life Sciences"
Specifying a Competitor	■ Deleting an account ■ Creating or identifying a competitor	Chapter 5, "Administering and Managing Accounts in Life Sciences" Chapter 4, "Managing Contacts in Life Sciences" Chapter 9, "Recording Calls in Pharma"
Administer Smart Calls	■ Creating a smart call template and making it available to end users	Chapter 10, "Creating Smart Calls" Chapter 8, "Managing Pharma Samples"

Table 7.   Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Managing Accounts Contacts in Life Sciences	■ Activating workflows for accounts contacts ■ Enabling server components for accounts contacts ■ Setting up targeting data for a new period ■ Activating new targeting data ■ Generating column maps for accounts contacts list ■ Creating product data to display in accounts contacts List	Chapter 12, "Managing Accounts Contacts in Life Sciences"
Configuring Time Off Territory	■ Configuring Time Off Territory approval process	Chapter 14, "Tracking Time Off Territory"
Administering MedEd	■ Setting up funds for medical education plans and associating them ■ Creating MedEd master plans ■ Creating MedEd activity templates ■ Customizing the list of available drop-down values and adding literature items to the application ■ Designating contacts as medical education speakers	Chapter 15, "Managing MedEd Events" *Siebel Enterprise Integration Manager Administration Guide*
Creating a Clinical Program	■ Creating a protocol ■ Revising protocols ■ Setting up regions (Optional) ■ Defining a subject visit template	Chapter 18, "Setting Up and Carrying Out a Clinical Trial" Chapter 6, "Managing Products for Life Sciences" Chapter 19, "Managing Sites and Clinical Contacts"
Managing Sites	■ Creating a protocol site template ■ Creating contact and account templates ■ Maintaining contact and account information ■ Setting up site contracts	Chapter 19, "Managing Sites and Clinical Contacts"

Table 7.   Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Setting Up Standard Payments	■ Setting up standard payment amounts in subject visit templates ■ Adjusting payment amounts and generating payments for sites	Chapter 20, "Setting Up and Making Subject Activity Payments"
Creating Trip Report Templates	■ Creating trip report templates ■ Approving trip report templates	Chapter 21, "Administering and Using Clinical Trip Reports"
Creating Project Templates	■ Creating project templates	Chapter 22, "Managing Clinical Projects"
Importing Data	■ Importing data with EIM ■ Importing, extracting, and routing syndicated data ■ Charting denormalized syndicated data	Chapter 17, "Importing Data into Life Sciences" Appendix A, "Configuring Siebel Life Sciences"
Administering products	■ Creating an external product ■ Creating an internal product or a market ■ Making a product inactive ■ Specifying additional product features ■ Entering information on related products ■ Associating related literature ■ Entering product comparison information ■ Creating a price list ■ Associating a price list with a product ■ Decision issues or product issues	Chapter 6, "Managing Products for Life Sciences"

Table 7.   Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Configuring Siebel Life Sciences	■ Targeting ■ New visit type ■ Charting denormalized syndicated data ■ Modifying business component user properties ■ Configuring the visit generation buttons ■ Changing read-only status of fields ■ MedEd special C++ classes ■ Submitting contact details from third-party applications	Appendix A, "Configuring Siebel Life Sciences"
Configuring Data for Oracle Pharma Sales Analytics	■ Transactional data requirements ■ Configuring product hierarchies and product costs ■ Configuring Product Catalog and Category Hierarchies ■ Setting Up Sales Objectives ■ Entering call activity data ■ Configuring sales territories for Oracle Pharma Sales Analytics ■ Creating target lists using Oracle Business Intelligence	Appendix B, "Configuring Data for Oracle Pharma Sales Analytics"
Editing the epharma.cfg	If you are using Oracle Pharma Sales Disconnected Analytics, edit the epharma.cfg file to allow: ■ Integration of Pharma Sales Analytics Home Page with Pharma Sales Disconnected Analytics ■ Importation of target list contacts into Oracle Pharma Sales Disconnected Analytics Client	The *Siebel Analytics Installation and Configuration Guide* (Integrating Oracle BI Delivers with Oracle Business Intelligence Applications)

About the My Team's Filter

The Show drop-down list 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 what records 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, 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 8 lists the default setting of the Manager List Mode user property for some Siebel Life Sciences screens and business components.

Table 8.   The Default Setting for the Manager List Mode Use Property

Screen	Business Component	Manager List Mode
Accounts	Accounts	Inactive
Contacts	Contact	Inactive
MedEd	Pharma ME Event Professional Invitee	Active
Objectives	Objective	Active
Protocols	Clinical Protocol	Active
Site Management	Clinical Protocol Site	Active

Using Assignment Manager in Siebel Life Sciences

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 on using and implementing Siebel Assignment Manager, see *Siebel Assignment Manager Administration Guide*. For additional information on creating territories and running territory realignments, see *Siebel Territory Management Guide*.

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

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 9 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 Industry SIC Code.

Table 9.   Assignment Objects Changes in Siebel Life Sciences

Assignment Object	Modifications
Account	The assignment criteria SIC Code has been renamed Account Class of Trade. Its assignment criteria are: ■ Account City State Country ■ Account Brick 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*. Its assignment criteria are: ■ Contact ■ Contact Medical Specialty Code ■ Contact Wildcard ■ Contact City ■ Contact State ■ Contact Country ■ Contact Zip Code ■ Contact City State Country ■ Contact Brick ■ Medical Specialty ■ Organization ■ Position
Opportunity	Siebel Pharma includes the Product Line or Product Line Wildcard assignment criteria.

Contact Assignments in Siebel Life Sciences

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

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 Contacts, Account Affiliations view tab

   ■ The Direct field in the Accounts, Contact Affiliations view tab

   For more information, see .

■ It does *not* denormalize positions from the opportunity team table to the contact team table.

■ It must be run after running batch mode jobs for contacts and accounts separately. Run three separate batch mode jobs in this order:

   ■ Contacts

   ■ Accounts

   ■ 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 enable 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 parameters:

```
Object Name = Contact Denormalization
Assignment Mode = Denorm
```

■ **Contact Denormalization mode does not evaluate rules.** Therefore, it is not necessary to create a Contact Denormalization rule-based object 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 will not be visible to managers on their local databases. However, if the desired behavior is for managers to see all contacts who are assigned to their team members, regardless the assignment method, set the ASGN_DNRM_ "Y".

Setting Up Mobile Web Clients for Position Rollup

In Siebel Clinical, a clinical research associate (CRA) 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.

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.*

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 > Data Maps view.

3 In the Integration Object Map list, query for Clinical*.

The query returns four 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 In the drop-down menu, 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.

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 > Data Maps view.

3 In the Integration Object Map list, select Import Data Map from the drop-down menu.

4 In the dialog box, select Browse and find PositionRollupDataMap.xml created in the second procedure in this topic,

5 In the Integration Object Map list, query for Clinical*.

The query returns four 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 Managing Contacts in Life Sciences

This chapter covers the following topics:

About Managing Contacts in Life Sciences

In Siebel Life Sciences, a *contact* is typically a physician, nurse, or pharmacist or other medical professional. In a more general sense, a contact can be any individual a pharmaceutical company deems significant to their business process including a formulary director, contracts administrator, or medical education event speaker.

This chapter describes how to manage Siebel Life Sciences contact information. Using the procedures given in this chapter, you will be able to perform the administrator tasks of defining and specifying medical specialities, deleting a contact, defining bricks, and associating contacts to a brick. End users such as sales representatives and managed care account managers can use the Contacts view to create and track a variety of contact information, including contact affiliations, contact and account relationships, contact assessments, and the best times to call on a contact.

Scenario for Managing Contacts

This topic outlines an example process performed by a Siebel administrator and end users. Your company may follow a different process according to its business requirements.

A pharmaceutical company is reviewing the contact information in their database to make sure it is as current and up-to-date as possible. During this update process, the administrator deletes obsolete contacts and associates new contacts with existing bricks (geographic areas).

Sales representatives use Siebel Contacts to manually enter and modify contact information. They add information that helps them track relationships between contacts.

Sales representative can add more depth to contact data by creating user-defined fields called categories. Using categories, representatives can track private or shared information about a contact.

Process of Managing Contacts

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

Administrator Procedures

The following list shows tasks administrators typically perform to manage contacts:

- "Setting Up Primary Specialties" on page 48. Define medical specialities within the system and specify a contact's primary speciality.

- "Deleting a Contact" on page 50.

- "Administering Bricks" on page 50.

- "Associating a Contact with a Brick" on page 51.

End-User Procedures

The following list shows tasks end users typically perform when managing contacts:

- "Creating a Contact (End User)" on page 52.

- "Specifying the Best Time to Call (End User)" on page 54.

- "Indicating Affiliations Between Contacts (End User)" on page 55.

- "Indicating Affiliations Between a Contact and an Account" on page 55.

- "Viewing Pre-Call Information (End User)" on page 56.

- "Tracking Documentation Associated with a Contact (End User)" on page 58.

- "Other Tasks for Managing Contacts" on page 59. Enter contact category information and create contact assessments.

Setting Up Primary Specialties

As a Siebel administrator, you are responsible for defining and entering the primary specialty information about contacts.

The Primary Specialty field is read-only and can be edited only through EIM. The list of specialities is defined in the Primary Specialty view of the Application Administration view.

NOTE: The Primary Specialty field is different from the Rep Specialty field on the Contacts screen. To create additional values for the Rep Specialty drop-down list, follow the procedures on modifying a list of values in the *Siebel Applications Administration Guide*.

To define a specialty

1 Navigate to the Administration - Application screen > Specialty view.

The Primary Specialty view appears.

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

Some fields are described in the following table.

Field	Comments
Code	The Specialty Short Code for the health care provider's designated area of expertise. This is normally provided by the syndicated data provider (for example, AMA, IMS, or NDC).
Name	A full description of the health care provider's designated area of expertise.

NOTE: On initial data load, you can use EIM to load Primary Specialty data into the base table S_MED_SPEC. For more information on using EIM, see *Siebel Enterprise Integration Manager Administration Guide*.

To specify specialties for Contacts

■ Specialties cannot be specified for contacts through the UI. Specialties are loaded into the MED_SPEC_ID field in the S_CONTACT table of the database using EIM.

■ Alternatively, configure the Primary Specialty field so that it can be edited.

Removing Contact Records

Three methods for removing contact records are described.

Merging Contact Records

If you find that two or more contact records contain the same information, merge the records into one in order to keep the database accurate. For more information on merging records, see *Siebel Fundamentals*.

Removing Employees from a Contact's Team

As an alternative to deleting a contact, consider making the Siebel administrator the primary team member so that he or she can remove all other employees from the account's team.

Deleting a Contact

Deleting a contact completely removes the contact from the system. Be aware that deleting a contact could have undesired consequences.

NOTE: If a Contact record is deleted from the Data Administration, Contacts view, any records for that contact in the Signature Audit Administration view display with blank Last Name, First Name, and Reference # fields. To avoid this problem, you might need to enforce a business rule that prevents the delete record function from operating in the Data Administration, Contacts view.

If you are certain that the contact is no longer active, use the following procedure to delete it.

To delete a contact

1 Navigate to the Contacts screen > Contact Administration view. The Contact Administration view appears.

2 In the Contacts list, select and then delete the appropriate contact. The contact is deleted from the list.

Administering Bricks

A brick is a collection of accounts and contacts, normally in a common geographic area. Bricks are sometimes referred to as geo zones. The primary purpose of a brick is to allow a company to publish RSA (retail sales analysis) data while making sure that specific sales cannot be tracked to a particular contact or account.

IMS Health publishes retail sales data and determines the definition of bricks. Brick definitions are reviewed every six months and adjusted to make sure that the brick is as small as possible while providing the required level of anonymity.

Because brick data is a key measure of return on a pharmaceutical company's investment in sales promotion, outside the United States most pharmaceutical companies build sales territories based on brick data available for that country. This provides a meaningful way to measure performance over time.

About Bricks in Siebel Pharma

As Siebel administrator, you can associate a contact or an account address with a brick. A contact can be associated with multiple bricks and an account with multiple addresses can have one brick for each address.

Siebel Pharma also supports mini-bricks. Mini-brick data is a subset of brick data that narrows the number of contacts and accounts in a geographic area. Mini-bricks provide a more detailed view of an area, without identifying the individuals in the unit.

It is the Siebel administrator's responsibility to set up and maintain brick definitions as well as associate bricks with contacts and account addresses. For information on associating a brick with an account address, see *"Associating a Brick with an Account Address" on page 67*.

Defining a Brick

This section includes information about defining bricks.

To define a brick

1 Navigate to the Administration - Data screen > Brick Details view.

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

Some fields are described in the following table.

Field	Comments
Parent Brick	The Pick Brick dialog box lists all the bricks in the database. If the new brick is a mini-brick, click the parent brick in the Pick Brick dialog box.
Active	If checked, the brick is active. Only active bricks are listed in the Pick Brick dialog box.
Position	Defines positions associated with the brick and controls visibility on the Analysis screen > Brick views. Note: For users to see the bricks for which they are responsible, the administrator must associate their position with those bricks.

NOTE: On initial data load, you can use EIM to load brick data into the base table S_REGION. For more information on using EIM, see *Siebel Enterprise Integration Manager Administration Guide*.

Associating a Contact with a Brick

You can associate a brick directly with one or more contacts.

To associate a contact with a brick

1 Navigate to the Administration - Data screen > Brick Details view.

2 In the Bricks list, select a Brick.

3 In the Contact list, create a new record for the contact you want to associate with the brick.

Creating a Contact (End User)

A contact can be any individual an end user deems significant in achieving their business goals. Multiple employees can be assigned, as a team, to a contact. Any employee assigned to the team can update the contact's information. The user who creates the contact is automatically designated as the *primary* contact team member. However, he or she can also be assigned to other contact teams by another user (such as a manager).

NOTE: The My Team's Contacts view is limited to showing only those contacts with a subordinate person as the *primary* on the team. It does not show contacts where the subordinate is on the team, but is not primary.

If you prefer the behavior of displaying all contacts who are on the team of the subordinate person, create a service request (SR) on My Oracle Support. Alternatively, you can phone Global Customer Support directly to create a service request or get a status update on your current SR.

Because the contacts shell is assigned to individual people (that is, employees) and not positions, this view does *not* show contacts who are assigned to a position that has no employee assigned. To prevent this behavior, assign a placeholder employee to every position.

Contacts can also be viewed on an account hierarchy tree that shows accounts, their child accounts and all activities, contacts, and opportunities associated with the accounts. For more information, see Chapter 5, "Administering and Managing Accounts in Life Sciences."

To create a contact record

1 Navigate to the Contacts screen > Contacts List > More Info view.

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

Some fields are described in the following table.

Field	Comments
Address	A contact can have multiple addresses. Use the Addresses dialog box to select an existing address or create a new one.
	NOTE: Be careful when editing an existing address. Editing an existing address changes it for all contacts currently associated with the address. If you are unsure whether the change applies to all contacts, create a new address.
	Each user must specify one address as primary by selecting the Primary field. Each sales representative assigned to a contact can specify a different primary address. For example, one representative might specify a private office as the primary address, while another representative might specify a hospital department as the primary address. In the All Contacts view and the My Team's Contacts view, the primary address displayed is the one assigned by the primary team member.
Brick	Indicates an impartial geographic code that groups contacts in a way that mirrors the definition provided by syndicated data providers. These codes are loaded by the administrator and are read-only for all users.
	For more information, see "About Bricks in Siebel Pharma" on page 50, and "Associating a Contact with a Brick" on page 51.
Clinical	Indicates if this contact has been involved in a clinical trial.
Company Identifier	A unique identifier for the contact that can be used to cross reference with other systems.
Consumer	Indicates if this contact is a customer.
Last Call Date	The date of the most recent call that has been submitted for each member of the team.
	In the My Contacts view, this field shows the last date that you, as the logged-in user, has made a call. In the other Contacts views, this field shows the last date the team's primary has made to the account.
License #	Used to record all contact's professional licenses.
Primary Specialty	Only Siebel administrators can define this value. For more information, see "Setting Up Primary Specialties" on page 48 and "Setting Up Primary Specialties" on page 48.
Primary TOP	The physician's primary type of practice.
Provider	Indicates if this contact is a health care provider.
Rep Specialty	The specialty or area of expertise the end user sees this contact has having within their organization.

Field	Comments
Rep TOP	The physician's primary type of practice according to the assigned sales representative.
Route	Allows users to select a when to visit an account from a predefined schedule. For more information, see "About Defining a Route Plan (End User)" on page 108.
Speaker	A check mark indicates this contact is a speaker for MedEd events. This field is used to track various speakers at any level. For more information, see "Designating MedEd Event Speakers" on page 240.
Team	Multiple people can be assigned to the contact's team. The team member who created the record is indicated as primary.
Territory	Territories are assigned to contacts using Siebel Assignment Manager.
Type	Indicates the type of contact.

NOTE: Contacts can only be deleted by a Siebel administrator in the Data Administration, Contacts view. For information on administering contacts, see "Deleting a Contact" on page 50.

Specifying the Best Time to Call (End User)

A contact can have more than one address. Using the Addresses view, end users can enter the best times to call on a contact based on a selected address. Entering information in this view automatically populates other views such as the PreCall view.

For more information about:

■ Creating addresses, see the addresses field description in "Creating a Contact (End User)" on page 52

■ Using the PreCall view, see "Viewing Pre-Call Information (End User)" on page 56

To specify the best time to call on a contact

1 Navigate to the Contacts screen > Contacts List.

2 In the Contacts list, select a contact and drill down on the Last Name.

3 Click the Addresses view tab.

4 In the Addresses list, select an address.

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

Indicating Affiliations Between Contacts (End User)

The Contacts Affiliations view allows end users to track referral relationships between contacts. Using this view, users can track:

■ **Referral or Referring Relationship**. Users can specify whether a contact receives or gives referrals to other contacts.

■ **Influence of Contacts on One Another**. Users can specify whether or not one contact influences another contact.

To indicate an affiliation between contacts

1 Navigate to the Contacts screen > Contacts List.

2 In the Contacts list, select a contact and drill down on the Last Name.

3 Click the Affiliations view tab.

4 To specify a referring relationship, in the Affiliations list, create a new record, and complete the necessary fields.

5 To specify an influencing relationship, in the Influenced list, create a new record, and complete the necessary fields.

Indicating Affiliations Between a Contact and an Account

Using the Account Affiliations view tab, end users can associate a contact with an account. One reason to indicate these affiliations is for greater efficiency in call reporting, as described in Chapter 9, "Recording Calls in Pharma."

Once you record an affiliation between an account and a contact, you can also:

■ **Specify a role for the affiliated contact.** This gives the end user some comprehension of the contact's occupation.

■ **Specify the best times to call the contact at the affiliated account.** This makes sure that the contact is not called at inconvenient of inappropriate times.

■ **Specify the role of the contact at the affiliated account.** This helps end users to track a contact's importance within an organization. They can then refer to this information prior to calls and adjust their discussions with each contact accordingly.

■ **Review products in the formularies of the affiliated account.** If the contact is affiliated with any MCOs, make sure to add the names of these to the Account Affiliations list.

The Formulary Status list (LS Formulary Status List Applet) shows the drugs that are in the MCO account's formulary. This is read-only information. Formulary status can be updated from the Plan Formulary view of the Accounts screen.

NOTE: If a PBM (pharmacy benefit management company) owns the formulary, you need to affiliate the PBM account instead of the MCO account, in order to see the formulary.

To indicate an affiliation between a contact and an account

1 Navigate to the Contacts screen > Contacts List.

2 In the Contacts list, select a contact and drill down on the Last Name.

3 Click the Account Affiliations view tab.

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

Some fields are described in the following table.

Field	Comments
Account	The account to be affiliated with the selected contact.
Start date	The beginning date on which the contact became affiliated with this account.
End date	The date on which the contact ended affiliation with this account.
Direct	Select this field to route profile data for the contact to the members of the team assigned to the *affiliated account*. The Siebel administrator must enable this behavior.
	Do not select this field to route the profile data for the contact to the members of the team assigned to the contact. (Users who are connected to the server see the profile data whether or not a check mark appears in the field.)

5 To specify the role of the contact at the affiliated account, in the Roles list, create a new record, and complete the necessary fields.

6 To specify the best time to call on the contact at the affiliated account, in the Best Times list, create a new record, and complete the necessary fields.

Viewing Pre-Call Information (End User)

The Pre-Call view tab is a single view that provides end users with a thumbnail view of important information about a contact. Users can access this view prior to making a call to get a summary of key information about the customer they are about to visit.

To view pre-call information

1   Navigate to the Contacts screen > Contacts List.

2   In the Contacts list, select a contact and drill down on the Last Name.

3   Click the PreCall view tab.

The following table describes the list applets in the PreCall view.

List	Comments	Link Bar
Rx Trends	Syndicated data about prescription trends. Data can be viewed as a chart or as a list.	Rx Trend
Rx Trends By Plan	Syndicated data about prescription trends. Rx Trend by Plan shows prescriptions by managed care plans. Data can be viewed as a chart or as a list.	Rx Trend By Plan
Rx Trends By Formulary	Syndicated data about prescription trends. Rx Trend by Formulary shows prescription trends and formulary status information at affiliated accounts. Data can be viewed as a chart or as a list.	Rx Trend and Formulary
Account Affiliations	Lists all accounts affiliated with this contact. This list can also be populated from the Account Affiliation view tab. For more information, see "Indicating Affiliations Between a Contact and an Account" on page 55.	Rx Trend Rx Trend By Plan Rx Trend and Formulary
Best Times	Lists the best times to visit the contact. This list can also be populated in the Addresses view tab. For more information, see "Specifying the Best Time to Call (End User)" on page 54.	
Calls	Features an historical list of all calls made on the contact.	
Formulary status	Provides formulary status information for products in affiliated accounts.	
Notes	Contains end-user notes regarding the selected contact.	
Campaigns	Lists all the current campaigns targeted for the contact. Marketing Communications are not editable in this view. This list is populated from the Campaigns screen. For more information, see the chapter about creating campaigns in the *Siebel Marketing User Guide*.	Marketing Communications[1]
Messages	Lists all the offers associated with the campaign selected in Campaigns.	

1.   Requires the Siebel Pharma Campaigns option.

4   To add information:

a Select the Calls, Best Times, Notes, or Account Affiliations lists.

b Create a new record and complete the necessary fields.

NOTE: The Rx Trend data is not editable in this view.

Tracking Documentation Associated with a Contact (End User)

Clinical research associates can attach electronic files, such as CVs, contracts, and reports, that may be associated with a contact and record significant dates, such as the date the document is sent, received, expected, or expires.

To add an attachment to a contact

1 Navigate to the Contacts screen > Contacts List.

2 In the Contacts list, select a contact and drill down on the Last Name.

3 Click the Document Tracking view tab.

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

Some fields are described in the following table.

Field	Comments
Activity	Must be 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 be received from the contact.
Expiration Date	The date the document expires.
Name	The document name. This is a hyperlink to the Attachments view tab.
Lock Assignment	Determine whether the Assigned To field is locked. If the activity is locked, Assignment Manager will not access it. If it is unlocked, Assignment Manager can reassign it.

5 Select the record you just created and click the Attachments view tab.

6 Create a new record and add the document as an attachment.

To track documentation associated with a contact

1 Navigate to the Contacts screen > Contacts List.

2 In the Contacts list, select for whom you want to track documentation and drill down on the Last Name.

3 Click the Document Tracking view tab.

4 In the Document Tracking list, query for the document of interest and complete the necessary fields.

For more information on associating electronic documents with contacts, see .

Other Tasks for Managing Contacts

Other tasks associated with contacts are:

■ **Creating contact assessments.** End users can use assessment templates to rate and rank contacts on key indicators. For example, sales representatives can use assessments to conduct primary market research during their sales calls. For information about creating assessment templates, see *Siebel Applications Administration Guide*. For information about performing assessments (contact assessments are performed the same way as account assessments), see *Siebel Applications Administration Guide*.

■ **Creating category information.** End users can create public or private categories to track additional contact information, such as a particular sports a contact enjoys or food a contact prefers. For information about categories, see *Siebel Applications Administration Guide*.

5 Administering and Managing Accounts in Life Sciences

This chapter covers the following topics:

About Administering and Managing Accounts in Life Sciences

An *account* is any healthcare business that generates sales for your company or potentially could generate business. Typical examples of accounts include hospitals, clinics, MCOs (managed care organizations), wholesalers, group purchasing organizations (GPOs), and pharmacies. An account can also be any organization with which multiple contacts are associated, such as a group practice or an assisted-living facility.

This chapter describes how to administer and manage Siebel Life Sciences account information. Using the procedures given in this chapter, you will be able to perform the administrator tasks of generating account hierarchies, deleting an account, specifying which accounts are competitors, and associating bricks with account addresses. End users use the Accounts views to track a variety of account information, including account affiliations, account and contact relationships, activities and opportunities associated with accounts, and formulary information.

For more information on specific administrator and end-user tasks, see "Scenario for Accounts" on page 63.

About Account Hierarchies

An account hierarchy is a group of accounts that are organized by parent-child relationships. All of the Siebel Life Sciences applications support displaying these account relationships and the contacts, activities, and opportunities associated with each account on a hierarchical tree.

The hierarchical tree is a visual representation of account hierarchy data that allows end users to view the relationships between accounts. By viewing an account rollup, users can see aggregated account information, including contacts, coverage teams, activities and opportunities.

When end users have access to an account, they can review the hierarchical structure for that account, its child accounts and the contacts who work there. Account hierarchies are stored in five subviews of the Account screen—Relationship Hierarchy view, Activity Roll-up, Contact Roll-up, Opportunity Roll-up, and Coverage Team Roll-up.

Depending on your configuration, an account that does not have a parent-child relationship with another account may not appear in the rollup views.

About Bricks

A brick is a collection of accounts and contacts, normally in a common geographic area. The primary purpose of a brick is to allow a company to publish RSA (retail sales analysis) data while making sure that specific sales cannot be tracked to a particular contact or account. For more information on creating bricks, see "Administering Bricks" on page 50.

IMS Health publishes retail sales data and determines the definition of bricks. Brick definitions are reviewed every six months and adjusted to make sure that the brick is as small as possible while providing the required level of anonymity.

In countries where physician-level prescription data is not available, brick data is a key measure of return on a pharmaceutical company's investment in sales promotion. In these markets, most pharmaceutical sales territories are built based on brick data available for that country. This provides a meaningful way to measure performance over time.

How Bricks Work in Siebel Pharma

In Siebel Life Sciences, you can associate a contact or an account address with a brick. A contact can be associated with multiple bricks and an account with multiple addresses can have one brick for each address.

This implementation of Siebel Pharma also supports "mini-bricks." Mini-brick data is a subset of brick data that narrows the number of contacts and accounts in a geographic area. Mini-bricks provide a more detailed view of an area, without identifying the individuals in the unit.

It is the Siebel administrator's responsibility to set up and maintain brick definitions as well as associate bricks with account addresses and contacts. For more information on associating a brick with an account address, see "Associating a Brick with an Account Address" on page 67.

Scenario for Accounts

This topic outlines an example process performed by a Siebel administrator and end users. Your company may follow a different process according to its business requirements.

A pharmaceutical company is updating account information in their database. During this update process, the administrator is responsible for setting up and updating Siebel Accounts so that sales representatives can plan, track, and access account information. The administrator first deletes any obsolete accounts, then enters new information about competitors, and generates an account hierarchy. Finally, the administrator associates new accounts with existing bricks (geographic areas), if applicable.

Sales representatives use Siebel Accounts to manually enter and modify account information. For accounts with multiple departments and divisions, representatives can enter additional information for subaccounts. They can also add more depth to account data by creating user-defined fields called categories. Using categories, representatives can track private or shared information about accounts (for example, which accounts have memberships to specific professional associations).

For greater efficiency in call reporting, representatives can associate a contact with a specific account. Once these relationships are tracked within the system, they can record attendee calls. Attendee calls (very similar to contact calls) allow users to record the account call and samples disbursements for contacts seen at the account. Prior to visiting an account, representatives can view a snapshot of important information related to an account using the Pre-Call view.

Finally, both representatives and managers can evaluate the business potential of accounts by using the Account Rankings and Ratings view and the various charts provided in the Charts views.

Process of Managing Accounts

This topic details sample tasks often performed by administrators and sales representatives to record account calls. Your company may follow a different process according to its business requirements.

Administrator Procedures

The following list shows tasks administrators typically perform to manage accounts:

■ "Specifying a Competitor" on page 64.

■ "Deleting an Account" on page 64.

■ "Generating Account Hierarchies" on page 65. The account hierarchy lists accounts, child accounts and the activities, contacts and opportunities associated with all the accounts.

■ "Associating a Brick with an Account Address" on page 67.

End-User Procedures

The following list shows tasks end users typically perform when managing account information in the field:

■ "Entering an Account (End User)" on page 67.

■ "Specifying an Account Profile (End User)" on page 68.

■ "Viewing Account Hierarchies in Roll-up Views (End User)" on page 69.

■ "Creating Category Information for an Account (End User)" on page 71.

■ "Indicating an Affiliation Between an Account and a Contact (End User)" on page 71.

■ "Indicating Affiliations Between Accounts (End User)" on page 72.

■ "Creating Subaccounts (End User)" on page 73.

■ "Viewing Pre-Call Information (End User)" on page 75.

■ "Viewing Departments and Contacts (End User)" on page 75.

■ "Tracking Documentation Associated with Accounts (End User)" on page 76. Representatives can review documentation associated with an account, the contacts responsible for each document and when reviews are due.

Specifying a Competitor

You enter competitors as accounts in Siebel Life Sciences, and with the Competitor field selected.

To specify an account as a competitor

1   Navigate to the Accounts screen > Accounts Administration view.

2   In the Accounts form, create a new record and click the show more button.

3   Complete the necessary fields.

4   Select the Competitor field.

For more information on creating accounts from the Accounts screen, see "Entering an Account (End User)" on page 67. For more information on adding competitive product information, see "Managing Competitor Information" on page 93.

Deleting an Account

Deleting an account completely removes the account from the system. Be aware that deleting an account could have undesired consequences.

As an alternative to deleting an account, consider making the Siebel administrator the primary team member so that he or she can remove all other employees from the account's team.

If you are certain that the account is no longer active, use the following procedure to delete it.

To delete an account

1 Navigate to the Accounts screen > Accounts Administration view.

2 In the Accounts list, select and delete the account.

Generating Account Hierarchies

Data aggregation is available using the Roll-up views provided the administrator defines one or more hierarchies. The application administrator typically defines a "default" hierarchy by associating accounts with one another using the parent field on a company form, or the subaccount view for child accounts. Administrators can define account hierarchies display aggregated data—the activities, opportunities, contacts, and coverage teams—across account organizational structures. For example, the top node of the hierarchy contains activities for the organization, the subsidiaries below the organization, the departments at the subsidiaries, and contacts working at any level of the tree. As the end users move up and down the tree, they see more or less data rolled up to the selected level.

The application administrator can define two types of hierarchies for data aggregation—a default hierarchy for all end users and specific hierarchies that are used only by certain end users.

Default Account Hierarchies

The application administrator sets up a default account hierarchy once, during the initial application setup. The default hierarchy is available to all end users who are not tied to a specific hierarchy and who have been granted view access to the accounts represented in the hierarchy. It is the administrator's responsibility to give end user access to Account views. For more information, see about Global Accounts in the *Siebel Applications Administration Guide*.

When new accounts are created, they are automatically added to the default hierarchy tree and the contacts, coverage teams, activities, and opportunities that are associated with the accounts are automatically displayed in the rollup views. For information about configuring the Generate Hierarchy button, see .

To generate a default account hierarchy

1 Navigate to the Account screen > Global Accounts Administration view.

2 In the Account Hierarchy list, click Generate Hierarchy.

The parent-child account relationships that have been defined in your application are registered for participation in the roll-up views. This process may take some time, depending on the quantity of account records that are in your existing environment.

When the account hierarchy has been generated, a new record appears in the Account Hierarchies list. If it is the only account hierarchy record, the Default field is automatically checked. The accounts that have been added for participation in the roll-up views appear in the Account Relationships list.

NOTE: If no accounts are visible in the Account Relationships list, click the query button, step off the query, and click Go to refresh the view.

3 (Optional) Rename the account hierarchy and, if necessary, check the Default field.

NOTE: If end users are using the application when you generate the account hierarchy, they must log off and log on again to see the default account hierarchy in the rollup views.

Custom Account Hierarchies

In some cases, users work with particular accounts or subaccounts of a large corporation, but not with others. In these instances, some end users do not need to or should not see aggregated data across the entire corporation. An administrator can define a custom hierarchical structure across which data can be aggregated. This customer hierarchy can be as simple or complex as needed and offers users the ability to aggregate data across the accounts they are interested in seeing.

To create a custom account hierarchy of selected accounts

1 Navigate to the Account screen > Global Accounts Administration view.

2 In the Account Hierarchy list, create a new record, and complete the necessary fields. Do not select the Default checkbox.

3 In the Account Relationships list:

    a Create new records for each of the top level parent accounts. Leave the Parent Account field blank for each of these.

    b Create new records for the child accounts, entering the Parent Account for each.

4 Associate the hierarchy with an organization. For information about assigning a custom hierarchy to an organization, see *Siebel Applications Administration Guide*.

End users can only see the account hierarchy with which their current position's primary organization is tied.

Associating a Brick with an Account Address

In Siebel Life Sciences, you can associate a brick with an account address. Because bricks are associated with an account's address (and not the account itself), you can associate accounts that have multiple addresses with multiple bricks.

To associate a brick with an existing account address

1 Verify that brick records have been set up.

For information, see "Administering Bricks" on page 50.

2 Navigate to the Accounts screen > Account Administration view.

3 In the Accounts list, select an account.

4 In the Account form, click the select button in Addresses to open the Account Addresses shuttle applet.

5 For a selected address, edit the Brick field.

If this procedure does not work, review the *Siebel Release Notes* on My Oracle Support (see the issue about pop-ups invoked from shuttle applets).

Entering an Account (End User)

Accounts are businesses and organizations that either currently generate sales for your company or have the potential to do so. Because formulary opportunities are created and managed based on accounts and contacts can be affiliated with one or more accounts, entering and maintaining accurate account information is a critical task.

Accounts are also used to track competitor information. An account record with the Competitor field selected represents a competing company. Only the administrator can edit the Competitor field to create a competitor record. For more information, see "Specifying a Competitor" on page 64.

Multiple employees can be assigned, as a team, to an account. Any employee assigned to the team can update the account's information. The user who creates the account is automatically designated as the *primary* account team member. However, he or she can also be added to an account team created by another user (such as a manager).

Accounts in Siebel Life Sciences can have multiple addresses. Users can edit existing addresses directly in the Address field. However, users must be careful when editing an existing address. Editing an existing address, changes it for all accounts currently associated with the address.

To create an account

1 Navigate to the Accounts screen > Accounts List view.

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

Some fields are described in the following table.

Field	Comments
Account Team	Multiple people can be assigned to the account team. The team member who created the record is indicated as primary.
Address	The account can have more than one address. One address must be specified as primary.
Brick	The brick (geographic area) code associated with the account's primary address.
Parent	If this account is a subaccount of another account, select the parent account.
Site	A unique location identifier that distinguishes this account from any other accounts with the same name. For example, enter a city or county name in this field to uniquely identify a hospital.

3   Drill down on the account record and click the More Info view tab.

4   In the More Info form, complete the necessary fields.

The More Info form is a dynamic applet. There are five dynamic form applets in addition to the default account profile form:

■   Hospital

■   Clinic

■   Pharmacy

■   Long Term Care

■   Managed Care

The fields that appear are dependent on the account's Type field value.

NOTE: Only a Siebel administrator can delete an account. For more information, see "Deleting an Account" on page 64.

Specifying an Account Profile (End User)

Using the Account Profile view, end users can track profile information about an account, including the call frequency, details about the account size, the best times to call on the account, and historical list of all activities at the account. The Account type field in the Account form (at the top of the screen) determines what fields appear in the Account Profile form.

To create an account profile information for an account

1   Navigate to the Accounts screen > Accounts List view.

2   In the Accounts list, drill down on an account.

3   Click the Account Profile view tab.

 NOTE: The fields that appear in the Account Profile form depend upon which Account Type field in the Account form at the top of the screen. All fields in the Account Profile form are editable.

4   In the Account Profile form, complete the fields.

 You can track the best times to call on the account in the Best Times list.

5   In the Best Times list, review, create, or modify best time to call records.

6   In the Activities list, review or modify records or create general activities for the account.

Viewing Account Hierarchies in Roll-up Views (End User)

End users can review the account and its parent organization, subsidiaries, contacts, opportunities, and relationships to other entities in the graphical relationship hierarchy tree control available in the roll-up views. By drilling down on hypertext links on the hierarchy tree, end users navigate to related views.

NOTE: If the account has not been added to a hierarchy tied to the user's position's organization (either default hierarchy or custom hierarchy), the hierarchy tree is not visible to the end user. Instead they see "The selected record is not included as part of your defined hierarchy. If you feel this is in error, please contact your system administrator." The administrator is responsible for associating positions with organizations and an organization with a hierarchy.

The Activities-Roll-up view shows all of the activities associated with the selected account and its children. End users can apply filters to the list to find specific activity records and save the filtered list.

To view aggregated activities for an account

1   Navigate to the Accounts screen > Accounts List view.

2   Drill down on an account.

3   Click the Activities - Roll-up view tab.

 The associated account hierarchy appears on the right side of the screen. All activities associated with the account and all of its child accounts appear in the Activities-Roll-up list.

 In the Activities-Roll-up List, you can:

 ■   Drill down on an activity type to navigate to the Activities > Attachments view.

 ■   Drill down on an account name to navigate to the Account > Contacts view.

 NOTE: If you create an activity in the Activities screen and do not set the Account field, the activity will not appear in the Activities-Roll-up list.

To view the aggregated coverage team for an account hierarchy

1   Navigate to the Accounts screen > Accounts List view.

2   Drill down on an account.

3   Click the Coverage Team-Roll-up view tab.

The associated account hierarchy appears on the right side of the screen. All coverage team members associated with the account and all of its subsidiaries appear in the Coverage Team-Roll-up list.

In the Coverage Team-Roll-up list, you can:

■   Drill down on a last name to navigate to the Employees screen.

■   Drill down on an email address to open a blank email message addressed to the team member who has that address.

To view the aggregated opportunities for an account hierarchy

1   Navigate to the Accounts screen > Accounts List view.

2   Drill down on an account.

3   Click the Opportunities-Roll-up view tab.

The associated account hierarchy appears on the right side of the screen. All opportunities associated with the account and all of its child accounts appear in the Opportunities-Roll-up list.

In the Opportunities-Roll-up list, you can:

■   Drill down on an opportunity name to navigate to the Opportunities screen.

■   Drill down on an account name to navigate to the Account > Contacts view.

To view an aggregated list of contacts an account

1   Navigate to the Accounts screen > Accounts List view.

2   Drill down on an account.

3   Click the Contact-Roll-up view tab.

The associated account hierarchy appears on the right side of the screen. All contacts associated with the account and all of its child accounts appear in the Contacts-Roll-up list.

In the Contacts-Roll-up list, you can:

■   Drill down on a last name to navigate to the Contacts screen.

■   Drill down on an account name to navigate to the Account > Contacts view.

■   Drill down on an email address to open a blank email message addressed to the contact who has that address.

Creating Category Information for an Account (End User)

End users can create categories to track additional account information. In creating a category, a user can:

■ Define possible category values.

■ Specify the relative importance of the category and each of its values.

By default, categories are visible system-wide. However, users can mark categories as private. Private categories are only visible to the user who created them.

To create category information for an account

■ Follow the procedure for adding a category in the *Siebel Applications Administration Guide.*

Indicating an Affiliation Between an Account and a Contact (End User)

For accounts having multiple contacts, you associate contacts with an account using the Contact Affiliations view. One reason to indicate these affiliations is for greater efficiency in call reporting, as described in .

NOTE: The records for contacts you want to affiliate must already exist in the system; you cannot create new contact in this view. For more information on creating contacts, see .

To indicate an affiliation between an account and a contact

1 Navigate to the Accounts screen > Accounts List view.

2 Drill down on an account.

3 Click the Contact Affiliations view tab.

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

Some fields are described in the following table.

Field	Comments
Direct	If a check mark appears in this field, profile data for the contact is routed to members of the team assigned to the *affiliated account*. If no check mark appears in this field, the profile data is routed only to the members of the team assigned to the contact. (Users who are connected to the server see the profile data regardless of whether a check mark appears in the field or not.)
Last Name	The contact affiliated with this account.

End users can track a contact's importance and influence level within an account by defining their role in the Roles list. Users can then refer to this information prior to calls and adjust their discussions accordingly.

To create a new role for an affiliated contact

1 Affiliate an account with a contact as described in the previous procedure, "To indicate an affiliation between an account and a contact" on page 71.

2 Scroll down to the Roles list, create a new record, and complete the necessary fields.

Indicating Affiliations Between Accounts (End User)

In addition to specifying affiliations with contacts, accounts can also have affiliations with one another. For example, a hospital can have affiliations with certain pharmacies and referring clinics. Users can use the Account Affiliations view to indicate affiliations between accounts and to indicate whether the relationship is an upward or downward affiliation.

NOTE: Do not use the Account Affiliations view to indicate a child account of an account, such as a department within a hospital or a subsidiary of an account. To specify this kind of association, see "Creating Subaccounts (End User)" on page 73.

The Account Affiliations view includes two lists users can use to distinguish between *upward* (or peer affiliations) and *downward affiliations*:

■ **Upward or Peer Affiliations list.** Indicates an affiliation in which the selected account is the *agent* of the affiliation, such as an organization responsible for referring patients to another hospital.

■ **Downward Affiliations list.** Indicates an affiliation in which the selected account is the object of the affiliation, such as an organization receiving referrals from another hospital.

To indicate an affiliation between accounts

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Account Affiliations view tab.

4 In Account Affiliations view, scroll down and select one of the following lists:

■ **Upward or Peer Affiliations.** Indicates an affiliation in which the selected account is the agent of the affiliation, such as an organization responsible for referring patients to another hospital.

■ **Downward Affiliations.** Indicates an affiliation in which the selected account is the object of the affiliation, such as an organization receiving referrals from another hospital.

5   In the Upward or Peer Affiliations list or the Downward Affiliations list, create a new record, and complete the necessary fields.

NOTE: If the relationship between the accounts is generic or unknown, add the record to the Upward or Peer Affiliations list.

You can add more than one account at a time by selecting multiple accounts in the Add Accounts dialog box.

To view an account's upward and downward account affiliations

1   Navigate to the Accounts screen > Explorer view.

2   Expand the account for which you wish to view upward and downward affiliations.

Creating Subaccounts (End User)

Some accounts may have child accounts or subaccounts; for example, a hospital can have several departments or clinics. End users can create subaccounts for existing accounts using the Sub Accounts view. End users can also use this view to indicate affiliations between contacts and subaccounts.

Once a user has created a subaccount, it can be viewed and modified in any of the views in the Accounts screen. All accounts—parent accounts and child subaccounts—exist as separate accounts in the system. In the Account Explorer view, however, a subaccount appears under its parent, reflecting the hierarchical relationship between the two.

Table 10 describes how parent and subaccount team membership affect account data access. Users assigned to a parent account team but not to a subaccount team, only have partial access to subaccount data. In contrast, users assigned to a subaccount team but not to the parent account team, have no access to the parent account except to the account name.

Table 10.   Access to Account and Subaccount Data

Access	Assigned Only to Parent Account's Team	Assigned Only to Subaccount's Team
Access to Parent Account Data	Full access	Partial access, account name only
Access to Subaccount Data	Partial access	Full access

NOTE: Do not use the Account Sub Accounts view to indicate affiliations between independent accounts, such as a hospital and a referring clinic. For more information on establishing this type of association, see "Indicating Affiliations Between Accounts (End User)" on page 72.

To create a subaccount

1   Navigate to the Accounts screen > Accounts List view.

2   In the Accounts list, drill down on an account.

3   Click the Sub Accounts view tab.

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

Some fields are described in the following table.

Field	Comments
Account Team	Multiple people can be assigned to the account's team. The team member who created the record is indicated as primary.
Name	Name of the subaccount.
Site	A unique location identifier that distinguishes this account from any other accounts with the same name. For example, enter a city or county name in this field to uniquely identify a hospital.

Adding a subaccount automatically adds a child record to the account hierarchy. For information about account hierarchies, see "Generating Account Hierarchies" on page 65.

NOTE: To enter detailed data for a subaccount (such as activities and best times to call), drill down on the Name field and complete the fields in the various account views.

To indicate an affiliation between a contact and a subaccount

1   Navigate to the Accounts screen > Accounts List view.

2   In the Accounts list, drill down on an account.

3   Click the Sub Accounts view tab.

4   In the Sub Accounts list, select a subaccount.

5   Scroll down to the Contact Affiliations list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Direct	If a check mark appears in this field, profile data for the contact is routed to members of the teams assigned to the *affiliated account*.
	If no check mark appears in this field, the profile data is routed only to the members of the team assigned to the contact. (Users who are connected to the server see the profile data regardless of whether a check mark appears in the field or not.)
Last Name	The contact affiliated with this subaccount.

6   Scroll down to the Roles list, create a new record, and complete the necessary fields.

Viewing Pre-Call Information (End User)

The Pre-Call view tab is a single view that provides end users with a thumbnail view of important information related to an account. Users can access this view prior to making a call to get a summary of key information about the account they are about to visit.

To view pre-call information

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Pre-Call view tab.

The Pre-Call view appears, displaying the lists described in the following table.

List	Comments
Product Sales	Product sales information associated with the account.
Contact Affiliations	Lists all contacts affiliated with the account.
	This list can also be populated in the Contact Affiliations view tab. For more information. see "Indicating an Affiliation Between an Account and a Contact (End User)" on page 71.
Activities	Features a historical list of all activities associated with the account. For more information on working with activities, see "About Creating Activities" on page 112.

4 (Optional) Select the Contact Affiliations or Activities lists, create a new record, and complete the necessary fields.

Viewing Departments and Contacts (End User)

Large hospitals can have a large number of doctors working in different medical departments within a hospital. Medical departments are generally organized around medical specialities. The Departments and Contacts view tab is a single view that allows end users to track the work department within the hospital where the contact performs his or her duties. Users can access this view prior to making a call to get familiar with the department of the contact they are about to visit.

An account can have multiple departments, but a department can belong to only one account. Departments are organized hierarchically within a hospital. A department can have one and only one parent department.

A contact can belong to multiple departments within a hospital. Membership to a child department does not define membership to any of the parent departments. However, membership to a child department does establish membership of the parent hospital Account.

To set up departments and contacts information

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, create a new record for the Hospital Department, and select Department as the value for the Type field.

3 Click the Parent Account field and from the Pick Applet, select the Parent Account for the Department.

4 Click the Contact Affiliation detail view tab.

5 In the List applet, click the New button, and open the Pick Applet on the Last Name field to associate a Contact to the Department.

6 Repeat Step 5 for other Contacts associated with the Department.

To view departments and contacts information

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, query for the Parent Account and drill down on the Account record.

3 Click the Departments and Contacts detail view tab.

The Departments and their affiliated Contacts are displayed in the list.

Tracking Documentation Associated with Accounts (End User)

Clinical research associates can use the Document Tracking view to review and track documents associated with accounts.

To track documentation associated with an account

1 Navigate to the Account screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Document Tracking view tab.

4 In the list, view, edit, create, and delete document records as required.

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 account.
Expiration Date	The date the document expires.

Field	Comments
Lock Assignment	Determine whether the Lock Assignment field should be selected. If the activity is locked, Assignment Manager will not access it. If it is unlocked, Assignment Manager can reassign it.
Name	The name of the document. This field is a hypertext link to the Attachments tab.
Received Date	The date that the signed document returns from the account.
Sent Date	The date that the document is sent to the account.

Clinical research associates can also create a documentation tracking activity and attach a document.
For more information, see "Tracking Documentation Associated with a Contact (End User)" on page 58.

About Configuring the Generate Hierarchy Button

In the preconfigured application, using the Generate Hierarchy button adds only parent account and
child accounts to the hierarchy. Any account that does not have a child or parent is not displayed in
the rollup views. In Siebel Tools, you can change the DynHierarchy LoadAllAccounts user property to
alter this behavior.

The DynHierarchy LoadAllAccounts user property on the Dynamic Hierarchy Direct Relationship
business component can be set to N or Y. When it is set to N (default), only parent and children
appear in the generated hierarchy. When DynHierarchy LoadAllAccounts user property is set to Y, all
accounts are added to the account hierarchy. For information on setting user properties, see *Siebel
Developer's Reference.*

6 Managing Products for Life Sciences

This chapter covers the following topics:

About Managing Products for Life Sciences

Consistent product and price list information allows your company to sell its products. This chapter describes how to manage product information and pricing structures by setting up and defining products, product lines, product features, and price lists.

Using the procedures given in this chapter, you will be able to perform the administrator tasks of defining products (both internal and external) and entering information about promotional items, competitive products, markets (therapeutic classes), medical equipment and devices, and compounds under clinical trial. End users use the Products views to view product information and enter product change requests.

For more information on the differences between administrator and end-user tasks, see "Scenario for Managing Products" on page 80.

How Siebel Life Sciences Stores Product Information

Siebel Life Sciences provides two different tables for storing product information:

■ An internal product table (S_PROD_INT)

■ An external product table (S_PROD_EXT)

These tables supply data used in various chart views, such as those in the Analysis screen.

About the Internal Product Table

The internal product table (S_PROD_INT) is used primarily for proprietary product data, including products that are detailed or distributed as (pharmaceutical) samples or promotional items by sales representatives. The administrator can categorize products according to product level, therapeutic class, and product type as well as define market categories, such as an antibiotics market. For more information on entering products in the internal product table, see "Defining Internal Products" on page 82.

NOTE: After you enter a product into the internal product table, you cannot delete it. However, you can prevent it from appearing in drop-down lists and dialog boxes by making it inactive. For more information, see the procedure "To make a product inactive" on page 89.

About the External Product Table

The external product table (S_PROD_EXT) is used for syndicated data from content providers, and for any additional data the administrator chooses to enter about competitive or complementary products. Check with your content provider for information on the product identifiers they use. For more information on loading syndicated data, see Chapter 17, "Importing Data into Life Sciences."

Products entered in the external product table can also be entered in the internal product table. However, for any product that is entered in both tables, make sure that the product name and other product identifiers match exactly in both tables.

For more information on entering products in the external product table, see "Defining External Products" on page 81.

Scenario for Managing Products

This topic outlines an example process performed by a Siebel Products administrator and end users. Your company may follow a different process according to its business requirements.

A medical devices company has a new product to bring to market. To make the new product available to sales representatives in the field, the administrator defines the new product within the system, creates a price list, and then associates the new product with the price list. Next he enters new background information (called decision issues) that the home office wants to communicate to the field. Finally, he uses the capture hierarchy command to update the product hierarchy so the new product can be inventoried by the sales representatives who are using the Medical Handheld application.

Sales representatives use Siebel Products to view product information and enter change requests.

Process of Managing Products

This topic details sample tasks often performed by administrators and end-users when managing products. In this scenario, the administrator is responsible for setting up Siebel Products so that end users can view product information. Your company may follow a different process according to its business requirements.

Administrator Procedures

The following list shows tasks administrators typically perform to set up product information:

■ "Defining Internal Products" on page 82. Create a new product (called an internal product).

■ "Specifying Additional Product Information" on page 90. Define product features and set up any product literature, entering additional product details including key features, information on related products, product comparison data, and associate literature.

■ "Defining External Products" on page 81. Create any competitive and complementary products (called external products).

■ "Adding Products to Catalogs" on page 95.

■ "Defining Price Lists" on page 91. Define a price list and then associate it with the new product.

■ "Defining Decision Issues" on page 94.

■ "Capturing Product Hierarchies for Medical Handheld" on page 98. If you are using the Medical Handheld application, you must capture product hierarchies.

End-User Procedures

The following list shows tasks end users typically perform when viewing product information:

■ "Viewing Product Information (End User)" on page 99.

■ "Creating a Product Change Request (End User)" on page 99.

Defining External Products

Use the External Products view to manage information about competitive and complementary products and to associate those products with the companies that produce them.

Siebel Life Sciences stores the information you enter in the External Products view in the external product table (S_PROD_EXT). In addition, it also displays this information in the Competitor Comparison Administration view. For more information on the internal and external product tables, see "How Siebel Life Sciences Stores Product Information" on page 80.

NOTE: Make sure that the product information you specify in the External Products view matches exactly the information specified for the same product in the Products view. For more information, see "Defining Internal Products" on page 82.

To create an external product

1 Navigate to the Administration - Product screen > External Products view.

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

Some fields are described in the following table.

Field	Comments
Competitor	Indicates whether or not the company specified in the Vendor field is a competitor. For more information on how to create account records, see "Specifying a Competitor" on page 64.
Product	If the product is also entered in the internal product table, the name entered here must match the name entered in the Product Administration view. For more information, see "Defining Internal Products" on page 82.
Product Type	Specifies whether the product is competitive or complementary.
Vendor	The manufacturer of this product.

Defining Internal Products

Use the Product Administration view to enter and update information about your company's internal products, promotional items, competitive products, markets (therapeutic classes), and compounds under clinical trial. Siebel Life Sciences stores the information entered in this view in the internal product table (S_PROD_INT). For more information, see "How Siebel Life Sciences Stores Product Information" on page 80.

To create a new internal product, you create a new record in the Product Administration view. In creating a new internal product you specify:

■ **Product categorization settings.** Use the values described in Table 11 on page 83 to categorize new products, or create market (therapeutic class) records.

■ **Samples and promotional items settings.** Use the values described in Table 12 on page 84 to define samples and promotional items.

NOTE: If you plan on tracking products using lot numbers, create lot numbers for samples. For more information, see "Defining Lot Numbers for Samples" on page 138 or "Setting Up Lot Numbers for Medical Products" on page 369.

Product Categorization Settings

You categorize products or create market (therapeutic class) records using the Product Administration field values described in Table 11.

Table 11.   Recommended Product Categorization Settings

Record Type	Product Level Field	Type Field	Inventory Field	Orderable Field	Sales Product Field	Sales Service Field
Market (therapeutic class)	1	Market	Null	Null	Null	Null
Detailed product. Product associated with call details, meetings, formularies, objectives, or opportunities	2	Detail	Null	Null	Selected	Null
Competitive product. For more information, see "About the External Product Table" on page 80.	2	Competitor	Null	Null	Null	Null
Sample products disbursed on contact calls or account calls [1]	3	Sample	Null if tracking by lot number Selected if tracking by product name	Selected	Selected	Null
Promotional item disbursed on contact calls or account calls [1]	5	Promotional Item	Selected (if desired)	Selected	Null	Null
Equipment, medical, or surgical devices	Null	Null	Null	Selected	Selected	Null
Services	Null	Null	Null	Selected	Selected	Selected
Product configuration models	Null	Null	Null	Selected	Selected	Null
Product available for clinical trial	Null	Compound	Selected (if desired)	Null	Null	Null

1.   If the product will be tracked by lot number, you must specify additional settings, as described in "About Samples and Promotional Items Settings" on page 84.

About Samples and Promotional Items Settings

The Food and Drug Administration (FDA) in the USA and similar agencies in other countries have regulations that stipulate that pharmaceutical samples disbursements must be tracked by lot number. However, it is not required that the actual samples inventory be tracked by lot number. Using Table 12:

■ Locate a product type and description that matches the product you are creating.

■ Configure the Inventory, Lot # Tracking, and Inventory by Lot fields using the values described in the last three columns.

For more information on defining lot numbers, see "Defining Lot Numbers for Samples" on page 138.

Table 12.   (Pharmaceutical) Sample and Promotional Items Settings

Product Type	Description	Inventory Field (Product Administration View)	Lot # Tracking Field (Product Administration View)	Inventory by Lot Field (Lot Setup View)
Samples	Full tracking by lot number: ■ Samples disbursements tracked by lot number ■ Samples inventory tracked by lot number No tracking by product name.	Null	Selected	Selected
Samples	Partial tracking by lot number: ■ Samples disbursements tracked by lot number ■ Samples inventory not tracked by lot number No tracking by product name.	Null	Selected	Null
Samples	Full tracking by product name: ■ Samples disbursements tracked by product name ■ Samples inventory tracked by product name No lot number tracking.	Selected	Null	Null

Table 12.   (Pharmaceutical) Sample and Promotional Items Settings

Product Type	Description	Inventory Field (Product Administration View)	Lot # Tracking Field (Product Administration View)	Inventory by Lot Field (Lot Setup View)
Samples	Partial tracking by product name: ■ Samples disbursements tracked by product name ■ Samples inventory not tracked by product name No lot number tracking.	Null	Null	Null
Promotional -items	Full tracking by product name: ■ Promotional-items disbursements tracked by product name ■ Promotional-items inventory tracked by product name	Selected	Null	Null
Promotional -items	Partial tracking by product name: ■ Promotional-items disbursements tracked by product name ■ Promotional-items inventory not tracked by product name	Null	Null	Null

To create an internal product or a market

1 Navigate to the Administration - Product screen > 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
Catalog #	Catalog number for a medical product.
Model #	Model number for a medical product.

Field	Comments
Name	The name of the product, promotional item, or market (therapeutic class).
	If this product also exists in the external product table, this name must match the product name in the External Product Administration view. For more information, see "Defining External Products" on page 81.
	If this product will be tracked in inventory, either by product name or by lot number, include both the product name and the dosage (for example, Axis 2mg).
Part #	The part number of this product. If a product image will be displayed on a Web site created with Siebel Life Sciences portals, do not include spaces or special characters in the part number.
Type	The type of product. For the recommended settings, see Table 11 on page 83.
	If this product also exists in the external product table, select Competitor so that the products will match up correctly.

3 Click the Release button.

4 Drill down on the product.

5 Click the More Info view tab.

6 In the form, click the show more button and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
>1 Barcode	This field is for Siebel Medical Handheld.
	Indicates that the product is labeled with more than one barcode.
Approval #	The approval number for a medical product given by the approval organization.
Approval Org	The authority who has approved a medical product, for example TÜV.
Barcode	This field is for Siebel Medical Handheld.
	Indicates the standard for the product barcode.
Doses/Unit	This field is for Adverse Events and Complaints Management.
Expression	This field is for Siebel Medical Handheld.
	This expression is used to generate unique asset numbers from the product's barcode. It is a concatenation of the data descriptions for barcode items. For the example shown, if the expression is Lot Number, Serial Number, then the serial number and lot number portions of the barcode are the product's unique asset numbers. These barcodes are provided in the Administration - Mobile screen > Barcode Administration view.

Field	Comments
Frequency	This field is for Adverse Events and Complaints Management.
	Indicates how many times each day the product is used.
Leaf Level	This field is for Siebel Medical Handheld.
	It is computed when the Capture Hierarchy button is clicked, and indicates that the product has no children in the product hierarchy.
	Only leaf-level products are physical products—products that can be purchased and inventoried. Products that are not leaf-level represent groups of products.
	For example, the Helix 15 mm Stent is a leaf-level product in the Stent group of products.
Lot # Tracking	Select this field if the product will be tracked by lot number, either for purposes of disbursement tracking or for inventory tracking. If you select this field:
	■ You must define lot numbers for the product as described in Table 12 on page 84. For more information on defining lot numbers, see "Defining Lot Numbers for Samples" on page 138.
	■ You should *not* check the Inventory field. This field is read-only if the Samples Lots Enabled system preference is set to FALSE.
	Only products of type Sample, Device, and Equipment can tracked by lot number. To use lot number tracking for products of other types, see "Configuring Lot Numbers for Other Products" on page 100.
Inventory	Applies to products that will be tracked in inventory by product name rather than by lot number. If you check this field, you should *not* check the Lot # Tracking field.
	For more information, see Table 11 on page 83 and then Table 12 on page 84.
Manufacturer	This field is for Adverse Events and Complaints Management.
Orderable	Select this field for any product or service that may be included in a samples order or in a sales order. For more information, see Table 11 on page 83.
OTC Product	This field is for Adverse Events and Complaints Management.
Parent Product	The parent products of this product within the product hierarchy. Products that are disbursed as samples should have a parent product. Parent products can be markets (therapeutic classes).
	Parent Product is a multivalue group that enables you to associate multiple parent product records. Ensure that you check the Primary flag when selecting the parent product.
	NOTE: For Siebel Medical Handheld, only the primary parent is considered. Other parent products are ignored.

Field	Comments
Pre-1938	This field is for Adverse Events and Complaints Management.
Level	Enter the appropriate value according to your product hierarchy. For the recommended setting, see Table 11 on page 83.
	If this product also exists in the external product table, enter 2 so that the products will be matched up correctly.
	In Siebel Medical Handheld, this field is set when the hierarchy is captured. For more information, see "Capturing Product Hierarchies for Medical Handheld" on page 98.
Requires Approval	This field is for Siebel Medical Handheld.
	If this box is selected and if the Requires Approval field in the Inventory screen > Inventory Locations view is set to Product, then customer approval (Handheld signature capture) is required when this product is taken from the corresponding inventory.
Rollup Level	This field is for Siebel Medical Handheld. It applies only to root-level products. (A root-level product is one that has no parent.)
	This field determines what levels of products are included in data rollup and also which levels of product appear in the inventories in the Medical Handheld application.
	For example, if Rollup Level is 3 for a product hierarchy that has six levels, the products at level 6, 5, 4, and 3 appear in Medical Handheld inventories. The root product (level 1) and its immediate children (level 2) do not appear.
Root	This field is for Siebel Medical Handheld. It is computed when the Capture Hierarchy button is clicked.
	This field indicates root product (the oldest ancestor) of the product's hierarchy.
	For example, for a level-2 product, the Root field displays the product's parent.
Route Used	This field is for Adverse Events and Complaints Management.
Sales Product	Check this field (and the Orderable field) for any product or service that your company actually sells (and will therefore be included in a sales order). For more information, see Table 11 on page 83.
Short Days	This field is for Siebel Medical Handheld.
	An asset or lot for this product is short dated this many days before expiration.

Field	Comments
Therapeutic Class	The therapeutic class (or market) of the product. There is no functionality associated with this drop-down list. Market type (or therapeutic class) functionality is tied to the Parent Product field; a new market is added by creating a new record in the Products view and setting the Type field to Market.
Unique Assets	This field is for Siebel Medical Handheld. Select this field to indicate that every instance of the product can be uniquely identified by a single field or by the concatenation of fields in the Expression field.
Unique Id	This field is for Siebel Medical Handheld. It must be unique to each product. It is used to identify the product based on barcode data. It is the HIBC, UCC/EAN, or NDC number. It is used to map barcode data to the product.
UoM	Unit of measure; that is, the measure by which the product is sold or marketed.
WAC	Wholesaler average cost; that is, the average wholesale cost of the product.

For more information on specifying additional product information, see "Specifying Additional Product Information" on page 90.

To make a product inactive

1 Navigate to the Administration - Product screen > Products view.

2 Drill down on the product that you want to make inactive.

3 Click the More Info view tab.

4 In the form, click the show more button and clear the following fields:

■ Product Level

■ Type

■ Lot # Tracking

■ Inventory

■ Orderable

■ Sales Product

■ Leaf Level

After end users synchronize with the server, they will not see the product in any drop-down list or dialog box. However, they will see the product listed in views that display products.

Specifying Additional Product Information

You can specify additional product information in the Product Administration view by drilling down on the product in the Products list, and then adding either Product Recommendations or Product Collateral.

Specifying Product Recommendations

Using the Recommendations view you can add related products, and recommended cross-sell and up-sell products to the product record.

To add related products to a product record

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on the required product.

3 Click the Recommendations View tab.

4 Click the Related Products link on the Recommendations tab.

5 In the Related Products list, create a new record.

6 In the Add Internal Products dialog box, select a related product, and click OK.

   The related product is added to the list.

7 Complete the remaining fields, including indicating the Integration Status, Effective End Date, and whether or not the product can be ordered.

Specifying Product Collateral

Using the Collateral view you can specify additional product features and product comparisons, associate product literature and images with the product, or add product news to the product record.

To specify additional product features

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on the required product.

3 Click the Collateral View tab.

4 Click the Key Features link on the Collateral View tab.

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

To add product comparison information

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on the required product.

3 Click the Collateral View tab.

4 Click the Key Features link on the Collateral View tab.

5 In the Product Comparison list, create a new record.

6 In the Add Product Comparisons dialog box, select one or more products and click OK.

The products are added to the Product Comparison list.

To associate related literature

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on the required product.

3 Click the Collateral View tab.

4 Click the Literature link on the Collateral View tab.

5 In the Product Literature list, create a new record.

6 In the Add Literature dialog box, select one or more records and click OK.

The selected records are added to the Literature list.

NOTE: For more information on adding other selections to the Add Literature dialog box, see the chapter on literature administration in *Siebel Applications Administration Guide*.

To add images for a product

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on the required product.

3 Click the Collateral View tab.

4 Click the Images link on the Collateral View tab.

5 In the Images form, click the Select button in the Image File name field.

6 In the Images dialog box, query for and select the required image.

The image is added to the product record.

NOTE: For more information on adding other selections to the Pick Product News dialog box, see the chapter on literature administration in *Siebel Applications Administration Guide*.

Defining Price Lists

You can use the Price List views to create and maintain an unlimited number of price lists for your products. Using these views, you can:

■ Create and update price lists

■ Define and update price list names and descriptions

■ Create new records based on existing price lists

■ Associate products with price lists

■ Enter pricing information (such as effective date, terms, and shipping information)

To create a price list

1 Navigate to the Administration - Pricing screen > Price List view.

2 In the Price Lists, More Info form, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Currency	The currency for this price list. The values that appear in the Pick Currency Code dialog box are defined in the Application Administration, Currency view.
Name	The name for the price list.
Payment Terms	The payment terms of the price list. The values that appear in the Pick Payment Terms dialog box are defined in the Application Administration, Payment Term view.
Shipping Method	The shipping method for products associated with this price list.
Shipping Terms	The shipping terms for products associated with this price list.

3 Click the Price List Line Items view tab.

4 In the Price List Line Items list, create a new record, and complete the necessary fields.

The products that appear in the Name field and the Add Internal Products dialog box are defined in the Product Administration view. For more information, see "Defining Internal Products" on page 82.

To associate a price list with a product

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, drill down on a product.

3 On the lower link bar, click Price Lists.

4 In the Product List list, create a new record and select the price list.

For more information on adding other selections to the Add Price Lists dialog box, see "Defining Price Lists" on page 91.

NOTE: You can also associate images with products so that the images appear in the Products. For more information, see the chapter on basic product administration in *Siebel Product Administration Guide.*

Managing Competitor Information

Effective sales and marketing requires that your company have up-to-date and consistent information about the competitive landscape. This topic describes how to administer information about competitors and competitive products.

Tracking competitor information in Siebel Life Sciences involves the following steps:

■ Creating account records for competitors and selecting the Competitor field. For more information, see "Specifying a Competitor" on page 64.

■ Creating records for competitors' products. For more information, see "Defining External Products" on page 81.

■ Adding comparative and competitive literature files to the application. For more information, see the chapter on literature administration in *Siebel Applications Administration Guide*.

To administer competitor information you must:

■ Define company features and product features that can be used to compare your company and its products with those of your competitors. For more information, see the procedures "To define company features" on page 93 and "To define product features" on page 93.

■ Enter information about competitive products, product and company comparisons, and competitive and comparative literature. For more information, see the procedure "To enter competitor comparison information" on page 94.

To define company features

1 Navigate to the Competitors screen > Company Features Administration view.

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

To define product features

1 Navigate to the Administration - Product screen > Product Features view.

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

Some fields are described in the following table.

Field	Comments
Category	The category in which this product feature is classified.
Product Line	Select the product line of which this product is a part.
Name	The product feature criterion; for example, Once a Day Formulation.
Description	A description of the feature, if necessary.

To enter competitor comparison information

1   Navigate to the Competitors screen > Competitor Administration view.

    The Competitors list appears.

    This list displays every account flagged as a competitor. Note that the Competitor Flag field is checked for every record. For more information on creating competitors, see "Specifying a Competitor" on page 64.

2   In the Competitors list:

    ■   Select a competitor.

    ■   Optionally, enter the competitor's World Wide Web address (URL) in the Home Page field.

3   In the Company Comparison list, create a new record, and complete the necessary fields.

    Some fields are described in the following table.

Field	Comments
Feature	The features listed in the Add Competitive Company Features dialog box are defined in the Company Feature Administration view. For more information on adding company features, see "To define company features" on page 93.
Rank	Enter the numeric rank of the feature as defined by your business process.

Defining Decision Issues

Contacts often raise important issues during a call. Decision issues are the objections a contact may raise when evaluating a product prior to making a prescribing decision. Often these objections are related to the efficacy of the product, its pharmacological properties, the recommended dosage, its safety profile, drug interactions, competitor's claims, product availability, price and generic substitution.

Using the Decision Issues Administration view, you can:

■   Create and edit decision issues within the application

■   Enter explanations about specific decision issues and provide instructions to representatives in the field on how to discuss them

■   Associate literature and related issues with decision issues

Sales representatives can then use this information to prepare for calls on contacts and accounts. They can also associate decision issues with particular calls, indicating which issues are of concern to particular contacts.

NOTE: Before you can use the procedures described in this topic, you must first add set up categories. (For general information about setting up categories, see the *Siebel Order Management Guide*.)

To create a decision issue

1 Navigate to the Administration - Data screen > Decision Issues view.

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

3 Click the Decision Issues Categories view tab.

4 Add records to the list.

The categories determine which users can see and select the decision issue. Users must have access to at least one of the categories in order to see the decision issue.

5 (Optional) Add literature to the decision issue:

a Click the Literature view tab.

b Add literature records to the list.

6 (Optional) Add related issues to the decision issue:

a Click the Related Issues view tab.

b Add decision issue records to the list.

Only decisions issues that belong to categories to which you have visibility can be added.

Adding Products to Catalogs

When simple and complex products have been created, administrators must add catalog visibility to these products. Starting with Siebel Life Sciences version 7.0.3, products—including samples and promotional items—and lot numbers need to be associated with catalogs to determine drop-down list visibility. Product catalogs may be assigned to groups of people to control which users may access the products. By adding catalog visibility to products, you allow them to be accessed by different groups of people in your company.

You can further subdivide catalogs into product categories. For example, when you create a catalog, you might want to create a Catalog for cancer drugs and further subdivide this into categories with the same active ingredients.

When creating catalogs, you can also provide effective start and end dates for the categories associated with the catalog. This may be useful if you are providing particular products only at particular times in a clinical trial, for example.

To give a product catalog visibility, you must do the following:

■ Creating the Product Catalog on page 96

■ Creating a Product Category on page 96

■ Adding Products to Catalogs and Categories on page 97

■ Adding Access Groups to Catalogs and Categories on page 97

For more information about product catalogs and categories, see *Siebel Order Management Guide*.

For more information about access groups, see *Siebel Security Guide*.

Creating the Product Catalog

The following procedure details how to create a product catalog.

To create a product catalog

1 Navigate to the Administration - Product screen > Product Catalog list.

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

Some fields are described in the following table.

Field	Comments
Name	The name of the new catalog.
Description	A description of the catalog.
Effective Start Date, Effective End Date	The date range between which the catalog is effective.
Private	Select this check box if you want the catalog to be visible only to users belonging to the access groups associated with it. If the catalog is private, all of its categories will also be private.
Active	Select this check box if the category is active.
Sequence	The sequence of this catalog in the list.

Creating a Product Category

You can further group products into product categories under catalogs.

To create a product category

1 Navigate to the Administration - Product screen > Product Catalog list.

2 In the Product Catalog list, query for and select the required catalog.

3 Drill down on the link in the Name field.

The Categories view appears.

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

Some fields are described in the following table.

Field	Comments
Name	The name of the new category.
Display Name	The display name for the category in drop-down lists.

Field	Comments
Effective Start Date, Effective End Date	The date range between which the category is effective. It is important that you complete these fields, as these dates are checked when you create a quote line item for effective catalogs.
Usage	Choose the area in which the product will be used.
Sequence	The sequence of this category in the list.
Private	Select this check box if you want the category to be visible only to users belonging to the access groups associated with it. If the catalog is private, all of its subcategories will also be private.
Count	The total number of products in the category and all of its subcategories.

5 Create new product categories and subcategories as required, and indent the new categories under the original catalog to create a category hierarchy if required.

Adding Products to Catalogs and Categories

After you have created product catalogs and categories, you can add products to them.

To add products to catalogs and categories

1 Navigate to the Administration - Product screen > Product Catalog list.

2 In the Product Catalog list, query for and select the required catalog.

3 Drill down on the link in the Name field, and select the required category in the Categories list.

4 Scroll down, click the Categories view tab, and then click the Products link.

5 In the Products list, create a new record.

6 The Add Internal Products selection dialog box is displayed.

7 Query for and select the required product, and click OK.

Most of the fields are populated when the product has been selected.

8 If necessary, enter the sequence in which the products added are to be displayed.

Adding Access Groups to Catalogs and Categories

When you have added products to catalogs and categories, you may add access groups to make the products visible to the required groups of people.

To add access groups to a catalog

1 Navigate to the Administration - Product screen > Product Catalog list.

2 In the Product Catalog list, query for and select the required catalog.

3 Drill down on the link in the Name field, and then click the Access Groups view tab.

4 In the Access Groups list, create a new record.

The Add Access Groups selection dialog box is displayed.

5 Query for and select the required access group, and click OK.

The remaining fields are populated when the required access group is chosen.

To add access groups to a category

1 Navigate to the Administration - Product screen > Product Catalog list.

2 In the Product Catalog list, query for and select the required catalog.

3 Drill down on the link in the Name field, and expand the catalog name to select the required category in the Categories list.

4 Click the Categories view tab, and then click the Access Groups link.

5 In the Access Groups list, create a new record.

The Add Access Groups selection dialog box is displayed.

6 Query for and select the required access group, and click OK.

The remaining fields are populated when the required access group is chosen.

Capturing Product Hierarchies for Medical Handheld

To appear in a Medical Handheld inventory detail view, a product must belong to a product hierarchy that has been captured. The following procedure describes how to capture a product hierarchy.

NOTE: Remember to recapture the hierarchy after editing the relationships between products.

To capture a product's hierarchy

1 Navigate to the Administration - Product screen > Products view.

2 Select the root products whose hierarchies you want to capture.

If you select a product that is not a root, that product is ignored. A dialog box lists these ignore records.

3 Click Capture Hierarchy.

This prepares the product data so that it can be used by Medical Handheld application to track inventory. It sets Root, Level, and Leaf Level fields based on the product relationships defined by the primary parent product.

Viewing Product Information (End User)

The views in the Products screen allow end users to view lists of products and obtain information such as prices, key features, and product defects. The Siebel administrator is responsible for entering information on products, product issues, price lists, and other information displayed in the Products views.

To view product information

1 Navigate to the Products screen > Internal Product List view.

2 In the Products list, drill down on a product.

3 Click a view tab.

   NOTE: To view hidden view tabs, scroll to the right.

Creating a Product Change Request (End User)

End users who receive information about a product change request that has not already been entered in the system, can create a product change request.

To create a product change request record

1 Navigate to the Products screen > Internal Product List view.

2 In the Products list, drill down on a product.

3 Click Change Requests.

4 In the Change Requests list, create a new record.

5 In the Add Change Request dialog box, click New.

The application adds a new record to the Change Requests list.

6 In the Change Requests list:

   ■ Enter a description in the Summary field.

   ■ Select the type of request in the Type field.

   ■ Drill down on the Change Request hyperlink.

The Change Request form appears.

7 In the Change Request form, complete the necessary fields.

Configuring Lot Numbers for Other Products

In the preconfigured application, only products of type Sample, Device, and Equipment can be tracked by lot numbers.

To enable lot number tracking for other types of product

■ Use Siebel Tools to edit the Lot Tracking Product Types user property of the Internal Product business component.

For information about the Lot Tracking Product Types user property, see Table 13.

For more information on editing user properties, see *Configuring Siebel Business Applications* and *Using Siebel Tools.*

Table 13.   User Property for Internal Product Business Component

User Property Name	User Property Value	Description
Lot Tracking Product Types	*,ProductType1,ProductType2,ProductType3,…,* *ProductType* is the Language Independent Code (LIC) for the product type you want to track with lot numbers. Value must start and end with a comma and have no spaces between LICs. Example: ,Sample,Equipment,Device,	Enables lot tracking for specified product types.

7 Planning Calls in Pharma

This chapter covers the following topics:

About Planning Calls in Pharma

This chapter describes the tools available in Siebel Life Sciences to plan account and contact calls. For more information on recording account and contact calls, see

Using the procedures given in this chapter end users can add products to personal lists, create and apply target lists, define route plans, create activities, set up meetings, and schedule calls.

Tools for Planning Calls

Siebel Life Sciences offers end users the following tools for planning their account calls:

■ **Personal Lists.** For more information, see "Personal Lists" on page 102.

■ **Targeting.** For more information, see "Targeting" on page 102.

■ **Routes.** For more information, see "Routes" on page 102.

■ **Activities.** For more information, see "Activities" on page 103.

Personal Lists

Personal lists allow for faster call reporting by limiting the number of products that appear in drop-down lists. *Before end users can record call details,* they must configure personal lists of the products they detail, the products they distribute as samples, and the products they provide as promotional items. For more information on personal lists, see the scenario "Scenario 1: Users Set Up Personal Lists" on page 103 and "Creating a Personal List (End User)" on page 106.

Targeting

Targeting using Global Target List Management is an extension of querying. In targeting, end users save the results of queries in a target list and then apply those saved lists to other views within the system. In Siebel Life Sciences, a target list can be a set of contacts or accounts and can be applied to any view that contains contacts or accounts.

Using the account and professional targeting list views in the List Management screen, users can create advanced queries on contacts and accounts. Users can apply target lists to views individually or in combination with other target lists. If combining multiple target lists, users have the option of applying an intersection or a union of the lists. For more information on targeting, see the scenario "Scenario 2: Users Create Target Lists" on page 103 and "Creating and Applying Target Lists (End User)" on page 107.

Routes

End users can create routes to schedule regular calls to groups of accounts. By defining a route, a user can plan the order in which to visit accounts and then determine a starting time for each account call. By arranging a group of accounts into an efficient route, users can minimize the amount of time spent traveling between accounts. After a route has been created, it can be used repeatedly to schedule future account calls. For more information on routes, see the scenario "Scenario 3: Users Define Route Plans" on page 104 and "About Defining a Route Plan (End User)" on page 108.

Activities

An *activity* is a scheduled task or event. Activities represent the ways in which users spend their time. Although activities are typically performed or planned for opportunities, contacts, or accounts, they can also be personal tasks that users want to track. For more information on activities, see the scenario "Scenario 4: Users Create Activities" on page 105 and "About Creating Activities" on page 112.

All activities with valid dates and times appear in the Calendar views as well as in the Activities views. The views in the Calendar screen provide a visual representation of each user's scheduled activities and appointments. For more information using the calendar, see "Creating a General Activity in the Calendar (End User)" on page 114.

Contact and Account Calls

Contact and account calls are a type of activity record. Although users create contact calls in the Contact screen, they actually record calls details in the Activities screen. For more information on scheduling calls, see "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119. For information on recording calls, see Chapter 9, "Recording Calls in Pharma."

Scenario 1: Users Set Up Personal Lists

This scenario describes how end users set up and configure their personal lists. Your company may follow a different process according to its business requirements.

Personal lists determine which products appear in various Name drop-down lists in Siebel Life Sciences. For more information, see "Personal Lists" on page 102.

A sales representative has recently joined a pharmaceutical company that uses Siebel Life Sciences in the field. During her sales training, the representative's sales manager tells her that before she can record calls within the system, she must first set up her personal lists. The sales manager explains that personal lists allow for faster call reporting by limiting the number of products that appear in the application's Name drop-down lists. The sales manager then demonstrates how to add products to the sales representative's Call Products Detailed, Samples Dropped, and Promotional Items Dropped views. Following her manager's instruction, the sales representative updates all her personal lists and is ready to record call details.

The process for this scenario comprises two end-user procedures:

- **Configure personal lists.** For more information, see "Creating a Personal List (End User)" on page 106.

- **Record contact and account calls.** For more information, see Chapter 9, "Recording Calls in Pharma."

Scenario 2: Users Create Target Lists

This scenario describes how end users use targeting to create lists of contacts and accounts. Your company may follow a different process according to its business requirements.

A sales representative for a pharmaceutical company has just been assigned a new territory. As a first step in becoming more familiar with her territory, she queries her contacts and accounts and creates target lists of the following information:

■ Contacts located within specific postal codes, bricks, or cities with NRx (new Rx) in Product A greater than 100 over the last two months

■ The highest-potential contacts in a given postal code or city with a Best Time To Call setting that includes noon to 1:00 p.m. on Tuesdays (useful if a lunch appointment cancels)

■ Accounts with sales in Product B greater than $60,000 over the last half-year that are available for calls on Monday afternoons, located within a specific range of postal codes, and last seen over five weeks ago

■ Accounts or contacts with high ratings in a product's therapeutic class but low ratings in a specific product

Once she has saved these target lists, she can apply them to other views within the application.

The process for this scenario comprises two steps:

1 **Create and save a target list.** For more information, see .

2 **Apply target lists to other views.** For more information, see the *Siebel Applications Administration Guide*.

Scenario 3: Users Define Route Plans

This topic illustrates how end users can use the Routes views to group accounts by location and then use that information to schedule calls. It also describes how sales managers can create routes and schedule calls for the sales representatives they manage.

Your company may follow a different process according to its business requirements.

Sales Representative Creates Routes to Schedule Account Calls

A sales representative for a pharmaceutical company needs to plan his account call schedule. Because he always visits the same accounts in the same order, he decides to organize his accounts into routes so that he can efficiently schedule all account calls.

He begins by dividing up his accounts into specific geographic areas. Then, he creates a four-day route that includes all accounts in the outlying portions of his sales territory. In addition to specifying which accounts fall into what routes, he defines additional details such as the starting time and the duration of each call. Once all routes have been defined, he schedules calls to all accounts in his territory for the upcoming month.

Sales Manager Creates Routes for New Direct Report

A sales manager for a pharmaceutical company manages 10 sales representatives. One of her representatives, a new employee, is not familiar with his territory. To help her new representative get up-to-speed, she organizes the new representative's accounts into a series of routes.

Each route is divided into sections and will be visited every two weeks. The sales manager creates 10 routes: one for each workday in a two-week period. Each route includes multiple accounts in the same neighborhood. Once the sales manager has finished creating the routes, she uses them to schedule a month's worth of account calls for her new sales representative.

Once her new direct report becomes familiar with his territory, she gives him the responsibility of maintaining and updating his routes. The new sales representative can then add new accounts to a route, change the order in which routes are visited, or adjust the start time and duration of each visit.

The process for this scenario comprises four procedures:

1 **Create a route.** For more information, see "To create a route" on page 109.

2 **Add accounts to a route.** For more information, see "To add accounts to a route using the Accounts view tab" on page 110.

3 **Schedule account visits using routes.** For more information, see "Using a Route to Schedule Calls (End User)" on page 112.

Scenario 4: Users Create Activities

This scenario describes how end users use activities to manage their own time, keep their manager informed of their workload, and track their expenses. Your company may follow a different process according to its business requirements.

Typically activities are performed or planned for opportunities, contacts, or accounts, but they can also be used to track personal tasks. Consider the following example.

A sales manager for a pharmaceutical company wants to review her schedule. She uses the Activities screen to create, categorize, and track all the activities on which she plans to spend her time during the next month.

From the My To Do List view, she prints a report detailing her current activities, their due dates, and all pertinent account information. Remembering she wants to meet with each of her direct reports in next two weeks, she prints a report summarizing all the calls her team has made over a 20-week period. Then, she schedules meeting with each of her direct reports to discuss their sales goals for the next quarter. Finally, she schedules a contact call with a prominent customer whose regular sales representative is on a long leave. Then, she reviews the Calendar screen to review her schedule for the upcoming weeks.

NOTE: End users also use the Activities screen to record and submit details of Contact and Account Calls. For more information, see Chapter 9, "Recording Calls in Pharma."

The process for this scenario comprises four procedures:

1 **Create general activities.** For more information, see "About Creating Activities" on page 112.

2 **Create contact or account call.** For more information, see "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119.

3 **Set up a meeting.** For more information, see "Setting Up a Meeting (End User)" on page 115.

4 **View activities and create new activities on the Calendar screen.** For more information, see "Creating a General Activity in the Calendar (End User)" on page 114.

Process of Planning Calls

This topic details sample tasks often performed by end-users when planning calls. Your company may follow a different process according to its business requirements.

The following list shows tasks end users typically perform when planning contact and account calls:

■ "Scenario 1: Users Set Up Personal Lists" on page 103. Personal lists determine which products appear in the Call Detail views in Siebel Life Sciences.

■ (Optional) "Scenario 2: Users Create Target Lists" on page 103. Using target lists users can query for accounts or contacts and then apply those lists to other views within the application.

■ (Optional) "Scenario 3: Users Define Route Plans" on page 104. Route plans are groups of accounts sorted by location. Once created, users can use route information to schedule calls.

■ (Optional) "Scenario 4: Users Create Activities" on page 105. Activities allow users to manage their own time, keep their manager informed of their workload, and track expenses.

■ "Creating a Contact Call (End User)" on page 117.

■ "Creating an Account Call (End User)" on page 119.

NOTE: After end users set up their personal list, they can record calls. For more information, see "Recording and Submitting Contact Calls" on page 168 and "Recording and Submitting Account Calls" on page 172.

Creating a Personal List (End User)

Personal lists determine which products appear in the drop-down lists of the Call Products Detailed, Samples Dropped, and Promotional Items Dropped views. End users must specify at least one product in a personal list or the corresponding drop-down list will be empty when they try to enter call details. For more information on recording calls, see Chapter 9, "Recording Calls in Pharma."

Setting up personal lists is a one-time setup procedure. Once end users have completed it, they do not need to repeat it. However, they can revise their personal lists at any time, deleting or adding products as necessary. For more information on personal lists, see "Personal Lists" on page 102 and the scenario "Scenario 1: Users Set Up Personal Lists" on page 103.

To add a product to a personal list

1 Navigate to the Activities screen > Personal List view.

2 From the Show drop-down list, select one of the following:

■ **Personal Details List.** Adds products to the Personal Details List.

■ **Personal Samples List.** Adds products to the Personal Samples List.

■ **Personal Promotional Items List.** Adds products to the Promotional Items List.

3 In the appropriate list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Product	The products being detailed during contact and account calls. This field appears in the Product Details List.
Sample	The products to be dropped as samples during contact and account calls. This field appears in the Personal Samples List.
Promotional Item	The promotional items being dropped during contact and account calls. This field appears in the Personal Promotional Items List.
Order	Enter a number that indicates where this product should appear in the drop-down list. This field appears in the Product Details List, Personal Samples List, and Personal Promotional Items List. For example, if you want a product in the Product Details List to appear first, enter 1. If this field is null for *all* products in the list, the products will appear in alphabetical order. If this field is null for some products but not for others, records with a null Order field appear at the beginning of the list, in alphabetical order.

4 Complete this procedure for each of the views:

■ Personal Details List view

■ Personal Samples List view

■ Personal Promotional Items List view

Creating and Applying Target Lists (End User)

Targeting is an extension of querying. In targeting, end users save the results of queries in a target list and then apply those saved lists to other views within the application. A target list typically consists of contacts or accounts and can be applied to various views and dialog boxes that contain lists of contacts or accounts.

For general information about creating and applying target lists, see the *Siebel Applications Administration Guide*.

This topic describes how to create target lists using the account and professional targeting list views, which are unique to the Siebel Life Sciences application. These views present data such as best times to call, and prescriber habits that sales representatives typically want to query when creating their contact and account target lists.

To create a target list from the List Management screen

1 Navigate to one of the following views:

View	Navigate to the List Management screen then	To create lists of	Based on
Contact Profile	In the link bar, click Professional Targeting List.	Contacts	Rx consumption
Contact Attributes	In the link bar, click Professional Targeting List. In the visibility filter, select Account Attributes.	Contacts	Best times to call, ranking and rating
Account Profile	In the link bar, click Account Targeting List.	Accounts	Profile data such as number of physicians, call frequency, and market share
Account Attributes	In the link bar, click Account Targeting List. In the visibility filter, select Account Attributes.	Accounts	Best times to call and sales data

2 Run a query in the view.

3 Review the query results in the list.

4 When the list of contacts or accounts contains the records you want to save as a target list, click the Save Target List button.

NOTE: The saved target list includes only those records that matched the query criteria *when the query was generated.* You should re-create your target lists periodically because data may have been modified or new contacts or accounts may have been added since you created the target list. For example, you must re-create your target lists after a territory realignment.

About Defining a Route Plan (End User)

End users can create routes to schedule regular calls to groups of accounts. By defining a route, a user can plan the order in which to visit accounts and determine a starting time for each account call. For more information, see "Routes" on page 102 and the scenario "Scenario 3: Users Define Route Plans" on page 104.

When creating a route, users must complete the following tasks in the order listed:

■ **Create a route.** Users must specify the person for whom they are creating the route. Although each user can be assigned multiple routes, each route can only be assigned to one user. For more information, see "To create a route" on page 109.

■ **Add accounts to a route.** Once users have established a route, they can add accounts to it.

■ **(Optional) Assign a target list to a route.** If users are using the Account Targeting features to create target lists, they can assign them to a route using the Target Accounts view.

■ **Schedule calls.** When a route has been created, users can use it to schedule calls to every account in the route. For more information, see "To schedule calls from the My Routes view" on page 112

Creating a Route (End User)

When creating a route, users must specify the person for whom they are creating the route (generally a field sales manager or sales representative). When creating a route remember that:

■ Each user can be assigned many routes

■ A route can have any number of accounts

■ A route can only be assigned to one user

■ A route name can only be used once for each user

■ The same route name can be used for routes assigned to different users

To create a route

1   Navigate to the Routes screen.

2   In the Routes form, create a new record, and complete the necessary fields.

NOTE: In the My Routes view, the Sales Person field is automatically filled with the current user name. If you are assigning a route to someone other than yourself, enter that person's name in the Sales Person field.

Some fields are described in the following table.

Field	Comments
Active	Select this field if the route is active and available for use in scheduling calls.
Last Updated	The application automatically populates this field with the time and date the route was last changed.
Route Name	A user-defined name for the route, such as Northeast Richmond. A route name must be unique to the end user to which it is assigned.
Sales Person	The sales person to whom the route is assigned. A route can be assigned only to one person.
Start Day	The day of the week on which the route is designated to begin. This is used as reference information only and does not prevent you from using the route to schedule calls starting on some other day of the week.
Updated By	The application automatically populates this field with the name of the user who last changed the route.

Adding Accounts to a Route (End User)

Once users have established a route, they can add accounts to it. There is no limit to the number of accounts that can be assigned to one route. Three views are available for adding accounts to routes:

■ **Accounts view tab.** Shows accounts associated with the selected routes. For more information, see "To add accounts to a route using the Accounts view tab" on page 110.

■ **Explorer view tab.** Shows routes and accounts in a hierarchical format. For more information, see "To add accounts to a route using the Explorer view tab" on page 110.

■ **Target Accounts view tab.** Shows all accounts and allows you to choose which you want to add to the selected route. For more information, see "To add accounts to a route using the Target Accounts view tab" on page 111.

To add accounts to a route using the Accounts view tab

1 Navigate to the Routes screen.

2 In the Routes list, drill down on a route.

3 Click the Accounts view tab.

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

Some fields are described in the following table.

Field	Comments
Account	Only accounts where the user is on the coverage team can be added.
Call Duration	The scheduled duration of the account call.
Call Time	The application automatically enters the current time in this field. Edit the value to reflect the time at which the account is to be visited.
Last Call	Identifies the date and time of the most recent call to this account.
Offset Day	Allows you to create routes that span more than one day. Indicates the number of days after the beginning of the route that an account should be visited. For example, if an account is to be visited on the first day of a route, this field should be set to 0. If the account is to be visited on the second day of a route, this field should be set to 1.

5 Repeat Step 4 on page 110 until all accounts have been added to the Accounts list.

To add accounts to a route using the Explorer view tab

1 Navigate to the Routes screen.

2 In the Routes list, drill down on a route.

3 Click the Explorer view tab.

4 In the Routes explorer tree, click the plus sign next to the route to which you want to add an account.

5 Click the plus sign next to the Accounts folder displayed under the route.

A list of all the accounts assigned to the route appears.

6 In the Accounts list, create a new record for the account you want to add to the route and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Call Duration	The scheduled duration of the account call.
Call Time	The application automatically enters the current time in this field. Edit the value to reflect the time at which the account is to be visited.
Last Call	Identifies the date and time of the most recent call to this account.
Offset Day	Allows you to create routes that span more than one day. Indicates the number of days after the beginning of the route that an account should be visited. For example, if an account is to be visited on the first day of a route, this field should be set to 0. If the account is to be visited on the second day of a route, this field should be set to 1.

7 Repeat for each account you want to add.

To add accounts to a route using the Target Accounts view tab

NOTE: When associating a target account with a route, only select accounts where the owner of the route is represented on the sales team. It is possible to pick any existing account in the database when associating a target account with a route. However, there is no check to determine whether you or the owner of the route has access to the account.

1 Navigate to the Routes screen.

2 In the Routes list, drill down on a route.

3 Click the Target Accounts view tab.

4 Select the accounts to add to the route.

One way to select the accounts is to apply a target list and select the accounts in the list.

5 Click Commit.

Using a Route to Schedule Calls (End User)

After a route has been created, end users can use it to schedule calls to all the listed accounts. Users can schedule route calls from a number of views. The following procedures demonstrate how to schedule routes from the My Routes view, the Target Accounts view, and the Daily Calendar view.

To schedule calls from the My Routes view

1 Navigate to the Routes screen.

2 In the form, click Schedule.

3 In the dialog box, enter a start date and click OK.

Appointments for each account in the route are created in the calendar of the end user to whom the route is assigned.

CAUTION: It is possible to schedule multiple appointments for the same time period when using the Routes views to schedule calls. Such scheduling conflicts do not trigger any sort of automatic notification. Sales representatives should check the Daily Calendar view for possible conflicts after routes have been added to their schedules. If scheduling conflicts exist, they should adjust the starting times of appointments or delete them as necessary to resolve the conflicts.

About Creating Activities

End users use general activities to manage their own time and keep their manager informed of their workload. Managers can also create general activities and assign them to members of their teams. The kinds of activities that end users can create in Siebel Life Sciences include:

■ **General.** Used to track non-call and non-meeting tasks such as to-do items, personal events, and correspondence. Users can create an alert for a general activity to remind them of significant tasks or events.

■ **Contact call.** Used to track a planned or past call activity with a contact. Users can record details about contact calls such as the products detailed, the samples and promotional items dropped, and decision issues discussed. Before users can record details about a contact call, they must set up their personal lists. For more information, see "Creating a Personal List (End User)" on page 106.

■ **Account call.** Used to track a planned or past call activity at an account. Users can record products detailed, attendees, promotional items dropped, and decision issues discussed. For more information, see Chapter 9, "Recording Calls in Pharma."

■ **Meeting.** Used to track meetings, such as a "lunch-and-learn" or a symposium, designed to increase sales through product awareness. A meeting typically involves one or more speakers who give presentations in support of one or more products. For more information, see "Setting Up a Meeting (End User)" on page 115.

■ **Time off territory.** Used to track blocks of time that users spend on activities not directly associated with an account or contact. Examples of time off territory can include field training sessions, national sales meetings, vacations, or personal activities such as doctor's appointments. For more information on working with time off territory activities, see Chapter 14, "Tracking Time Off Territory."

■ **MedEd activity.** Used to track and plan medical education events such as a "lunch-and-learn" meetings or seminars. A MedEd event is similar to a meeting activity, but offers planning, budgeting, and cost aggregation functionality. MedEd activities are only associated with the separate Siebel MedEd module. For more information, see "Process of Managing MedEd Events" on page 233.

■ **Subject activities.** Used to track subject activities for a protocol. Subject activities are generated by applying the visit template based on the screening or enrollment date. Visit activities can also be created for a non-scheduled visit. For more information, see "Creating a Subject and Setting Up Visits and Visit Activities (End User)" on page 303.

■ **Clinical protocol site activities.** Used to track the activities associated with initiating the protocol sites, for example, collecting the essential documents. For more information, see "Creating Site Activity Plans (End User)" on page 321.

■ **Checklist activities.** Used to provide a checklist for clinical research associates (CRAs) to check activities associated with visiting a protocol site. Once a trip report record has been created, checklist activities are generated by selecting a trip report template. Checklist activities specific to a trip report can also be created for a trip report from the Trip Report Details view. For more information, see "Selecting a Trip Report Template Before a Site Visit (End User)" on page 341.

■ **Follow-up activities.** Used to record follow-up issues for a trip report. Users can create a follow-up activity to a trip report from the Trip Report Details view. Only the follow-up activities with open status are listed in a Follow-up Activities report generated from the Reports menu. For more information, see "Selecting a Trip Report Template Before a Site Visit (End User)" on page 341.

■ **Project Activities.** Used to track activities associated with clinical projects. These activities appear in the Projects screen and the Activities screen and can be created by project activity templates. For more information, see "Creating Activities and Tasks for a Project (End User)" on page 353.

For more general information on activities, see "Activities" on page 103 and "Scenario 4: Users Create Activities" on page 105.

NOTE: End users also use the Activities screen to record and submit details of contact and account calls. For more information, see Chapter 9, "Recording Calls in Pharma."

Creating a General Activity (End User)

End users use general activities to manage their own time and to keep their manager informed of their workload. Managers can also create general activities and assign them to members of their teams.

To create a general activity

1 Navigate to the Activities screen > Activity List view.

2 Create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Duration	The length of time, in minutes, that you expect the activity to take.
Employees	Delegate the activity to someone else. Select the appropriate employee and click OK. If you delegate an activity this way, the activity appears in the My Delegated Activities view.
Type	The type of activity. If you select Alert, the activity appears in the My Alerts view. The values displayed in this drop-down list depend on the value of the Activity field. For example, the activity types that you can select for a contact call are different from those that you can select for a general activity.

Creating a General Activity in the Calendar (End User)

The views in the Calendar screen provide visual representations of a user's scheduled activities, or *appointments*; that is, activities with a start time. For instance, in the Daily view, users can see a particular day's agenda, their unscheduled activities, or a to-do list. To appear in the Calendar views, all activities must have a start time.

Users who work as part of a team may find it useful to share access to their calendar.

To create a general activity in the Calendar view and to grant others access to your calendar

■ Follow the procedures for adding an activity to the calendar and granting access to your calendar in *Siebel Fundamentals*.

To create specialized activities in the Calendar view

1 Navigate to the Activities screen > Activity List view.

2 Do one of the following:

  ■ Click New Contact Call to schedule a call to a contact.

  ■ Click New Acct Call to schedule a call to an account.

  ■ Click New Meeting to schedule a meeting and to list activities, meeting speakers and invitees.

Setting Up a Meeting (End User)

Use the Meetings subviews of the Activities screen to manage information about activities, speakers, and invitees associated with meetings. Meetings themselves are activities that appear in the My Activities view.

NOTE: A MedEd event is similar to a meeting activity, but offers planning, budgeting, and cost aggregation functionality. MedEd activities are only associated with the separate Siebel MedEd module. For more information, see Chapter 15, "Managing MedEd Events."

Setting up a meeting involves the following steps:

■ **Create a new meeting record.** For more information, see "To create a meeting" on page 115.

> **NOTE:** Users can also create a meeting by clicking the New Meeting button in the Activities list of the My Activities view.

■ **Create activities for the meeting.** For more information, see "To create a meeting activity" on page 116.

■ **Add speakers for the meeting.** For more information, see "To add a meeting speaker" on page 116.

■ **Add invitees for the meeting.** For more information, see "To add a meeting invitee" on page 116.

To create a meeting

1 Navigate to the Activities screen > Activity List view.

2 In the Activities list, click New Meeting.

3 In the Meetings form, complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Account	The account associated with this meeting. Select an account from the Pick Account dialog box. The Location and Site fields are automatically filled based on the account you specify.
Cost	The application calculates this field based on costs entered for meeting activities. For more information, see "To create a meeting activity" on page 116. The application calculates this field when you click the Distribute Costs button in the Meeting Invitees view and updates it each time you click the Distribute Costs button again. For more information, see "To add a meeting invitee" on page 116.
Start Date	The application automatically populates this field with the date and time that the record was created. If needed, make additional changes.
Status	This field is hard-coded so that its value cannot be set to Submitted to avoid interference with other activity types, such as contact calls and account calls that are based on the same class of Siebel business components.

Add information about activities, speakers, and invitees, as described in the following procedures.

To create a meeting activity

1 Navigate to the Activities screen > Meeting List view.

2 In the Activities list, do one of the following:

■ Create a new meeting. For more information, see "To create a meeting" on page 115.

■ Select an existing meeting and then drill-down on the Name field.

3 Click the Meeting Activities view tab.

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

Some fields are described in the following table.

Add information about speakers and invitees, as described in the following procedures.

NOTE: Meetings are activities that appear in the My Activities view. However, activities that you create for a meeting are child records of the meeting. These records appear in the Meeting Activities tab view and as activities in the Calendar views.

To add a meeting speaker

1 Navigate to the Activities screen > Meeting List view.

2 In the Activities list, do one of the following:

■ Create a new meeting. For more information, see "To create a meeting" on page 115.

■ Select an existing meeting and then drill-down on the Name field.

3 Click the Meeting Speakers view tab.

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

Affiliated contacts are those associated with the account (if any) specified in Step 3 in the "To create a meeting" procedure on page 115. For more information, see "Indicating an Affiliation Between an Account and a Contact (End User)" on page 71.

To add a meeting invitee

1 Navigate to the Activities screen > Meeting List view.

2 In the Activities list, do one of the following:

■ Create a new meeting. For more information, see "To create a meeting" on page 115.

■ Select an existing meeting and then drill-down on the Name field.

3 Click the Meeting Invitees view tab.

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

The application calculates the value of the Cost field the Meeting Invitees list based on values entered in Cost field of the Meeting Activities list. It then distributes the costs across all invitees whose Invitee Status field is set to Attended.

To update the Cost field in the Meeting Invitees list

1   Click the Meeting Activities view tab.

2   In the Meeting Activities list, record the costs associated with each meeting activity in the Cost field.

3   To distribute the meeting costs across those individuals who attended the meeting, click the Meeting Invitees view tab.

4   In the Meeting Invitees list, update the Invitee Status for each invitee.

Selecting the status Attended includes the selected invitee in the count of contacts for distribution of meeting costs.

5   Click Distribute Costs.

As you add costs and attendees to the meeting, repeat the previous steps as many times as needed.

Creating a Contact Call (End User)

End users track details about calls made on a contact with contact call records. Although users can create and display contact calls on the Contacts screen, they enter details about the actual call on the Activities screen. Also, as activities, contact call records can also be viewed in the Calendar screen as planned events.

For more information on entering call details, see "Recording and Submitting Contact Calls" on page 168.

NOTE: Before user can enter information about products detailed, samples, and promotional items dropped during a contact call, they must set up their personal lists. For more information, see "Creating a Personal List (End User)" on page 106.

This topic presents four different methods of creating contact calls:

■   To create a contact call from the Activities screen on page 117

■   To automatically schedule contact calls using the Schedule button on page 118

■   To manually schedule a contact call in the Calls view tab on page 119

■   To schedule a contact call in the Calendar on page 119

Creating a Contact call from the Activities Screen

To create a contact call from the Activities screen

1   Navigate to the Activities screen > Activities List view.

2   In the Activities list, click New Contact Call.

3   In the Contact Call form, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Last Name	The contact to be visited during this call.
Ref #	A reference number for this call. This reference number becomes the transaction number (Transaction # field) for a samples transaction corresponding to this call. For information on samples transactions, see Chapter 8, "Managing Pharma Samples."
Smart Call	The Smart Call template to be associated with this call. Make a selection from the Pick Smart Call dialog box. A Smart Call is a template that you apply to contact calls that defines information about the products detailed, samples and promotional items distributed, and issues discussed on a call. Once you apply a Smart Call template to a call, you can make additional edits any fields in the Contact Call Detail view. For more information on Smart Calls, see Chapter 10, "Creating Smart Calls."
Status	The status of this call. The default value is Planned. This value changes to Synchronized after synchronization. Be aware, you cannot select the value Submitted. To change the status of the call to Submitted, you must submit the call. For more information, see "Recording and Submitting Contact Calls" on page 168.

For more information on how to enter information in Call Products Detailed, Sample Products Dropped, Promotional Items Dropped, and Issues lists, see "Recording and Submitting Contact Calls" on page 168.

NOTE: If you applied a Smart Call to the call (as described in Step 3), you may only need to verify that all the information in the four lists is accurate.

Creating Calls Using the Schedule Button From the Contacts Screen

When you use the schedule button to create calls, the auto-scheduling function:

■   Tries to schedule a call at a best time for each contact at their primary address

■   Schedules a call even if it does not find a best time

■   Distributes the calls over the time period (For example, if you select 10 contacts to be scheduled over a 5-day week, two calls each day are scheduled.)

To automatically schedule contact calls using the Schedule button

1   Navigate to the Contacts screen > Contacts List view.

2 In the Contacts list, select one or more contacts.

3 Click Schedule.

4 In the Auto Schedule dialog box, review the displayed values, make any needed changes, and click OK.

NOTE: The auto-scheduling function does *not* check for scheduling conflicts. Therefore, users need to verify that automatically scheduled calls do not conflict with other activities in their calendar.

Manually Scheduling a Contact Call from the Contacts Screen

To manually schedule a contact call in the Calls view tab

1 Navigate to the Contacts screen > Contacts List view.

2 Drill down on a contact.

3 Click the Calls view tab.

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

   NOTE: You cannot change the call's Status field to Submitted from this view. To change the status of the call to Submitted, you must submit the call. For more information, see "Recording and Submitting Contact Calls" on page 168.

5 To go to the Contact Call Detail view, drill down on the date hyperlink in the Start Date field.

   The Contact Call Detail view appears.

For more information on recording calls, see "Recording and Submitting Contact Calls" on page 168.

Scheduling a Contact Call from the Calendar Screen

To schedule a contact call in the Calendar

1 Navigate to the Calendar screen > Calendar view.

2 Select either the Daily or Weekly view tab.

3 Navigate to the day on which you want to schedule the call and click New Contact Call.

   The Contact Call Detail view appears.

For more information on recording calls, see "Recording and Submitting Contact Calls" on page 168.

Creating an Account Call (End User)

End users track details about calls made on specific accounts with account call records. An account call is a type of activity record. Although users can create and display account calls on the Accounts screen, they enter details about the actual call on the Activities screen. Also, as activities, account call records can also be viewed in the Calendar screen.

For more information, entering call details see "Recording and Submitting Contact Calls" on page 168.

NOTE: Before users can enter information about products detailed, attendees, and activities associated with an account call, they must set up their personal lists. For more information, see "Creating a Personal List (End User)" on page 106.

This topic presents five different methods of creating account calls:

■ To create an account call from the Activities screen on page 120

■ To automatically schedule an account call using the Schedule button on page 120

■ To manually schedule an account call in the Account view tab on page 121

■ To create an account call using the New Call button on page 121

■ To schedule an account call in the Calendar on page 121

To create an account call from the Activities screen

1 Navigate to the Activities screen > Activity List view.

2 In the Activities list, click New Acct Call.

3 In the Account Call form, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Account	The account to be visited during this call.
Smart Call	The Smart Call template to be associated with this call.
	A Smart Call is a template that you apply to contact calls that defines information about the products detailed, samples and promotional items distributed, and issues discussed on a call. Once you apply a Smart Call template to a call, you can make additional edits any fields in the Account Call Detail view. For more information on Smart Calls, see Chapter 10, "Creating Smart Calls."
Status	The status of this call. The default value is Planned. You cannot select the value Submitted. To change the status of the call to Submitted, you must submit the call. For more information, see "Remaking Electronic Signatures" on page 174.

For information on how to enter information in the Call Products Detailed, Attendees, and Activities lists, see "Recording and Submitting Contact Calls" on page 168.

NOTE: If you applied a Smart Call to the call (as described in Step 3), you may only need to verify that all the information in the four lists is accurate.

To automatically schedule an account call using the Schedule button

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, select an account and click Schedule.

3 In the Auto Schedule dialog box, review the displayed values, make any needed changes, and click OK.

NOTE: The auto-scheduling function does *not* check for scheduling conflicts. Therefore, users need to verify that automatically scheduled calls do not conflict with other activities in their calendar.

To manually schedule an account call in the Account view tab

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Calls view tab.

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

NOTE: You cannot change the Status field to Submitted from this view. To change the status of the call to Submitted, you must submit the call. For more information, see "Remaking Electronic Signatures" on page 174.

To enter details about the call, drill-down on the Date hyperlink in the Date field to display the Account Call Detail view.

For more information on recording calls, see "Recording and Submitting Account Calls" on page 172.

To create an account call using the New Call button

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 In the More Info view tab, click New Call.

The Account Call Detail view of the Activities screen appears. The selected account automatically appears in the Account Call form.

For more information on recording calls, see "Recording and Submitting Account Calls" on page 172.

To schedule an account call in the Calendar

1 Navigate to the Calendar screen > Calendar view.

2 Select either the Daily or Weekly view tab.

3 Navigate to the day on which you want to schedule the call and click New Acct Call.

The Account Call Detail view appears.

For more information on recording calls, see "Recording and Submitting Account Calls" on page 172.

About Features for Call Planning Specific to the Japanese Pharmaceutical Market

The Japanese pharmaceutical market has some unique characteristics concerning patient safety as stipulated by government regulations. These market characteristics dictate how sales representatives engage with physicians and hospitals in their territories and how they plan future calls. For example, pharmaceutical companies must provide safety information about a product to a physician. Additionally, after a new product is released, sales representatives are required to meet with physicians at pre-determined intervals to gather information about any anomalous effects the product may be having on the patients.

NOTE: Features specific to the Accounts Contacts in the Japanese pharmaceutical market are not covered in this section. For information about Accounts Contacts features specific to the Japanese market, see "About Japanese Pharmaceutical Market Features for Accounts Contacts" on page 205.

The following Siebel Life Sciences features address the distinctive traits of the Japanese pharmaceutical market:

■ **Post Market Surveillance (PMS).** The purpose of the PMS process is to encourage feedback relating to adverse effects that may have been noted in patients taking new drugs to be reported back to the drug company. When a drug is approved, sales representatives must visit each institution that purchases the drug. As stipulated by government regulation, these visits must occur every 2 weeks for the first 2 months after a hospital purchases the drug, and monthly thereafter for a period of 6 months after the launch date of the drug. For a specific example of how calls are scheduled for PMS after a product is released, see "Visit Timeline During the PMS Period" on page 123.

The purpose of these visits is to remind the health care professionals of their obligations to report any adverse effects that they have observed, or that have been reported to them. This process is initiated only when a hospital (account) purchases a drug (product) for the first time. This an activity associated at the account level. For information about managing PMS, see "Managing the PMS and Pre-Explain PMS Features" on page 123.

Pre-Explain PMS. A process that is a precursor to the PMS process. This process is triggered when a new hospital (account) is targeted for a drug (product). Using the Pre-Explain PMS feature will automatically set up a call for each hospital. The goal of the ensuing call is for the sales representative to explain to the hospital (account) contact how the PMS process will work. The Pre-Explain PMS typically occurs before any hospital (account) purchases a new drug (product). For information about managing Pre-Explain PMS, see "Managing the PMS and Pre-Explain PMS Features" on page 123.

Package Insert Delivery (PID). Pharmaceutical companies are required to offer safety information about a drug (product). This safety information is called a package insert. Its purpose is to improve the doctor's recognition of the product, and protect patient safety in accordance with Japanese government regulations. Pharmaceutical companies are required to monitor whether their representatives are carrying out these calls whenever a package insert is updated for a product. After a modified package insert is delivered and the call has been made to the hospital contact, the sales representative is responsible for recording the call as having been completed. For information about managing PID, see "Managing the PID Feature" on page 126.

■

Visit Timeline During the PMS Period

As stipulated by Japanese government regulation, sales representatives from pharmaceutical companies must visit hospitals at preset intervals for six months after a drug is launched. These visits must occur every two weeks for the first two months after a hospital purchases the drug, and monthly thereafter for a total period of six months after the launch date of the drug.

For example, Drug XYZ is launched on February 1, 2009. The PMS period will also begin on February 1, 2009. The PMS period will end for Drug XYZ six months after its release: on August 1, 2009.

Hospital 1 buys Drug XYZ on February 1, 2009. This means that they will have the maximum amount of PMS visits from the pharmaceutical company. There will be a total of eight visits that will occur approximately on the following dates:

■ Biweekly dates: February 15th, March 1st, March 15th, April 1st

■ Monthly dates: May 1st, June 1st, July 1st, August 1st

Hospital 2 buys Drug XYZ on April 1, 2009. As a result, there will be a total of six PMS visits that will occur approximately on the following dates:

■ Biweekly dates: April 15th, May 1st, May 15th, June 1st

■ Monthly dates: July 1st, August 1st

Hospital 4 buys Drug XYZ on July 15, 2009. As a result, there will be a total of one PMS visit that will occur approximately on the following date:

■ Biweekly date: August 1st

NOTE: Once six months have elapsed after the launch date, there are no more PMS calls.

Managing the PMS and Pre-Explain PMS Features

After a drug is released in the Japanese market, a series of follow-up calls must be scheduled with hospitals purchasing the drug in order to track any possible side effects. Although users can create and display account calls on the Accounts screen, calls can be created for this purpose using the PMS and Pre-Explain PMS features. For more information about PMS and Pre-Explain PMS, see "About Features for Call Planning Specific to the Japanese Pharmaceutical Market" on page 122.

This topic presents different tasks involved for creating account calls relating to PMS and Pre-Explain PMS:

■ "Enabling a Product for PMS" on page 124

■ "Scheduling Calls for Pre-Explain PMS" on page 124

■ "Scheduling Calls for PMS" on page 124

■ "Viewing or Editing PMS Account Products" on page 125

■ "Viewing Upcoming Pre-Explain PMS and PMS Calls for All Accounts" on page 125

■ "Viewing All Missed Calls for Account Contacts" on page 125

Enabling a Product for PMS

The following procedure describes how to enable a product for PMS.

To enable a product for PMS

1 Navigate to the Administration - Products screen > Products view.

2 Select a product.

3 Define a date in the Period Start Date column.

   NOTE: The date should be the product's launch date.

4 Define a date in the Period End Date column.

   NOTE: The date should be six months after product's launch date.

Scheduling Calls for Pre-Explain PMS

The following procedure describes how to schedule calls for Pre-Explain PMS.

To schedule calls for Pre-Explain PMS

1 Navigate to the Administration - Products screen > Schedule PMS Activities view.

2 Select a product.

3 Select an account list.

4 Enter a value for Due Date.

5 Click Pre PMS Call.

   A Pre-Explain PMS call will be scheduled for each hospital in list of Accounts.

Scheduling Calls for PMS

The following procedure describes how to schedule calls for PMS.

To schedule calls for PMS

1 Navigate to the Administration - Products screen > Schedule PMS Activities view.

2 Select a product.

3 Select an account list.

4   Enter a value for Due Date.

5   Click PMS Call.

A series of follow-up calls will be scheduled for each hospital in list of Accounts.

NOTE: Depending on the defined PMS period, each hospital may have up to eight follow-up calls scheduled. These are out-of-the-box default values.

Viewing or Editing PMS Account Products

The following procedure describes how to view or edit PMS Account Products.

To view or edit PMS Account Products

1   Navigate to the Administration - Product screen > PMS Account Product view.

All products set up for Pre-Explain PMS and PMS will appear in this view.

2   Select a product.

3   Modify any of the fields.

Viewing Upcoming Pre-Explain PMS and PMS Calls for All Accounts

The following procedure describes how to view all upcoming Pre-Explain PMS and PMS calls for all accounts.

To view all upcoming Pre-Explain PMS and PMS calls for all accounts

1   Navigate to the Calendar screen > Account Call Planning view.

2   Select an account.

3   Scroll left to move to past calls and right to move to future calls.

4   Calls will be denoted by different blocks of color, according to the legend below the Account Call Planning view.

NOTE: PMS calls for all accounts also appear on the Home screen.

Viewing All Missed Calls for Account Contacts

The following procedure describes how to view all missed calls for account contacts:

To view all missed calls for account contacts

1   Navigate to the Home screen.

2   Scroll to the Missed Calls section.

Viewing All Account and Contact Level Attachments for a PMS Call

The following procedure describes how to view all account and contact level attachments for a PMS call.

To view all account and contact level attachments for a PMS call

1   Navigate to the Post Market Surveillance screen > Activity Details view.

2   Select a PMS account product.

3   Scroll to the bottom of the view.

The Account Attachment section will list any account-level attachments, and the Contact Attachment section will list any contact-level attachments.

Managing the PID Feature

After pharmaceutical companies modify safety information in a package insert for a drug in the Japanese market, a call must be scheduled with all the hospitals distributing the drug. Although users can create and display account calls on the Accounts screen, calls can be created for this purpose using the PID feature. For more information about PID, see "About Features for Call Planning Specific to the Japanese Pharmaceutical Market" on page 122.

This topic presents different tasks involved for creating account calls relating to PID:

■   "Creating a Package Insert" on page 126

■   "Scheduling a Call for PID" on page 127

■   "Viewing All Upcoming PID Calls for All Accounts" on page 127

Creating a Package Insert

The following procedure describes how to create a package insert:

To create a package insert

1   Create a product for the package insert. While creating the package insert, ensure that the following fields are set:

■ Effective Start Date

NOTE: The value given to Effective Start Date should represent the issue date for the product.

■ Item Size

NOTE: The value given to the Item Size field should reflect the number of pages in the package insert.

■ Type

NOTE: The Type field must be set to Insert.

For more information about creating products, see "Process of Managing Products" on page 81.

2 Click the Release button.

3 Add visibility through the category. For more information about product categorization, see"Product Categorization Settings" on page 83.

4 Add the package insert to a personal list. For more information about personal lists, see "Personal Lists" on page 102.

Scheduling a Call for PID

The following procedure describes how to schedule a call for PID.

To schedule a call for PID

1 Navigate to the Administration - Products screen > Schedule PID Activities view.

2 Select the product insert from the list of products.

3 Select an account list.

4 Enter a value for Due Date.

5 Click PID Calls.

A series of calls will be scheduled for each hospital in the list of accounts.

Viewing All Upcoming PID Calls for All Accounts

The following procedure describes how to view all upcoming PID calls for all accounts.

To view all upcoming PID calls for all accounts

1 Navigate to the Calendar screen > Account Call Planning view.

2 Select an account.

3 Scroll left to move to past calls and right to move to future calls.

Different types of calls will be denoted by different blocks of color, according to the legend below the Account Call Planning view.

NOTE: PID calls for all accounts also appear on the Home screen.

8 Managing Pharma Samples

This chapter covers the following topics:

About Managing Pharma Samples

Most pharmaceutical manufacturers provide free samples to health care professionals in an effort to influence the prescribing habits of physicians across the United States and the world. In the United States, samples distribution is regulated by the FDA and must be reconciled at least once a year.

This chapter describes how to manage and maintain an electronic inventory of samples and promotional items using Siebel Pharma Samples Management. Using the procedures given in this chapter, you will be able to perform the administrator tasks of setting up and maintaining a home-office master inventory (optional) and monitoring samples disbursements, orders, transfers, receipts, discrepancies, adjustments, and inventory counts. End users use the Samples Management screens to track an electronic inventory of samples stock, create samples request order and transfers, acknowledges receipt of samples transfers, and adjust inventory balances for reconciliation purposes.

Siebel Samples Management allows sales representatives and administrators to measure and monitor sample disbursements at every level throughout the organization. For more information on the differences between administrator and end-user tasks see "About Scenarios for Managing Samples" on page 133.

About Samples Transactions

Siebel Samples Management maintains a samples transaction record for every sample transfer, receipt, disbursement, order, and inventory adjustment. The application assigns each samples transaction record a unique identifier for tracking purposes. Depending on the type of transaction, you can display this identifier as a transaction number, an order number, an invoice number, or a transfer number.

Each samples transaction record represents a single transaction consisting of one or more line items. As shown in Figure 1, the application tracks a transfer of multiple samples as a single transaction record with multiple corresponding line item records—one line item for each type of product transferred. These line item records are child records of the parent transaction record.
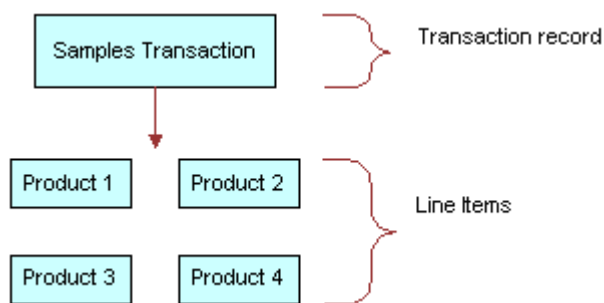
Figure 1.   Transaction Record and Line Item Relationship

Inventory Reconciliation

In the United States, pharmaceutical companies may request that sales representatives perform an inventory reconciliation from one to twelve times a year to remain compliant with the Prescription Drug Marketing Act (PDMA). (Sampling regulations vary significantly in North America, Europe, Asia, and Latin America.) If sales representatives' physical sample inventories do not match their disbursement and transaction histories, they may perform inventory adjustments to justify the discrepancies. For more information, see "Reconciling an Inventory Period (End User)" on page 155.

It is also possible to create sample products by lot numbers and to disburse samples to contacts by lot numbers and yet not reconcile by lot numbers. For more information, see "Reconciling an Inventory Period (End User)" on page 155.

PDMA Compliance and Lot Numbers

Companies in the United States may need to perform additional tasks to meet PDMA requirements. According to the Food and Drug Administration's Final Ruling of December 3, 1999 (21 CFR Part 203 and 205), samples must also be tracked by lot number to the level of disbursement. Siebel Samples Management provides additional functionality that allows you to meet this lot number tracking requirement. For more information on using lot numbers, see "About Samples Transactions" on page 137.

Inventory Periods

Because samples inventory reconciliation can happen as often as once a month, Siebel Samples Management allows you to reconcile as often as you like and provides three types of inventory periods for maximum flexibility. These period types are described in Table 14.

Table 14.   Samples Inventory Periods

Period Type	Description
Active	The current period; it shows no end date and it is not reconciled. You can enter any type of samples transaction, including adding new products; inventory counts will be adjusted accordingly.
Inactive	A past, unreconciled period; it shows an end date but has not been reconciled yet. Except for adding new products into inventory, you can enter any type of samples transaction; inventory counts will be affected accordingly. The default application configuration provides one inactive period, but can be configured for multiple instances.
Reconciled	A past, inactive period; it shows an end date and has been reconciled. Although you can enter samples disbursements for a reconciled period, the inventory counts for the active period will not be affected.

The default Siebel Samples Management configuration provides two unreconciled periods: one active period and one inactive period. The Siebel administrator can control the number of unreconciled periods allowed. For more information, see "Reconciling an Inventory Period (End User)" on page 155.

How Siebel Samples Management Works with Calls

This topic describes how Siebel Samples Management works with the Contact Call Detail and Account Call Detail views. For more information on recording calls, see Chapter 9, "Recording Calls in Pharma."

When you click the Submit button in either the Contact Call Detail and Account Call Detail views, the application verifies that:

■ At least one product has been recorded and detailed.

This requirement can be changed by the administrator. For more information, see Appendix A, "Configuring Siebel Life Sciences."

■ The call's date and time is the same as or earlier than the current date and time. A call cannot be submitted with a future date.

If dropped samples are recorded for the call, the application checks that:

■ A valid paper or electronic signature has been obtained.

■ The Ref# field is not empty.

■ The samples exist in the inventory for the period indicated by the call's date and time.

■ The period into which the samples will be recorded is an unreconciled period. If it is a reconciled period, a warning message appears.

■ A valid lot number has been specified for dropped samples tracked by lot number.

NOTE: When the Lots for Disperse Only system preference is set to TRUE, the lot number is not required. For more information, see "Managing Inventory Tracking and Reconciliation Without Lot Numbers" on page 143.

If the call passes these checks, the application:

■ Creates a samples disbursement transaction, with a line item for each dropped sample recorded for the call.

■ Creates a samples disbursement transaction, with a line item for each dropped sample recorded for the call when Signature is saved for Electronic Signature Calls.

■ Submits a disbursement transaction to update the samples inventory. If the submission of the disbursement transaction is successful, the application changes the call's Status field to Submitted.

■ Sets the Last Call Date field for the contact or account to the date of the submitted call, and many fields in the call record become read-only.

As an administrator, you can change the fields that become read-only after a call is submitted (or synchronized with Siebel Pharma Handheld on a PDA). For information, see Appendix A, "Configuring Siebel Life Sciences."

NOTE: If attendees are recorded in an account call, an attendee call is created for each attendee, and the process described above is performed for each attendee call. Attendee calls are the same as contact calls except that they do not appear in the Activities view and they are submitted automatically when the account call is submitted.

About Samples and Lot Numbers

The use of product samples for product promotion by pharmaceutical companies around the world is governed by local country legislations. Siebel Samples Management maintains a samples transaction record for every sample transfer, receipt, disbursement, order, and inventory adjustment.

The following three options are available to customers who are implementing Siebel Samples Management:

■ Use Lot numbers for samples creation, transfer, adjustment, order, disbursement, inventory, and reconciliation.

This option is the default setting. It is made possible with the system preferences settings shown on the following table.

System Preference	Value
Lots for Disperse Only	FALSE
Sample Lots Enabled	TRUE

NOTE: An administrator sets the system preferences by navigating to the Administration - Application screen > System Preferences view.

■ Use Lot numbers for samples creation, transfer, adjustment, order, disbursement, but do not use lot numbers for inventory and reconciliation.

This option is made possible with the system preferences settings shown on the following table.

System Preference	Value
Lots for Disperse Only	TRUE
Sample Lots Enabled	TRUE

In addition to these system preference changes, a Siebel administrator must use Siebel Tools to control product visibility associated with this behavior. For more information, see Appendix A, "Configuring Siebel Life Sciences."

NOTE: The Lot# Tracking flag on the Administration - Product screen must be checked.

■ Do not use lot numbers for samples management at all.

This option is made possible with the system preferences settings shown on the following table.

System Preference	Value
Lots for Disperse Only	FALSE
Sample Lots Enabled	FALSE

The Lot# Tracking flag on the Administration - Product screen does not have to be checked.

About Scenarios for Managing Samples

This chapter outlines three scenarios that are examples of workflows performed by a samples administrator and the sales representatives who distribute samples to health care professionals. Your company may follow a different process according to its business requirements.

A pharmaceutical company has new products to bring to market. To set up a samples inventory, the samples administrator adds the products to the database, associates any lot numbers, and transfers samples to the managers and sales representatives in the field. Once sales representatives and managers receive the samples, they add them to their personal lists so they are available options in their call reporting. The sales representatives then visit the doctors in their territories and drop the new samples. After a month goes by, each sales representative is required to reconcile his or her inventory. One sales representative realizes there are some discrepancies in her inventory. After she makes the needed adjustments, she reconciles her inventory and starts a fresh inventory period.

Scenarios discussed in this chapter include:

■ **Scenario 1: Administrator Establishes a Master Inventory.** The Siebel samples administrator establishes and transfers inventory to end users.

■ **Scenario 2: Administrator and End Users Establish a Master Inventory.** The Siebel samples administrator and the end user establish an initial inventory and then reconcile it before they disburse any samples.

■ **Scenario 3: Users Transfer Samples to One Another.** Describes the basic process of how users can exchange samples inventory within the system.

Using the procedures described in this chapter, sales representatives can track their samples inventories, record inventory transfers, and track lost or damaged inventory. However, to record samples disbursements, sales representative should use the procedures described in Chapter 9, "Recording Calls in Pharma."

Scenario 1: Administrator Establishes a Master Inventory

In this scenario, samples administrators are responsible for their company's samples inventory and making sure it complies with regulatory rules and regulations. In this role, they take the responsibility for establishing a master samples inventory and then transferring samples to each end user.

Having the samples administrator establish a master inventory and then transfer samples to each end user is a simpler process from the end user's perspective. Once the samples administrator establishes the master samples inventory, the next step is to transfer inventory to each end user. When each recipient electronically receives the shipment, they submit a receipt and application automatically enters the received samples into their inventory counts.

In this process, the representative, the representative's manager, and the samples administrator can monitor discrepancies between shipped quantities and received quantities.

Administrator Procedures

The samples administrator requires administrative responsibilities in Siebel Samples Management to:

■ **Define samples as products.** For more information, see Chapter 6, "Managing Products for Life Sciences."

- **Define lot numbers (optional).** For more information, see "Defining Lot Numbers for Samples" on page 138.

- **Set up and reconcile initial master inventory.** For more information, see "Establishing an Initial Inventory" on page 141.

- **Transfer inventory to end users.** For more information, see "Creating a Samples Transfer" on page 145.

- **Monitor samples activities.** Activities for samples include disbursements, orders, transfers between employees, user inventory counts, and inventory adjustments. For more information, see "Monitoring Samples Activities" on page 147.

- **Manage electronic signatures.** For more information, see "Checking Electronic Signatures" on page 151.

- **Identify sample locations in the event of recalls.** Follow your company's guidelines for managing sample recalls.

End-User Procedures

The end users are the sales representatives who distribute samples to health care professionals. They enter information to:

- **Acknowledge receipt of the inventory transfers.** For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154.

- **Add inventory to personal lists.** For more information, see "Creating a Personal List (End User)" on page 106.

- **Use the new samples in regular call reporting.** For more information, see Chapter 9, "Recording Calls in Pharma."

- **Transfer samples to other end users.** Sales representatives exchange samples among themselves. For more information, see "Creating a Samples Transfer" on page 145.

- **Request more samples.** For more information, see "Creating a Samples Order (End User)" on page 153.

- **Perform inventory adjustments.** For more information, see "Adjusting a Past Samples Transaction" on page 149.

- **Reconcile inventory periods as needed.** For more information, see "Reconciling an Inventory Period (End User)" on page 155.

Scenario 2: Administrator and End Users Establish a Master Inventory

In this scenario, both the samples administrator and the end user establish a master samples inventory or inventory count. Samples administrators are again responsible for their company's samples inventory and making sure it complies with regulatory rules and regulations.

From a process perspective, this process requires more steps for the end user because they must first establish an initial inventory and then reconcile it before they can disburse any samples.

Administrator Procedures

Samples administrators require administrative responsibilities in Siebel Samples Management to:

■ **Define samples as products.** Product inventory is maintained in the database. For more information, see Chapter 22, "Managing Clinical Projects."

■ **(Optional) Define lot numbers.** Samples may be tracked by lot numbers For more information, see "Defining Lot Numbers for Samples" on page 138.

■ **Set up and reconcile initial master inventory.** This step is required only if you are not using a third-party system to populate the samples inventory. For more information, see "Establishing an Initial Inventory" on page 141.

■ **Monitor samples activities.** Samples activities that are monitored include disbursements, orders, transfers between employees, user inventory counts, and inventory adjustments. For more information, see "Monitoring Samples Activities" on page 147.

■ **Check electronic signatures.** Regularly check Signature Audit Administration to verify that signatures collected from contacts are consistent. For more information, see "Checking Electronic Signatures" on page 151.

■ **Identify sample locations in the event of recalls.** Follow your company's guidelines for managing sample recalls.

End-User Procedures

The end users are the sales representatives who distribute samples to health care professionals. They enter information to:

■ **Set up and reconcile initial master inventory.** For more information, see "About Establishing an Initial Inventory Count (End User)" on page 152.

■ **Add inventory to personal lists.** For more information, see "Creating a Personal List (End User)" on page 106.

■ **Use the new samples in regular call reporting.** For more information, see Chapter 9, "Recording Calls in Pharma."

■ **Transfer samples to other end users.** Sales representatives exchange samples among themselves. For more information, see "Creating a Samples Transfer" on page 145.

■ **Acknowledge receipt of the inventory transfers.** End users must acknowledge receipt of a samples transfer transaction before the transfer can be completed. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154.

■ **Perform counts and adjustments.** For more information, see "Adjusting a Past Samples Transaction" on page 149.

■ **Reconcile inventory periods as needed.** For more information, see "Reconciling an Inventory Period (End User)" on page 155.

Scenario 3: Users Transfer Samples to One Another

This scenario describes the basic process for exchanging inventory with other users within the system. This process can be used by both the administrator and end users to exchange samples. When a user creates a samples transfer to move inventory to another user, the recipient electronically receives a shipment of samples. Once the recipient submits a receipt for that shipment, the application automatically enters the received samples into their inventory counts.

Figure 2 illustrates this process.
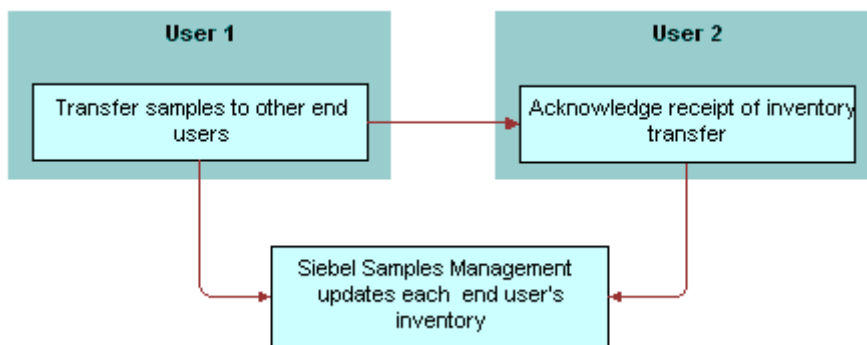
Figure 2.   Process for Users to Transfer Samples to One Another

Prerequisites for Managing Samples

Administrators. Before you can set up Siebel Samples Management, you must first define your products. For more information, see Chapter 6, "Managing Products for Life Sciences."

End-users. Before they can drop samples, they must configure personal lists of the products they detail, the products they distribute as samples, and the products they provide as promotional items before they can record information about contact calls or account calls. For more information on creating personal lists, see "Creating a Personal List (End User)" on page 106.

About Samples Transactions

In the default configuration, Siebel Samples Management supports two open inventory periods. The samples administrator can override this default behavior by adding additional open periods using Siebel Tools. When users click the Submit button for a samples transaction, the system checks the transaction date and time to determine the inventory period into which the transaction should be entered.

For all transactions except receipts, the application enters the transaction into the inventory period that includes the transaction's date and time. If no such period exists, the transaction submission fails.

If the situation involves samples receipts (that is, received samples transactions displayed in the Received Samples view) and no inventory period exists that includes the transaction's date and time, Siebel Samples Management creates a new inventory period.

For example, this situation might occur during initial deployment, before any inventory periods have been opened. The new period's start date and time are set to the invoice receipt's date and time. However, the application first checks whether any pending transaction has an earlier transaction date than the one being submitted. This is done to prevent any impasse that might occur if a second invoice receipt is later submitted with an earlier transaction date.

NOTE: Once the first inventory period has been created, another period with an earlier start date and time cannot be created.

Submitted samples transactions impact inventory counts in the following ways:

■ Samples orders are independent of inventory periods because they have no effect on inventory counts.

■ Received Samples (transactions whose Type field is Transfer In) are added to the submitter's inventory counts.

■ Sent Samples (transactions whose Transfer Type or Transaction Type field is Transfer Out or Return) are subtracted from the submitter's current inventory counts. In addition, a corresponding invoice receipt is created for the receiving party.

  NOTE: Typically, samples returns (samples transfers whose Transfer Type field is Return) are expired products that are sent back to the home office to be destroyed. Samples returns are *not* added back into the home office's master inventory counts. The samples administrator can track samples returns by using the Sent Samples administration view or the Samples History administration views and querying for those samples transactions with a type equal to Return.

■ Samples adjustments (transactions whose Transaction Type field is Inventory Adjustment) are either added to or subtracted from the submitter's inventory counts. Samples adjustments are the only type of samples transaction in which negative quantities are allowed.

In the Samples History view, the Add, Adjust, and Submit buttons are enabled or disabled as follows:

■ If the transaction's Status field is set to Submitted, the Adjust button is enabled and the Add and Submit buttons are disabled.

■ If the transaction's Status field is set to Adjusted, all the buttons are disabled.

■ If the transaction's Status field is set to In Progress, the Submit button is enabled and the Add and Adjust buttons are disabled.

Defining Lot Numbers for Samples

Siebel Samples Management allows you to define your samples and promotional items according to a number of different implementation scenarios. By specifying certain product settings, you can make Siebel Samples Management suit your company's strategy for inventory tracking and distribution of samples. You can implement samples using lot numbers in the following ways:

■ Tracking samples for inventory purposes at a lot level or a sample product level.

■ Disbursing some products with lots and others without lots.

■ Managing existing samples that have already been distributed and tracked without lot numbers in Siebel Samples Management.

■ Using lot numbers for samples creation, transfers, adjustments, orders, and call reporting, but not using lot numbers for inventory and reconciliation. For more information, see "Managing Inventory Tracking and Reconciliation Without Lot Numbers" on page 143.

Before you can track samples by lot number, you must:

■ Verify that the Samples Lots Enabled system preference is set to TRUE (the default setting). For more information, see "Disabling Lot Number Tracking" on page 140.

■ Define the products that will be disbursed as samples. For more information, see "Defining Internal Products" on page 82.

■ Define the lot numbers for each product. For more information, see the procedure "To define lot numbers" on page 139.

If you track disbursements at the lot number level, you may track inventory with or without using lot numbers. For more information on disabling lot number tracking see "Disabling Lot Number Tracking" on page 140. For more information on reconciliation without lot numbers, see "Managing Inventory Tracking and Reconciliation Without Lot Numbers" on page 143 and "Enabling Inventory Reconciliation Without Lot Numbers" on page 482.

If you are implementing either full or partial lot number tracking for samples use the following procedure to define the lot numbers associated with those samples. This procedure creates lot number records that are children of the parent sample product record. For more information setting up lot tracking, see "Defining Internal Products" on page 82.

Existing products (that is, products that were previously defined without lot number tracking specified) cannot be tracked by lot number if they exist in any user inventory. To begin tracking lot numbers for an existing product, you must create a new product record with a product name indicating that this product will be tracked by lot number. For example, if the existing product is named Aracid 200, you could name the new product Aracid 200 (Lot).

To define lot numbers

1 Verify that you have specified the correct settings for the products to be disbursed as samples.

   For more information setting up lot tracking, see "Defining Internal Products" on page 82 paying specific attention to Table 11 on page 83 and Table 12 on page 84.

2 Navigate to the Administration - Samples screen > Lot Setup view.

3 In the Lot Setup list, create a new record, and complete the necessary fields.

   Some fields are described in the following table.

Field	Comments
Expiration Date	This information can be used for recalls of expired products.
Effective Start Date	The date of manufacture, the date on which the product was received, or another date defined by your company.

Field	Comments
Lot #	Enter an unique value that corresponds to the lot number printed on the label of the product.
Inventory By Lot	Check this field if inventory tracking by lot number is required For more information, see "Defining Internal Products" on page 82 paying specific attention to Table 11 on page 83 and Table 12 on page 84.
Sample	The name of the product for which this lot number will be affiliated. This field should indicate both product name and dosage. Only products that are set up for lot number tracking appear in the dialog box. For more information, see "Defining Internal Products" on page 82 paying specific attention to Table 11 on page 83 and Table 12 on page 84.

4 Repeat Step 3 to define other lot numbers.

NOTE: Multiple lot numbers can be defined for a sample product, as long as each lot number is unique.

You can also include the lot number in the product name when defining the product. For more information, see "Defining Internal Products" on page 82. However, using this method can make the drop-down lists that users select from very long. Only use this method if the number of products that will be disbursed is small.

Disabling Lot Number Tracking

Lot number tracking for sample products is enabled by default. With lot number tracking enabled, the constraints and data checks described in "How Siebel Samples Management Works with Calls" on page 131 and "Defining Internal Products" on page 82 become active.

Regardless of whether you have set the Samples Lots Enabled system preference to TRUE or FALSE, samples dispersed with lot numbers should appear in both the Samples History and the Inventory Count views. Thus, even if you decide not to use lot numbers, your samples history is fully recorded.

To disable lot number tracking for samples

■ Set the Samples Lots Enabled system preference to FALSE.

For general information about setting system preferences, see the *Siebel Applications Administration Guide*.

Setting the Lots for Disperse Only system preference to TRUE allows you to ship samples to users by lot numbers and allows sales representatives to disburse the samples by lot numbers while maintaining and reconciling inventory without lot numbers. To retain sample product visibility, the samples administrator must reconfigure the Siebel repository. For more information, see "Managing Inventory Tracking and Reconciliation Without Lot Numbers" on page 143.

NOTE: By default, Sample Lots Enabled is set to TRUE and Lots for Disperse Only is set to FALSE. If you do not want to use lot numbers, you can change both of these system preferences, setting Sample Lots Enabled to FALSE and Lots for Disperse Only to FALSE.
Lots for Disperse Only works only when Sample Lots Enabled is set to TRUE. If Sample Lots Enabled is set to FALSE, the system ignores Lots for Disperse Only.

Establishing an Initial Inventory

Establishing an initial master inventory is only necessary if you are manually entering and tracking samples. If you are populating your samples inventory from a third-party system, it is not recommended that you establish an initial master inventory.

As outlined in "About Scenarios for Managing Samples" on page 133, either an administrator or an end user may establish an inventory. However, because Siebel Samples Management routes and maintains transactions by Employee ID, only the user who creates an inventory (the initial inventory count) can create or manipulate that inventory.

Before adding products to the master inventory, you must verify that the products are correctly defined for inventory tracking. For more information, see "Defining Internal Products" on page 82 paying specific attention to Table 11 on page 83 and Table 12 on page 84.

In particular, in the Products form, you must select one of the following fields:

■ Orderable

■ Either Inventory or the Lot# Tracking

When neither Inventory nor Lot # Tracking are checked, the sample is not tracked in inventory.

For more information, see "Defining Internal Products" on page 82 and "About Samples Transactions" on page 137.

NOTE: End users do not need to perform the procedures described in this topic if their initial counts consist only of samples transfers routed to them by their samples administrator. Instead, they should simply acknowledge the receipt of those shipments. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154. However, end users do need to perform the procedures described in this topic if their initial counts contain any records that they entered manually. End users who enter records manually must submit those counts and reconcile the initial inventory period.

To establish an initial master inventory:

■ **Count products on-hand.** Establish an inventory count by physically counting the products currently on-hand. This process creates a list of the products in your inventory and an inventory period solely for your initial count.

■ **Add products and submit count.** Add products to the inventory and submit an initial count. (See "To add products to inventory and submit an initial count" on page 142.)

■ **Submit adjustments.** Create and submit adjustments for the initial count. (See "To create and submit initial count adjustments" on page 143.)

■ **Reconcile.** Reconcile the initial inventory period. (See "To reconcile the initial inventory period" on page 145.)

To add products to inventory and submit an initial count

1   Navigate to the Samples screen.

2   On the link bar, click Inventory Count.

3   In the Inventory Count list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Count	The amount of your initial inventory.
Difference	Shows a negative number after you enter a value in the Count field.
Lot	The lot number for this sample.
Sample	The name of the sample to be added.

Repeat Step 3 to create a new record and count for each product in your inventory.

NOTE: Records created in this view can be deleted only if the value of the On Hand Quantity field is zero.

4   Click Submit.

The Difference field is cleared for all records. The application transfers the number you entered in the Count field to the On Hand Quantity field and clears the Count field.

Once you submit an initial count, the Siebel Samples Management deactivates the inventory period into which you entered your initial counts and creates a new active inventory period.

5   On the link bar, click Samples History.

The Samples History view appears.

The inventory period into which you entered your initial counts becomes inactive—a date and time appear in the End Date field, and there is no check mark in the Active field. In addition, a new active period has been opened.

Create adjustment transactions for the period, as described in the next procedure.

NOTE: You cannot submit an adjustment transaction if the product is not currently active. Siebel Samples Management considers a product inactive if the administrator has made it inactive, or the product does not exist in the inventory count list (it could have been deleted if the on-hand quantity was zero). Inactive products do not display in drop-down lists or dialog boxes, although they may be visible in views displaying products.

Managing Inventory Tracking and Reconciliation Without Lot Numbers

Siebel Samples Management supports using lot numbers for samples creation, shipment, receipt, transfers, adjustment, ordering, and disbursement while not using lot numbers for inventory and reconciliation.

To enable this behavior, you must make three changes:

■ Set the value of two system preferences—Samples Lots Enabled and Lots for Disperse Only—to "True."

■ Check the Lot# Tracking flag in the Administration - Product screen.

■ Implement product visibility. For more information, see "Retaining Sample Product Visibility" on page 482.

When this behavior has been enabled, the Lot No. field is available but not required for samples creation, shipment, receipt, transfers, adjustment, ordering and call reporting. In addition, the Lot No. field is disabled in the Inventory Count and Reconciliation views.

To track and reconcile inventory without lot numbers

1 Set the Samples Lots Enabled system preference to TRUE.

2 Set the Lots for Disperse Only system preference to TRUE.

For general information about setting system preferences, see the *Siebel Applications Administration Guide*.

To create and submit initial count adjustments

1 Navigate to the Samples screen.

2 On the link bar, click Sample Adjustments.

3 In the My Samples Adjustments list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Adjustment Reason	Select Initial Count from the drop-down list.
Inventory Period	Selecting an Inventory Period automatically enters a validated date in the Transaction Date (Txn Date) field, making sure that the adjustment is entered into the appropriate inventory period.
Transaction #	The application automatically generates an unique identifier. You can change this value.
Transaction Date	It is recommended that you complete the Inventory Period field to auto-fill this field so that the adjustment is entered into the correct period.
Transaction Status	The application automatically changes this field value to Submitted when you submit the adjustment.

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

Some fields are described in the following table.

Field	Comments
Item #	The application automatically generates this value. If you want to have the items appear in a particular order, edit this value in the Administration - Product screen.
Item Status	The application automatically changes this field value to Submitted when you submit the transaction.
Lot Name	The lot number for this sample.
Quantity	The amount of your initial inventory. This quantity should be the same as the value you entered in the Count field in the Inventory Count view. For more information, see "To add products to inventory and submit an initial count" on page 142).
Sample	The sample to be adjusted.

Repeat Step 3 and Step 4 to enter a line item for each sample needing adjustment.

5 Click Submit.

The values in the Transaction Status field (in the Samples Adjustment form) and the Item Status fields (in the Line Items list) are changed to Submitted.

Reconcile the initial inventory period, as described in the next procedure.

To reconcile the initial inventory period

1 Navigate to the Samples screen.

2 On the link bar, click Reconciliation.

The Reconciliation view contains the following lists.

List	Description
Unreconciled Inventory Periods	Shows all inactive (past, unreconciled) inventory periods. An active period becomes inactive once you submit an inventory count for the period (as described in *"To add products to inventory and submit an initial count" on page 142*).
Unreconciled Inventory	Shows the products in your inventory, their physical and electronic counts, and the difference between the two counts (if any). The Difference field must be zero for all products before you can reconcile the period.
Samples History	Shows samples transactions entered for the currently selected product in the Unreconciled Inventory list. If no transactions were entered for the selected product during the inactive inventory period, this list is empty.

3 In the Unreconciled Inventory list, verify that the Difference field shows zero for the products listed.

If a product shows a value other than zero, you must make an adjustment to correct the difference. For more information, see *"Adjusting a Past Samples Transaction" on page 149*.

4 In the Unreconciled Inventory Periods list, click Reconcile.

The lists in the view are cleared.

5 From the Show drop-down list, select My Samples History.

The Samples History view appears. In the Inventory Periods list, a check mark appears in the Reconciled field of the inactive period that you just reconciled.

Creating a Samples Transfer

You create a samples transfer whenever product samples are exchanged within your company. This procedure can be used by:

■ A samples administrator to send shipments to end users in the field

■ End users to exchange samples between themselves

■ End users to return samples to the home office

Once the samples transfer has been submitted into the system, the recipient receives a samples transfer. After the recipient acknowledges the receipt of the transaction, the application enters the new inventory into his or her inventory count. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154.

NOTE: Samples returns are defined as transfer transactions for which corresponding received shipment transactions have *not* been created. Returned samples are subtracted from the sender's inventory counts but are *not* added to the master inventory, because they are typically expired or damaged products.

To create a samples transfer

1 Navigate to the Samples screen.

2 On the link bar, click Sent Samples.

3 In the My Sent Samples list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Transfer #	The application automatically generates an unique identifier. You can change this value.
Transfer Date	The application automatically generates a date and time value that falls in the active period.
Transfer Status	The application automatically changes this field value to Submitted when you submit the transaction.
Transfer to Last Name	The employee to whom you are transferring the samples. If the value of the Transfer Type field is Transfer Out, you must complete this field. Leave this field empty if the value of the Transfer Type field is Return.
Transfer Type	Select the appropriate value: ■ Transfer Out - Indicates you are transferring samples to another employee. ■ Return - Indicates you are returning samples to the home office. Samples are typically returned because they are expired or damaged products that should be destroyed. Transfers with the Transfer Type field set to Return do not generate shipment transactions, and they are *not* added to the master inventory counts. However, the samples administrator can see returned samples transactions in the Administration - Samples views. For more information, see "Monitoring Samples Activities" on page 147.
Inventory Period with Comments	Inventory period restricts the available products and Lot #'s for selection when adding line items. Also ensures that only valid product and Lot # for the selected inventory period are available for selection and that the Transfer Txn is entered for the appropriate inventory period.

Managing Pharma Samples ■ Monitoring Samples Activities

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

Some fields are described in the following table.

Field	Comments
Item #	The application automatically generates an unique identifier. Edit this value to have the items appear in a particular order.
Item Status	The application automatically changes this field value to Submitted when you submit the transaction.
Lot #	The lot number for this samples transfer.
Quantity	The quantity that you are transferring.
Sample	The samples being transferred.

Repeat Step 4 to enter a line item for each product or promotional item you are transferring.

5   Click Submit.

NOTE: A transfer transaction cannot be modified or deleted after it has been submitted.

The value of the Transfer Status field (in the Sent Samples list) and the Item Status field (in the Line Items list) changes to Submitted.

6   On the link bar, click Samples History.

When you select a product that has been transferred in Inventory List, the line items of the transfer transaction appear in the Samples History list.

Monitoring Samples Activities

As the samples administrator you are responsible for your company's samples inventory and making sure it complies with regulatory rules and regulations. Use the views described in Table 15 on page 148 to monitor samples activity across the enterprise.

To access monitor samples activities

1   Navigate to the Administration - Samples screen.

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2 On the link bar, click one of the view names listed in the left column of Table 15.

NOTE: The views discussed in Table 15 are read-only and appear only when you are connected to the server.

Table 15.   Administrator Views for Monitoring Samples Activity

View	Description
Inventory Count	Shows samples inventory counts that have been submitted within the enterprise.
Inventory Adjustments	Shows inventory adjustments for the organization. Adjustment transactions can be submitted by end users or by the samples administrator to resolve discrepancies between physical and electronic inventory counts. Adjustment transactions provide a clear audit trail of samples inventory adjustments.
Received Samples	Shows samples receipt transactions submitted by end user. The Line Items list shows the line items of the samples receipt currently selected in the Samples Receipts list. This view allows the administrator to review sent shipments between end users.
Sample Discrepancies	Shows samples receipts submitted by users in which the received quantity did not match the shipped quantity. The Line Items list shows the line items for the receipt currently selected in the Sample Discrepancies list. This view allows the administrator to make sure that samples are not being diverted.
Samples History	Shows a list of samples transactions. Be aware that: ■ If a Contact record is removed, the application removes that name from all lists that reference that contact's name in the S_CONTACT table. This can cause the name fields in Samples History records to appear empty. Use caution when deleting Contacts records. ■ Drilling down on the Transaction # takes users to the view where the transaction was created. In order to assure that users can take advantage of these hyperlinks, they must have the destination view for product hyperlinks in their responsibilities.

Table 15.   Administrator Views for Monitoring Samples Activity

View	Description
Samples Orders	Shows samples order transactions submitted by end users or their managers. The Line Items list shows the line items of the samples order currently selected in the Samples Orders list. This view allows the administrator to review samples order sent from end users.
Sent Samples	Shows samples transfer transactions submitted. The Line Items list shows the line items of the samples transfer currently selected in the Sent Samples list. This view allows the administrator to review samples returns or shipments sent between end users.

Adjusting a Past Samples Transaction

The samples administrator and end users can adjust inventory counts of samples stock by making adjustments to past samples transactions. Common reasons for adjusting past transactions include product loss or expiration, counting mistakes, or data entry errors. You can add products or adjust quantities for any type of samples transaction (disbursement, transfer, order, and so on).

NOTE: You cannot add a product to your inventory that did not exist when the original transaction was created.

You adjust a past samples transaction in the Samples History view.

When you select a product in the Inventory List, the Samples History list shows samples transactions entered for that product. For example, if a sales representative dropped multiple samples on a call, the Samples History list would display one line-item record for each sample. Also, if an adjustment has been made to an item in the transaction, an additional row (corresponding to the adjustment) will appear in this view.

To add a product to a samples transaction

1   Navigate to the Samples screen.

2   On the link bar, click Samples History.

3   In the Inventory List, select a product.

When you select a product in the Inventory List, the Samples History list shows all samples transactions entered for that product. You can identify the transaction record in the Samples History list by the Transaction Date, Last Name, or Transaction # field values.

4   In the Samples History form, create a new record.

When you create a new record, the application adds a new line-item record for the transaction in the Samples History list and sets the line-item record's Item field Status to In Progress. With the exception of the Item Status value, the new record is a copy of the record selected in Step 3.

5 In the Samples History form, modify the new record to reflect the correct product information. Some fields are described in the following table.

Field	Comments
Created By Full Name	The full name of the creator of the transaction.
Description	A description of the product or comment describing the transaction.
Item Status	The application automatically changes this field value to Submitted when you submit the adjustment. For any row that shows an item status of Submitted, you can also see one or more rows with the identical sample name and transaction number but with an item status of In Progress or Adjusted. Valid values include: ■ In Progress — Indicates that the adjustment record has not yet been submitted, so it can still be modified. However, the record's data is not reflected in the inventory count. ■ Submitted — Indicates that the record has been submitted and therefore cannot be modified. Because it has been submitted, the record's data is reflected in the inventory count. ■ Adjusted — Indicates that a previously submitted record has been superseded by a subsequent adjustment record. The record cannot be modified.
Lot #	The correct lot number for this sample.
Quantity	The quantity of samples shipped or disbursed in the transaction.
Sample	Verify that the correct product name is selected.
Transaction #	The transaction number or, in the case of samples disbursements, the reference number. The Transaction # value corresponds to the Ref # value displayed in the Contact Call Detail view.
Transaction Date	The date the transaction was created.
Transaction Status	An indicator of the status of the original sample transaction.
Transaction Type	Shows the type of transfer. Valid values include Transfer Out and Transfer In.
Transfer To/ From Full Name	The name of the employee receiving or generating the transaction. Used only if the transaction type is Transfer Out or Transfer In.

To adjust a quantity in a samples transaction

1 Navigate to the Samples screen.

2 On the link bar, click Samples History.

3 In the Inventory Periods list, select the period containing the transaction for which you want to adjust a quantity.

The products for the selected period are displayed in the Inventory List.

4 In the Inventory List, select the product whose quantity you want to adjust.

When you select a product in the Inventory List, the Samples History list lists all samples transactions entered for that product. You can identify the transaction record in the Samples History list by the Transaction Date, Last Name, or Transaction # field values.

5 In the Samples History form, click Adjust Qty and then OK.

The application first verifies that you have sufficient rights to make the adjustment and then adds a new line-item record for the transaction in the Samples History list and sets the line-item record's Item Status field to In Progress. With the exception of the Item Status value, this record is a copy of the record you selected in Step 4.

6 In the Samples History form, enter the correct quantity in the Quantity field.

7 Click Submit, and then OK.

The application creates a new item with an Item Status of Submitted and changes the original item record (whose quantity you adjusted) to an Item Status of Adjusted. The new quantity is reflected in the on-hand quantities in the Inventory Count view.

Checking Electronic Signatures

End users can use Siebel Pharma or Siebel Pharma Handheld to electronically capture signatures. The Signature Audit Administration view lists the four most recent electronically captured signatures of a contact to whom samples were dropped.

As the samples administrator, be sure to check Signature Audit Administration regularly and perform signature capture verification to make sure that signatures collected from each contact are consistent.

The signature capture verification determines if the call information has been modified by comparing the information captured from the signature (the signature event string) with the current call information (the current call string). Reasons for call information modification include:

■ Recreation of a sample receipt

■ Sample adjustments

■ Fraud

Signature capture verification is launched from the Verify button on the Signature Audit Administration view. For an example of signature audit administration, see *Siebel Pharma Handheld Guide*.

As the samples administrator you are responsible for your company's samples inventory and making sure it complies with regulatory rules and regulations. Use the views described in Table 15 on page 148 to monitor samples activity across the enterprise.

To display Signature Audit Administration

■ Navigate to the Administration - Samples screen > Signature Audit Administration view.

NOTE: If a Contacts record is deleted, the application removes the contact name from lists that reference that contact's name in the S_CONTACT table. Therefore, if the Contact Id is deleted from the S_ACT_SIGN table, the last name and first name fields appear empty in the Signatures form within the Signature Audit Administration view. However, deleting a Contacts record does not affect the Contact Full name because it is stored in a text field in the same table. In the Pharma Signature Receipt Form, the control above the Signature shows the full name of the contact at the time of the call (that is, no reference to the S_CONTACT table). Because the contact's name is not removed from this list, a permanent and complete electronic record of calls captured with signatures recorded electronically is maintained.

Generating a Receipt for Calls with Electronic Signatures

The Sample Event Administration view shows an entire sample transaction as it was recorded at the time the signature was captured. Sales representatives can submit electronically captured signatures using Siebel Pharma or Siebel Pharma Handheld.

To display Sample Event Administration

■ Navigate to the Administration - Samples screen > Sample Event Administration view.

Creating New Disclaimer Text for Signature Capture Display

The Disclaimer Administration view shows the disclaimer information that appears in the LS Pharma Call Signature Form Applet (in Siebel Pharma) or the Siebel Signature Capture display (in Siebel Pharma Handheld).

To display the Disclaimer Administration view

1 Navigate to the Administration - Samples screen > Disclaimer Administration view.

2 To replace existing disclaimer text, create a new record in the Disclaimers list and complete the necessary fields.

   The new disclaimer becomes active immediately. Only one disclaimer can be active at a time.

About Establishing an Initial Inventory Count (End User)

End users only need to establish an initial inventory count when their initial counts contain records that they manually entered into Siebel Samples Management. If that is the case, they must set up an initial master inventory, make adjustments, and then reconcile it as described in "Establishing an Initial Inventory" on page 141.

If their initial counts only contain samples routed to them by their samples administrator, they simply need to acknowledge the receipt of those shipments. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154.

Creating a Samples Order (End User)

End users can request additional samples by creating a samples order. Once submitted, the application routes the samples order to the samples administrator. The samples administrator then creates a samples transfer that is routed back to the requestor. Once the requestor acknowledges receipt of the transfer, Siebel Samples Management automatically enters the new inventory into their inventory counts.

NOTE: Creating samples orders is optional. Siebel Samples Management allows users to acknowledge receipt of samples shipments, even if they have not created orders for those samples. The Siebel administrator determines whether or not users are required to create samples orders for record-keeping purposes.

To create a samples order

1 Navigate to the Samples screen.

2 On the link bar, click Samples Orders.

3 In the Samples Orders list, create a new record.

   The application creates a new record and automatically sets the Order Date field to a date and time in the active period.

   NOTE: It is not necessary to change the Order Type field. You can include both samples and promotional items in a single order.

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

   Some fields are described in the following table.

Field	Comments
Item Status	Initially set to In Process. The application automatically changes this field value to Submitted when you submit the transaction.
Sample	The product to be ordered.

   Repeat Step 4 to enter a line item for each product or promotional item you want to order.

5 Click Submit.

   NOTE: An order cannot be modified or deleted after it has been submitted.

The values of the Order Status field (in the Samples Order list) and the Item Status field (in the Line Items list) change to Submitted.

Acknowledging Receipt of a Samples Transfer (End User)

Siebel Samples Management supports two ways of electronically moving samples inventory:

■ By creating a samples transfer, see "Creating a Samples Transfer" on page 145

■ By creating a samples order, see "Creating a Samples Order (End User)" on page 153

In either case, the application creates a samples transfer transaction and routes it to the recipient for acknowledgement. Once the recipient submits a receipt, the application transfers the new inventory into their active inventory period. End users can then view the new inventory in the Samples History screen. For more information on displaying the Samples History view, see "Adjusting a Past Samples Transaction" on page 149.

To acknowledge receipt of a samples transfer

1 Navigate to the Samples screen > Received Samples view.

2 In the Received Samples list, select the transfer that you want to acknowledge.

Samples transfers that have not been acknowledged as received show an Invoice Status value of In Progress. Those that have been acknowledged as received show an Invoice Status value of Submitted.

3 In Line Items list, modify the Received Quantity field if the value does not accurately reflect the quantity received.

4 Click Submit.

NOTE: The samples transfer quantities do not appear in end users inventory counts until they submit a samples receipt. However, once the samples receipt has been submitted, it cannot be modified or deleted.

The values in the Invoice Status field (Received Samples list) and the Item Status field (Line Items list) change to Submitted.

End users can track discrepancies between shipped quantities and received quantities by using the My Received Samples Transfer Discrepancies filter. A manager's version of this view is also provided, and the samples administrator can track samples discrepancies system-wide by using an Administration - Samples view. For more information on available administration views, see "Monitoring Samples Activities" on page 147.

5 Navigate to the Samples screen > Samples History view.

The Samples History view appears. Selecting a period in the Inventory Periods list shows the line items of the received transfer in the Samples History list.

Adjusting an Inventory Count (End User)

The administrator and end users can adjust inventory counts of samples stock by making adjustments to past samples transactions. Common reasons for adjusting past transactions include product loss or expiration, counting mistakes, or data entry errors. When adjusting an inventory account, users may add products or adjust quantities for any type of samples transaction (disbursement, transfer, order, and so on). For more information on adjusting inventory counts, see "Adjusting a Past Samples Transaction" on page 149.

Recording Thefts and Losses (End User)

End users record sample thefts or losses in the Samples Adjustments view.

To record a sample theft or loss

1 Navigate to the Samples screen.

2 On the link bar, click Sample Adjustments.

3 In the Samples Adjustments list, create a new record.

4 In the Adjustment Reason field, select Lost.

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

6 Click Submit.

Reconciling an Inventory Period (End User)

At least once a year, end users are required to perform an inventory reconciliation to remain in PDMA compliance. Users might also need to perform an inventory reconciliation if they are receiving a promotion or leaving the company. For more information on reconciliation, see "Inventory Reconciliation" on page 130.

Prior to starting inventory reconciliation, users must perform the steps outlined in Figure 3.
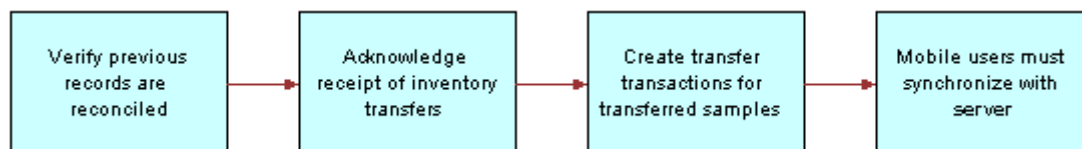

Figure 3.   Inventory Reconciliation Prerequisites

These inventory reconciliation prerequisites must be performed in the following order:

■ **Verify previous inventory periods are reconciled.** End users must reconcile previous inventory periods in chronological order. This is only a concern if a company's configuration allows more than one inactive, unreconciled period. For more information, see "About Establishing an Initial Inventory Count (End User)" on page 152.

■ **Acknowledge receipt of inventory transfers.** End users must send acknowledgements for all received sample inventory shipments. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 154.

■ **Create transfer transactions for transferred samples.** End users must create transfer transactions for any samples transferred to another representative or returned to the home office. For more information, see "Creating a Samples Transfer" on page 145.

■ **Mobile users synchronize with server database.** Mobile end users must synchronize their local database with the server database before submitting an inventory count. This is especially important if they are recording samples received in a prior period or to be received in a future period. For more information on synchronizing a local database, check with your Siebel administrator.

NOTE: Counts for transferred and received samples are not reflected in the inventory count until their records have been submitted.

An inventory period cannot be reconciled if any discrepancy exists between the physical and electronic counts. If a discrepancy exists, it must be corrected before a user can reconcile the period. For more information, see the procedure "To identify discrepancies in inventory counts" on page 157.

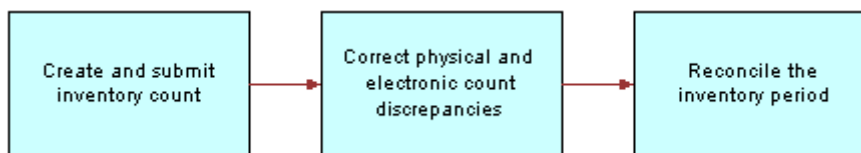The reconciliation process consists of the steps outlined in Figure 4.

Figure 4.   Inventory Reconciliation Process

These reconciliation steps must be performed in the following order:

■ **Create and submit an inventory count.** End users must create and submit an inventory count (either by product or lot number) of the products currently on-hand. For more information, see the procedure "To create and submit an inventory count" on page 157.

End users cannot submit a count differently from the way they submitted the previous period's count *unless the previous period has been reconciled*. For example, if they submitted the previous period's count by product name, they must reconcile that period before they can submit a subsequent count by lot number.

■ **Correct physical and electronic count discrepancies.** End users must correct any discrepancies between the physical counts and the electronic counts by:

■ Creating and submitting a sample adjustment transaction with one or more line items. For more information, see the procedure "To adjust multiple quantities with a new adjustment transaction" on page 158.

This method allows end users to adjust the inventory counts of multiple products with a single adjustment transaction (containing multiple line items). However, they may want to use this method if they need to adjust more than two or three counts.

■ Adjusting previous transactions. Adjusting line-item records of previously entered transactions. For more information, see the procedure "To adjust a quantity in a samples transaction" on page 150.

This method allows end users to adjust the quantity of a selected line item in a previously entered transaction. However, they may want to use this method if they only need to adjust one or two counts.

■ **Reconcile the inventory period.** For more information, see the procedure "To reconcile an inventory period" on page 159.

To create and submit an inventory count

1 Physically count all samples currently on-hand.

2 Navigate to the Samples screen.

3 On the link bar, click Inventory Count.

The Inventory Count list lists records for every product in your inventory.

NOTE: Records in the Inventory Count view can be deleted only if the value of the On Hand Quantity field is zero. Do not delete records from this view unless you are certain that you will not need to enter adjustments to any transactions containing the product in the future or in a past unreconciled period.

4 In the Inventory Count list, enter a value in the Count field for all records.

The Difference field in some records may show a value other than zero.

Proceed in one of the following ways:

■ If the Difference field in any record shows a value other than zero, click Submit and follow the procedure "To identify discrepancies in inventory counts" on page 157.

■ If the Difference field in all records is equal to zero, click Submit and follow the procedure "To reconcile an inventory period" on page 159.

To identify discrepancies in inventory counts

1 Navigate to the Samples screen.

2 On the link bar, click Reconciliation.

3 In the Unreconciled Inventory Periods list, select the period that you want to reconcile.

4 In the Unreconciled Inventory List, scroll to determine how many product records show a value other than zero in the Difference field.

5 For every record in the Unreconciled Inventory List whose Difference field does not equal zero, write down the sample name, the lot number, and the value displayed in the Difference field.

A positive value in the Difference field means that your electronic count (the Stock Quantity field) is greater than your physical count (the Counted Quantity field). A negative value in the Difference field means that your electronic count (the Stock Quantity field) is less than your physical count (the Counted Quantity field).

Proceed in one of the following ways:

■ If only a small number of records require adjustments, enter individual line-item adjustments for those transactions. In this case, write down the transaction numbers of the transactions you plan to adjust.

The Samples History list displays all transactions corresponding to the product selected in the Unreconciled Inventory List. You can find the transaction number in the Transaction # field of the Samples History list. Then use the following procedure: "To adjust a quantity in a samples transaction" on page 150.

■ If multiple records require adjustments, enter a single adjustment transaction, with multiple line items, that adjusts all the quantities. To do this use the following procedure: "To adjust multiple quantities with a new adjustment transaction" on page 158.

To adjust multiple quantities with a new adjustment transaction

1 Navigate to the Samples screen.

2 On the link bar, click Samples Adjustments.

3 From the Show drop-down list, select My Samples Adjustments.

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

Some fields are described in the following table.

Field	Comments
Adjustment Reason	Follow your company's guidelines for what to select for this field.
Transaction #	The application automatically generates an unique identifier. You can change this value.
Transaction Date	The application automatically generates an unique identifier for this field.
Transaction Status	The value will be changed to Submitted when you submit the transaction.

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

Some fields are described in the following table.

Field	Comments
Expiration Date	This field is automatically filled when you complete the Lot # field.
Item Status	The application changes value in this field changes to Submitted when you submit the transaction.
Item #	The number of this item in the transaction. Line numbers are automatically generated but can be edited. You might want to edit this value to have the items appear in a particular order (other than the order in which you entered them).
Lot Name	The lot number for this sample.
Quantity	The amount of the sample adjustment. The quantity you enter can be positive or negative, depending on the value you recorded in Step 5 on page 158: ■ If the value that you recorded was positive, enter a negative quantity. ■ If the value that you recorded was negative, enter a positive quantity.
Sample	The product for which you want to enter a quantity adjustment.

Repeat Step 5 until you have entered a line item for each needed adjustment.

6 In the Samples Adjustments list, click Submit.

The values of the Transaction Status field (in the Samples Adjustments list) and the Item Status field (in the Line Items list) change to Submitted.

7 Reconcile the inventory period, as described in the following procedure.

To reconcile an inventory period

1 Navigate to the Samples screen > Reconciliation view.

2 In the Unreconciled Inventory Periods list, select the inventory period that you want to reconcile.

3 Scroll through the records.

4 In the Unreconciled Inventory List, scroll through the records and verify that the value of the Difference field for each record is zero.

5 Click Reconcile.

The Samples Reconciliation view is cleared.

9 Recording Calls in Pharma

This chapter covers the following topics:

About Recording Calls in Pharma

This chapter describes how to record account and contact calls in Siebel Life Sciences. For more information on planning account and contact calls, see Chapter 7, "Planning Calls in Pharma."

Using the procedures in this chapter, you can perform the end-user tasks of recording contact and account calls such as adding information about products detailed, capturing signatures electronically, and submitting calls.

If you are using Siebel Pharma Campaigns, you can record contacts responses to campaign offers to achieve closed-loop marketing.

Contact and account calls are both types of activity records. Although you can create contact and account calls in the Contacts and Accounts screens, you can only record the details of calls in the Activities screen.

About the Submit Button

Clicking the Submit button in Siebel Life Sciences causes a number of important events to occur within the application. Table 16 describes the specific actions that occur when clicking the Submit button in the view listed in the left column.

Table 16.   Effects of the Submit Button on Siebel Life Sciences Views

View	Access Path	Transaction Type	Clicking the Submit button...
Contact Call Detail	Activities > Contact Call Detail	Disbursement	Changes the contact call detail Status field to Submitted.
			Except for the Comment field, sets the record to read-only.
			Sets all child records to read-only.
			NOTE: The Disburse on Signature Capture system parameter is set to TRUE by default. This means that when the user clicks the Save button on Signature Capture view, the application decrements the inventory count for Samples Dropped only. For Promotional Items Dropped, transaction records are generated upon submitting the call.
			If samples were dropped, and the Disburse on Signature Capture system parameter is set to FALSE, then clicking the Submit button creates a Samples Transaction History record.
Account Call Detail	Activities > Account Call Detail	Disbursement	Changes the account call detail Status field to Submitted.
			Except for the Comment field, sets the record to read-only.
			Sets all child records to read-only.
			If the Disburse on Signature Capture system parameter is set to TRUE, the application decrements the inventory count for Samples Dropped only when the user clicks the Save button on Signature Capture view.
			If samples were dropped, clicking the Submit button creates a Samples Transaction History record only if the Disburse on Signature Capture system parameter is set to FALSE.

Table 16.   Effects of the Submit Button on Siebel Life Sciences Views

View	Access Path	Transaction Type	Clicking the Submit button...
Inventory Count	Samples > Inventory Count		Verifies each a value has been entered in the Count field. Changes the status of each record to inactive. Creates an active transaction by moving the count in the latest inventory period. **NOTE:** Products with Expired Lot# and with zero physical count will not be moved in to the new inventory period.
Received Samples	Samples > My Received Samples	Transfer In	Updates the user inventory to reflect the quantity entered in Received Quantity field of the Line Items list. Updates Sample Invoices by setting the Active flag to N (No). If the Invoice Status is submitted, the application updates the Line Items list by: ■ Setting the Stock Update flag to Y (Yes) ■ Updates the Stock Position ID ■ Changes the Item Status to Submitted
Sample Order	Samples > My Samples Order	Sample Order	Updates the Samples Orders list by setting the Active flag to N (No). If the Order Status is submitted, the application updates the Line Items list by: ■ Setting the Stock Update flag to Y (Yes) ■ Updates the Stock Position ID ■ Changes the Item Status to Submitted

Table 16.   Effects of the Submit Button on Siebel Life Sciences Views

View	Access Path	Transaction Type	Clicking the Submit button...
Samples Adjustments	Samples > My Samples Adjustments	Inventory Adjustment	Updates the user inventory to reflect the quantity entered in Quantity field of the Line Items list. Updates Sample Adjustments by changing the Active flag to N (No). If the Transfer Status is Submitted, the application updates Line Items list by: ■ Setting the Stock Update flag to Y (Yes) ■ Updating the Stock Position ID ■ Changing the Item Status to Submitted
Sent Samples	Samples > My Sent Samples	Transfer Out	Updates the user inventory to reflect the quantity entered in Line Items list Quantity field. Updates My Sent Samples by setting the Active Flag to N (No), Changes the Status to Submitted. If the Transfer Status is Submitted, the application updates the Line Items list by: ■ Setting the Update Flag to Y (Yes) ■ Updating the Stock Position ID ■ Changing the Item Status to Submitted

When a user clicks the Submit button in either the Contact Call Detail or Account Call Detail views, the application verifies that:

■ At least one product has been recorded and detailed.

  This requirement can be changed by the administrator. For more information, see Appendix A, "Configuring Siebel Life Sciences."

■ The call's date and time is the same as or earlier than the current date and time. A call cannot be submitted with a future date.

If dropped samples are recorded for the call, the application checks that:

■ The samples exist in the inventory for the period indicated by the call's date and time.

■ The period into which the samples will be recorded is an unreconciled period. If it is a reconciled period, a warning message appears.

■ A valid lot number has been specified for dropped samples tracked by lot number.

■ The Ref # field is not empty (paper signature only).

If the call passes these checks, the application:

■ Creates a samples disbursement transaction, with a line item for each dropped sample recorded for the call.

   NOTE: If the Disburse on Signature Capture system parameter is set to TRUE, the application decrements the inventory count for Samples Dropped only when the user clicks the Save button on Signature Capture view.

■ Submits a disbursement transaction to update the samples inventory. If the submission of the disbursement transaction is successful, the application changes the call's Status field to Submitted.

■ Sets the Last Call Date field for the contact or account to the date of the submitted call, and many fields in the call record become read-only.

   The Siebel administrator can change the fields that become read-only after a call is submitted (or synchronized with Siebel Pharma Handheld on a PDA). For information, see "Configuring the Submit Button" on page 175 (Changing Read-Only Fields).

   NOTE: If attendees are recorded in an account call, an attendee call is created for each attendee, and the process described above is performed for each attendee call. Attendee calls are the same as contact calls except that they do not appear in the Activities view, and they are submitted automatically when the account call is submitted.

About Electronic Signature Capture

Users can capture signatures for samples disbursement within Siebel Pharma running on a mobile client. End users can capture signatures directly on the screen for samples dropped to qualified contacts.

NOTE: Electronic signature capture is enabled for Siebel Mobile Web Clients only; it is not enabled on Siebel Web Clients connected to the Siebel Server.

For information about configuring logic behind the Sign button and the appearance of the LS Pharma Call Signature Form Applet, see "Configuring the Sign Button" on page 176.

Signature capture is supported on tablet PCs using Windows XP on versions 7.7, 7.8, and 8.0. See *Siebel System Requirements and Supported Platforms* on Oracle Technology Network for information about which operating systems and devices are supported with the current release of Siebel Pharma. (For example, some releases are not certified on the Tablet PC platform.)

Electronic signature capture is also available on handheld devices. For more information, see *Siebel Pharma Handheld Guide*.

Scenario for Recording Calls

This topic outlines an example process performed by end users when recording contact and account calls. Your company may follow a different process according to its business requirements. A sales representative for a pharmaceutical company has a busy day of calls to both individual physicians and to accounts.

Recording Call Information

As he makes calls, the sales representative records the information about the call. He records information relating to samples delivered to the physicians during the call, including details such as the lot number and the quantity.

The sales representative records information about the products discussed and the indications for which the products were promoted. The representative also delivers promotional items, a coffee mug and some memo pads, which he also records as part of the call information. He logs the issues that the contact raised during the call so he can follow up on them prior to his next visit.

Obtaining Signatures for Dropped Samples

This sales representative is using the electronic signature capture: the physician acknowledges receipt of dropped samples by using a stylus to sign directly on screen, and the signature is recorded in the Pharma application. (Alternatively, sales representatives can collect paper signatures and record a reference number for the paper signature in the Pharma application.)

Delivering Marketing Messages and Recording the Contact's Response

Some of the physicians he visits have been targeted in specific marketing campaigns. Information about these campaigns appears automatically in the appropriate contact call records—this reminds the sales representative to deliver the marketing messages. The sales representative enters the physicians' responses to the messages.

(The response information is later reviewed by the marketing manager; she uses the information for refining segmentation and targeting.)

Submitting the Call

After making sure that all data about the call is correctly entered, the sales representative submits the calls. This changes most fields to read-only so that the call records cannot be accidentally changed or tampered with.

In the Event of a Mistake, Remaking Electronic Signatures

Unfortunately, after submitting the final account call, the sales representative realizes that the two doctors attending the call mistakenly signed for each other's samples. The next day, the sales representative returns to the account and the doctors sign again for their samples.

Process of Recording Calls

This example process represents the tasks that are carried out in the "Scenario for Recording Calls" on page 166. Your company may follow a different process according to its business requirements.

NOTE: Prior to recording calls, end users need to set up and update their personal lists, create target lists and route plans, and create activities. For more information, see Chapter 7, "Planning Calls in Pharma."

1 "(Optional) Recording Marketing Responses in Contact Calls" on page 167. (Requires Siebel Pharma Campaigns.)

2 "Recording and Submitting Contact Calls" on page 168.

3 "Recording a Contact Call for a Different Contact at the Time of Signature Capture" on page 170.

4 "Remaking Electronic Signatures" on page 174. If you are using electronic signature capture and you discover after submitting a call that a professional signed the wrong receipt, you can re-create the receipt.

For more information on planning calls and setting up meetings, see Chapter 7, "Planning Calls in Pharma" and "Setting Up a Meeting (End User)" on page 115.

(Optional) Recording Marketing Responses in Contact Calls

If your license includes Siebel Pharma Campaigns, information about the contact's response to campaign offers can be recorded for the contact call, through the Contact Call Detail - Marketing view.

These campaign offers may be actual offers, such as an invitation to an event. Or, the offers may be messages about products that the sales representative conveys during the contact call. These messages augment the call products detailed by delivering more granular information and by recording the responses received during detailing. These messages are part of marketing campaigns, and responses must be recorded in order to capture the bidirectional flow of information.

The contact's response also appears in the Track Results view for the campaign; this closes the loop on the marketing strategy and allows the marketing manager to assess the effectiveness of the campaign and to further refine segmentation and targeting.

To record offer responses in contact calls

1 Display the call in the Contact Call Detail - Marketing view, for example, in one of the following ways:

■ Navigate to the Activities screen > Activities List view, and drill down on a planned contact call activity.

■   Navigate to the Contacts screen > Contacts List view, drill down on a contact, click the Calls view tab, and drill down on the call.

NOTE: For more information on scheduling and creating contact calls, see "Creating a Contact Call (End User)" on page 117.

2   In the Marketing Communications list, select an offer.

This list displays campaign offers where:

■   The offer is of channel type Contact Call

■   The contact is a prospect associated with the offer's campaign

3   In the Response list, create a new record, and complete the necessary fields.

The choices for the Response field are restricted to the response templates set up for the offer. For more information, see about contact call offers in the *Siebel Marketing User Guide*.

After the call is submitted, the responded to offer record will not be available for future calls to that contact. If no response was recorded for the offer, the offer record is not included in the submitted call and will be available for future calls to the contact.

Recording and Submitting Contact Calls

Some end users carry their laptops with them throughout the day and enter call information as they make the calls. (This is necessary if signatures are captured electronically when samples are dropped.) Others choose to enter all call details at the end of the day.

End users track details about calls made on a contact with contact call records. Although users can create and display contact calls on the Contacts screen, they enter details about the actual call in the Activities screen. To record a contact call, users must complete the following procedures:

■   Display the Contact Call Detail view

■   Enter information on products detailed

■   Enter information about any samples dropped and obtain signatures for these dropped samples

■   Enter information about any promotional items dropped

■   Record any decision issues discussed during the call

■   Submit the call

NOTE: End users can view all activities, contacts, and opportunities associated with an account and its child accounts on the account hierarchy tree. For more information, see Chapter 5, "Administering and Managing Accounts in Life Sciences."

This task is a step in "Process of Recording Calls" on page 167.

To record contact calls

1   Display the call in the Contact Call Detail view, for example, in one of the following ways:

■ Navigate to the Activities screen > Activities List view, and drill down on a planned contact call activity.

■ Navigate to the Contacts screen > Contacts List view, drill down on a contact, click the Calls view tab, and drill down on the call.

NOTE: For more information on scheduling and creating contact calls, see "Creating a Contact Call (End User)" on page 117.

2 In the Call Product Detailed list, create a new record for each product discussed during the call and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Indication	The purpose or therapeutic area for which a drug is designed.
Priority	Priority of this product relative to others discussed during the call. **NOTE:** This field can be configured to automatically assign 1 to the first record and then sequentially number each additional record. For more information, see Appendix A, "Configuring Siebel Life Sciences."
Product	The product detailed during the call. The products appearing in this drop-down list are based on the products added to your Personal list. For more information on adding products to your personal lists, see "Creating a Personal List (End User)" on page 106.

3 In the Samples Dropped list, create a new record for each product dropped during the call and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Lot #	The lot number (if applicable) of the products dropped during the call. If tracking samples by lot number, select a lot number in the Pick Lot dialog box. For more information, see "Defining Lot Numbers for Samples" on page 138.
Name	The name of the products dropped during the call. The products appearing in this drop-down list are based on the products available in your samples inventory. For more information on samples, see Chapter 8, "Managing Pharma Samples."
Quantity	The quantity of sample dropped during the call.

NOTE: If the sample you dropped does not appear in the Name field drop-down list, either you need to add it to the Personal Samples list or the sample has not been defined as a product. For information about adding products to the Personal Samples list, see To add a product to a personal list on page 106. It is the responsibility of your administrator to define products.

4 If you are collecting an electronic signature for the dropped samples:

a Click Sign.

    b   Obtain the professional's signature and click Save.

    c   Enter sample reference number (if required) in the Ref # field.

5   If you are collecting a paper signature for the dropped samples:

    a   Select the Paper Sign check box.

    b   Obtain the professional's signature on the paper record.

    c   Enter sample reference number (if required) in the Ref # field.

    NOTE: If you want to create a new activity for a different contact at the time of capturing a signature, click New Sample Drop button. The Pick Contact Applet is displayed.

6   In the Promotional Items Dropped list, create a new record for each item dropped during the call and complete the necessary fields.

    Some fields are described in the following table.

Field	Comments
Name	The promotional item dropped during the call. The items appearing in this drop-down list are based on items added to your Personal Promotional Items list. For more information, see "Creating a Personal List (End User)" on page 106.
Quantity	The quantity of the promotional item dropped during the call.

7   In the Issues list, create a new record for each issue discussed during the call and complete the necessary fields.

    NOTE: Decision issues are the objectives a contact may raise when evaluating a product before making a prescribing decision. For more information, see "Defining Decision Issues" on page 94.

8   Verify that all information entered is correct and click Submit.

    NOTE: Once you submit a call, you cannot delete the call nor modify any fields except the Comment field.

    CAUTION: If you are a mobile user, submit your calls *before* connecting to the server, and then synchronize. Mobile users should *not* submit calls while connected to the server or they run the risk of introducing errors into their inventory counts.

Recording a Contact Call for a Different Contact at the Time of Signature Capture

A sales representative creates a call for a contact, but prior to saving the signature, sales representative might need to choose a different contact or change the address of the call. The representative might need to create a new sample drop call for another contact whom he or she might have met while waiting for the first contact to arrive.

A representative can change an existing call, and click Pick And Sign to quickly navigate back to the Signature Capture view.

A representative can also create a new Call record based on an existing call directly from within the Contact Call view. The New Sample Drop button on the Contacts Call applet enables users to create a Contact Call record with contact Id, address and samples dropped based on data setup from an existing call. The created Call records are displayed in the Contacts Call Detail view under Activities. The user is prompted to select the contact name, and click Pick And Sign to capture the signature.

To create a new Sample Drop based on an existing contact call for a new contact

1 Navigate to the Contacts List screen.

2 Select a Contact record from the list.

3 Click New Call.

   A new Contact record is created and the Contact Call Detail view is displayed.

4 Add Sample Drop records based on the personal list or choose a Smart Call Template to prepare the sample drops.

5 Click Sign.

   If all the business rules are valid, the signature capture window is launched.

6 Verify the contact's name, address, DEA number and license number displayed in the call header.

To change the contact or address of an existing call

1 Click Cancel on Signature Capture view.

2 Click the small icon on the Last Name field.

   The Pick Contact Applet is displayed. You can query All Contacts, Affiliated Contacts, and By Location to find the relevant contacts.

3 Select a contact from the list, and click Pick And Sign to navigate back to the Signature Capture view.

4 Click the small icon on the Address field.

   The Pick Address Applet is displayed.

5 Select the correct address from the list, and click Pick And Sign to navigate back to the Signature Capture view.

To create a new Sample Drop contact call based on an existing call

1 Click Cancel on Signature Capture view.

2 Click New Sample Drop in the Contact Call Detail view.

   The Pick Contact Applet is displayed. You can query All Contacts, Affiliated Contacts, and By Location to find the relevant contacts.

3 Select a contact from the list, and click Pick And Sign to navigate back to the Signature Capture view.

NOTE: The sample drop records are copied when the user clicks New Sample Drop. The details, promotional items, and decision issues are not copied over.

4 Save the signature of the contact.

This action decrements the inventory and creates sample transaction history records.

Recording and Submitting Account Calls

End users track details about calls made on an account with account call records. Although users can create and display account calls on the Accounts screen, they enter details about the actual call on the Activities screen. To record an account call, users must complete the following procedures:

■ Display the Account Call Detail view

■ Enter information on products detailed

■ Enter attendee information (the names of contacts met and any samples dropped)

■ Obtain signatures for dropped samples

■ Enter information about any activities related to the call (optional)

■ Submit the call

This task is a step in "Process of Recording Calls" on page 167.

To record account call

1 Display the account call in the Account Call Detail view, for example, in one of the following ways:

■ Navigate to the Activities screen > Activities List view, and drill down on a planned account call activity.

■ Navigate to the Accounts screen > Accounts List view, drill down on an account, click the Calls view tab, and drill down on the call.

NOTE: For more information on scheduling and creating account calls, see "Creating an Account Call (End User)" on page 119.

2 In the Call Products Detailed list, create a new record for each product detailed during the call and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Indication	The purpose or therapeutic area for which a drug is designed.
Priority	Priority of this product relative to others discussed during the call. **NOTE:** This field can be configured to automatically assign 1 to the first record and then sequentially number each additional record. For more information, see Appendix A, "Configuring Siebel Life Sciences."
Product	The product detailed during the call. The products appearing in this drop-down list are based on the products added to your Personal list. For more information on adding products to your personal lists, see "Creating a Personal List (End User)" on page 106.

3 For each contact and employee who attended the account call: in the Attendees list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Name	The Add Attendees dialog box displays both contacts and employees. Affiliated contacts are those associated with the account. For more information, see "Indicating an Affiliation Between an Account and a Contact (End User)" on page 71.
Samples Dropped	Remember to specify quantity and lot number (if required). **NOTE:** The items appearing in the Sample Dropped dialog box are based on items added to your Personal Promotional Items list. For more information, see "Creating a Personal List (End User)" on page 106.
Sample Reference Number	Reference number for any samples dropped. This reference number becomes the transaction number (Transaction # field) for a samples transaction corresponding to this call. For information on samples transactions, see "Managing Pharma Samples" on page 129.

The application creates an attendee call record (similar to a contact call) for each contact you include as an attendee of the account call. These attendee call records are child records of the account call and appear in the Activities screen under each contact's name.

4 Drill down on the Name field for each attendee added to the account call.

5 In the Contact Call Detail view:

a Enter any further information such as promotional items dropped and issues discussed.

b Obtain a paper or an electronic signature for the dropped samples.

For more information, see Step 4 on page 169 or Step 5 on page 170 of the procedure "To record contact calls" on page 168.

6 Return to the parent account call, in the Account Call Detail view by clicking the back button.

7 In the Activities applet at the bottom of the Account Call Detail view, add any general activities records for the call, such as a reminder to send information about an upcoming medical education event.

8 Verify that all information entered is correct and click Submit.

NOTE: Once you submit a call, you cannot delete the call nor modify any fields except the Comment field.

CAUTION: If you are a mobile user, submit your calls *before* connecting to the server, and then synchronize. Mobile users should *not* submit calls while connected to the server or they run the risk of introducing errors into their inventory counts.

Remaking Electronic Signatures

The sales representative can create an updated sample receipt and signature in the event that the original call information was incorrect.

For example, if Dr. Smith mistakenly signs for the receipt of samples on a request form having a different physician's name (such Dr. Jones), then the sample form is inaccurate. In this example, the sales representative must change the name on the original call to the correct physician (Dr. Smith) and have Dr. Smith sign again.

Using the Recreate Receipt button, the sales representative can capture a second signature on the corrected sample form. The Pharma application automatically tracks the appropriate audit trail information required by the FDA and similar agencies in other countries in the recreate receipt functionality.

This task is a step in "Process of Recording Calls" on page 167.

To remake a receipt

1 Display the submitted call in the Contact Call Detail view, for example, in one of the following ways:

■ Navigate to the Activities screen > Activities List view, and drill down on the contact call activity.

■ Navigate to the Contacts screen > Contacts List view, drill down on a contact, click the Calls view tab, and drill down on the call.

■ Navigate to the Activities screen > Activities List view, drill down on a planned account call activity, and drill down on the Attendee's name.

■ Navigate to the Accounts screen > Accounts List view, drill down on an account, click the Calls view tab, and drill down on the Attendee's name.

2 Click Recreate Receipt.

3 Edit the name and address fields for the professional.

4 Click Sign.

5 Obtain the professional's signature and click Save.

NOTE: Signature records are not sent to the local database in order to avoid sizing issues, and in case your local database is re-extracted.

The Recreate Receipt process first attempts to deactivate current signatures before capturing a new one. If you re-extracted your local database after having captured a signature, the original signature record will not be available to you, hence the process is aborted and you will not be able to capture a recreated receipt signature. Nothing happens when you click the Recreate Receipt button for calls created and signed prior to the re-extraction of your local database.

If you require that local signatures are downloaded from the server to your local database, contact your Oracle sales representative for Oracle Advanced Customer Services to request assistance from Oracle's Application Expert Services.

Configuring the Submit Button

This topic provides information about how to configure the Submit button.

Changing the Requirement That One Product Must Be Detailed

When you click the Submit button in either the Contact Call Detail and Account Call Detail views, the application verifies that at least one product has been recorded and detailed. Table 16 on page 162 describes the specific actions that occur when clicking the Submit button in the views in which it appears.

This one-product-dropped requirement can be changed by the administrator using Siebel Tools. The business component user property is Must Detail Products. Table 48 on page 487 shows the user property values that are to be changed.

NOTE: A call cannot be deleted after it has been submitted. This behavior is controlled by a specialized class and, for regulatory and data integrity reasons, cannot be configured to allow for deletion.

LOVs That Should Not be Changed

Table 17 lists LOVs that are required in the submit process. Do not delete or inactivate these LOVs.

Table 17.   LOVs Required for the Submit Process

Type	Language-Independent Code
SAMPLE_INVOICE_TYPE	Return
	Transfer In
	Transfer Out
	Inventory Adjustment
	Invoice Receipt
	Disbursement
	Sample Order
SAMPLE_TXN_STATUS	Submitted
	In Progress

Changing Read-Only Fields

As mentioned in this chapter and in Chapter 8, "Managing Pharma Samples," the Siebel administrator can change the fields that become read-only after a call is submitted or synchronized with Siebel Pharma Handheld on a PDA. By default, only Comment is editable after clicking the Submit button. Edit the Update After Submit user property to change which fields are editable after a call is submitted. See Table 48 on page 487 for details.

Configuring the Sign Button

About the Sign Button

A special validation process is carried out before the physician can sign for dropped samples. The default validation when the user clicks the Sign button (on the Activities screen > Contact Call Detail view) is as follows:

■ Check that the dropped samples have lot numbers

■ Check that the physician is OK to sample

■ Check that the physician has a valid and active license number

■ If any of the dropped samples are controlled substances, check that the address at which the call is being made has a valid DEA number. A DEA number checksum algorithm is run to check that DEA# is populated, valid for the address, and not expired.

■ Check that Last Name, First Name, Title, and Address fields are populated for the physician

If any of checks are not met, the Signature Capture view does not display and an error message specifies the specific point of failure.

Because not all pharmaceutical companies require validation, Siebel Pharma can be configured to turn the validations on or off using user properties.

Figure 5 on page 179 illustrates the default validation for the Sign button. (This is very similar to the validation logic used in Siebel Pharma Handheld.) User properties can be used to alter the Sign button's validation logic. These are described in Table 18 on page 180.
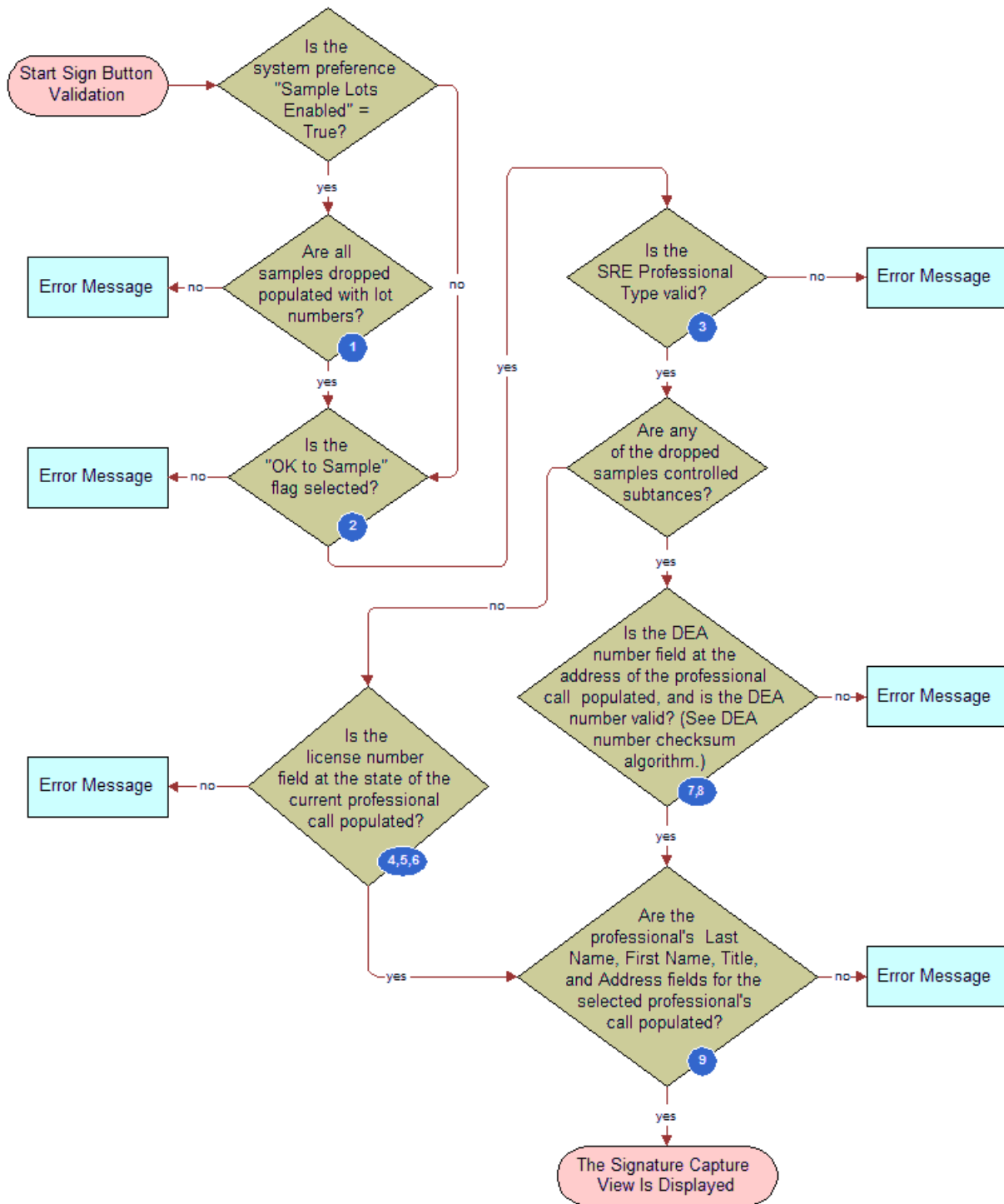
Figure 5.   Default Validation Logic Flowchart for Sign Button

Table 18.   Sign Button User Properties in the Pharma Professional Call Business Component

Flowchart Reference	User Property	Action if Y…	Action if N…	Default Value
1	"Validate Sign Lot Number" Use to validate if the lot number is populated on launching the Signature Capture display.	Enforce the Signature button Lot Number validation.	Skip the Signature button Lot Number validation.	Y
2	"Validate OK to Sample" Use to enforce confirmation that the OK to Sample flag is selected before launching the Signature Capture display.	Enforce the OK to Sample validation.	Skip the OK to Sample validation.	Y
3	"SRE Professional Types" Use to require that the professional type be valid for signature recorded electronically (SRE) calls.	The professional type (for example, "Physician") must match the value of this user property. If the value is null, all professional types are valid.		null
4	"Validate License Number" Use to enforce validation that the License # is populated before launching the Signature Capture display.	Enforce the License Number validation.	Skip the License Number validation.	Y
5	"Validate License Number Status" Use to enforce validation that the License # status = Active before launching the Signature Capture display.	Enforce the License Number Status validation.	Skip the License Number Status validation.	Y
6	"Validate License Number Expiration" Use to enforce validation that the Expiration date on the License # is later than Today before launching the Signature Capture display.	Enforce the License Number Expiration validation.	Skip the License Number Expiration validation.	Y

Table 18.   Sign Button User Properties in the Pharma Professional Call Business Component

Flowchart Reference	User Property	Action if Y...	Action if N...	Default Value
7	"Validate DEA Number" Use to enforce that the DEA number is populated and that the value is valid (DEA # checksum algorithm) before launching the Signature Capture display.	Enforce the DEA Number validation in the Sign button (field is populated *and* number is valid).	Skip the DEA Number validation in the Sign button (DEA number is valid per the checksum routing *and* the field is populated).	Y
8	"Validate DEA Number Expiration" Use to enforce validation that the Expiration date on the DEA is later than Today before launching the Signature Capture display.	Enforce the DEA Number Expiration validation in the Signature button (expiration date is later than today).	Skip the DEA Number Expiration validation in the Signature button (expiration date is later than today).	N
9	"Validate Professional Profile" Use to validate if the professional's Last Name, First Name, Title, and Address fields are populated before launching the Signature Capture display.	Enforce the Professional Profile validation.	Skip the Professional Profile validation.	Y

Configuring the LS Pharma Call Signature Form Applet

Various display features of the LS Pharma Call Signature Form Applet can be edited. See Table 19 on page 181.

Table 19.   User Properties for the Signature Capture Control in the LS Pharma Call Signature Form Applet

User Property	Description	Default
AxProperty: ActiveBorderColor	Border color when the control has the focus	10485760
AxProperty: BackgroundColor	Background color of the control window	*null* (=white)
AxProperty: BorderColor	Border color when the control is enabled but does not have focus	10485760
AxProperty: BorderStyle	Single, double, 3D, or no border on the window	1

Table 19.   User Properties for the Signature Capture Control in the LS Pharma Call Signature Form Applet

User Property	Description	Default
AxProperty: DisabledBorderColor	Border color when the control is disabled	*null* (=white)
AxProperty: DisabledColor	Ink color when the window is disabled	*null* (=white)
AxProperty: InkColor	Current color of pen input	10485760
AxProperty: InkWidth	Current width of pen input	3
AxProperty: CompressionEnabled	Enables/Disables compression of the ink data	0
AxProperty: CompressionLevel	The compression level for compression of the ink data (0 - 5, with best fidelity at level 0 and highest compression at level 5)	0
AxProperty: DisplayMode	0 - Normal - Ink is displayed as collected without any scaling or offsetting. This is the default. 1 - Force To Fit 2 - Shift To Control 3 - Proportional Fit 4 - Custom	0

Marking Package Insert Delivery and Post Market Surveillance Calls as Complete

After Package Insert Delivery (PID) and Post Market Surveillance (PMS) calls have been completed, sales representatives will need to mark them as complete in Siebel Pharma.

This section contains instructions about marking PID and PMS calls as complete.

For information about PID and PMS calls see .

Marking a PID Call as Complete

The following instructions explain how to mark a PID call as complete.

To mark a PID call as complete

1 Navigate to the Package Insert Delivery screen > Mark Completion view.

2 Select an insert from the Products list.

3 Select the account from the Mark Completion list.

4 Select the check-box in the Executed column.

The status of the activity will change to In Progress if there are multiple inserts associated with the activity or Complete if this is the only insert associated with the activity.

Marking a PMS Call as Complete

The following instructions explain how to mark a PMS call as complete.

To mark a PMS call as complete

1 Navigate to the Post Market Surveillance screen > Activity Details view.

2 Select an Account Product combination.

3 Select an Activity.

4 Click Submit.

10 Creating Smart Calls

This chapter covers the following topics:

About Creating Smart Calls

A *Smart Call* is a template that users can apply to contact calls and account calls to simplify and speed up the call-reporting process. A Smart Call defines a set of information about the products detailed, samples and promotional items distributed, and issues discussed on a call.

Smart Calls can be also be used for calls related to a particular campaign or promotional effort, or for everyday call reporting. They are intended for situations where sales representatives report details about a number of calls that are identical in content (the same products are detailed in the same order, the same samples are dropped, and so on).

This chapter describes how to create and modify Smart Calls. Using the procedures given in this chapter, you will be able to perform the administrator tasks of creating a new Smart Call template and then making it available to end users. Using the Smart Calls screens, end users can also create new Smart Call templates, enter Smart Call information, and modify Smart Call information after it has been applied to a call.

For more information on the differences between administrator and end-user tasks see *"Scenario for Smart Calls" on page 185*.

Scenario for Smart Calls

This topic outlines an example process performed by the Siebel administrator and end users. Your company may follow a different process according to its business requirements.

A pharmaceutical company is bringing a new product to market. The Siebel administrator adds this new product into the database and then creates a Smart Call template to distribute to the sales representatives in the field. The administrator then makes the Smart Call available to representatives in the field.

Once the Smart Call has been defined and made public, field sales representatives then apply it to their contact calls and account calls. By applying a Smart Call template, the representatives can automatically fill in various pieces of information in the Contact Call and Account Call Detail views, such as the products they detail, the samples they drop, and information they should provide. Representatives can also create Smart Call templates that suit their individual purposes. These end-user Smart Calls are only visible to each Smart Call creator.

The Siebel administrator requires administrative responsibilities in Siebel Smart Calls to:

■ Create a new Smart Call and enter Smart Call information

■ Make a Smart Call template available to end users

The end users are sales representatives in the field. They enter information to:

■ Create Smart Call templates and enter Smart Call information

■ Apply a Smart Call template to an account or contact call

■ Modify Smart Call information after it has been applied to a call

Figure 6 and Figure 7 illustrate the workflows for these scenarios.
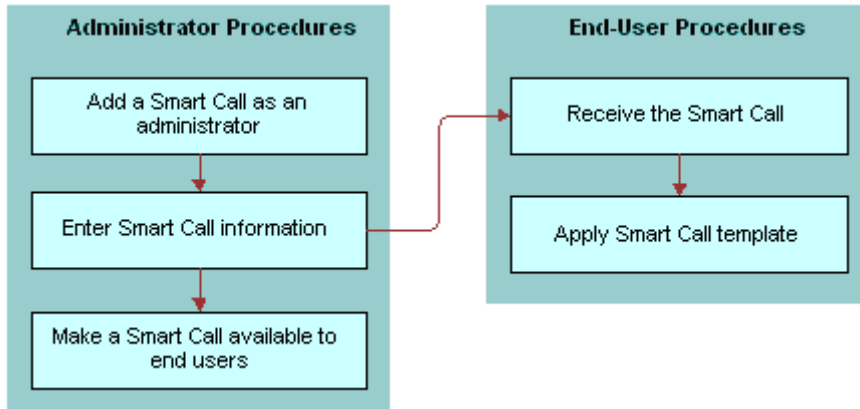
Figure 6.   Administrator Creates Smart Call Templates
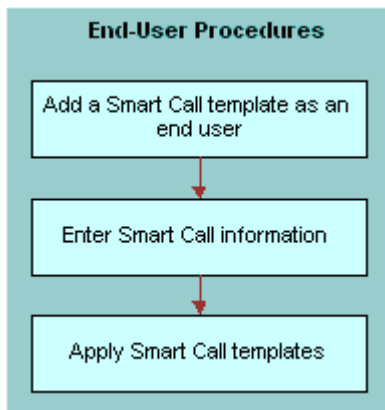
Figure 7.   End User Creates Smart Call Templates

Administering Smart Calls

The following administrator procedures are described in this topic:

■   To create a Smart Call as an administrator

■   To enter Smart Call information as an administrator on page 188

■   To make a Smart Call template available to end users on page 189

By default, a Smart Call is accessible only to the user who created it. However, the Siebel administrator can make a Smart Call available to users system-wide by using the Smart Call Administration view. The administrator can also create and modify Smart Calls using the Application Administration, Smart Call Detail view.

NOTE: Both end users and the Siebel administrator can create and modify Smart Calls using the views in the Smart Calls screen. For more information, see "Creating a Smart Call (End User)" on page 189.

To create a Smart Call as an administrator

1 Navigate to the Administration - Application screen > Smart Calls view.

2 In the Smart Call form, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Created By Name	The user who created the Smart Call.
Expense	This amount will appear in the Cost field of the contact call or account call. For more information, see "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119.
Name	Name of the Smart Call.

Enter information in the Smart Call Detail screen, as described in the next procedure.

NOTE: Deleting a Smart Call permanently removes the Smart Call from the system. Before you delete a Smart Call, make sure that it is no longer needed. Calls that were completed using a deleted Smart Call are not affected.

To enter Smart Call information as an administrator

1 Navigate to the Administration - Application screen > Smart Calls view.

2 In the Smart Calls list, drill down on a Smart Call name.

3 In the Smart Call Detail view, select any of the four lists:

■ Call Products Detailed

■ Samples Dropped

■ Promotional Items Dropped

■ Issues

NOTE: You may not need to enter information in every one of these lists.

4 For the appropriate lists, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Name	The name of the samples or promotional items dropped during the call. This field appears in the Call Products Detailed and Promotional Items Dropped lists.
Quantity	The quantity of samples or promotional items dropped during the call. This field appears in the Call Products Detailed and Promotional Items Dropped lists.

To make the Smart Call available to users, see the next procedure.

To make a Smart Call template available to end users

1 Navigate to the Administration - Application screen > Smart Calls view.

2 In the Smart Calls list, select the Smart Call that you want to make available to end users.

3 Click the Private field to clear the check mark.

NOTE: Mobile end users must synchronize before they can access or modify a Smart Call.

Creating a Smart Call (End User)

By default, a newly created Smart Call is private; that is, it is available only to the user who created it. The Siebel administrator can make a Smart Call available to users. For more information, see the procedure "To make a Smart Call template available to end users" on page 189.

NOTE: For account calls where attendees are specified, users can also apply a Smart Call to each of the attendees. For more information, see the Smart Call field descriptions in "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119.

To create a Smart Call as an end user

1 Navigate to the Smart Calls screen.

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

Some fields are described in the following table.

Field	Comments
Created By Name	The user who created the Smart Call.
Expense	This amount will appear in the Cost field of the contact call or account call. For more information, see "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119.
Name	Name of the Smart Call.

Enter information in the Smart Call Detail view as described in the next procedure.

NOTE: Deleting a Smart Call permanently removes the Smart Call from the system. Before you delete a Smart Call, make sure that it is no longer needed. Calls that were completed using a deleted Smart Call are not affected.

To enter Smart Call information as an end user

1   Navigate to the Smart Calls screen.

2   In the Smart Calls list, drill down on a Smart Call.

3   Click the Smart Call Detail view tab.

4   Make sure that the correct Smart Call appears in the Smart Call form.

5   Select any of the four lists in the Smart Call Detail view:

 ■   Call Products Detailed

 ■   Samples Dropped

 ■   Promotional Items Dropped

 ■   Issues

 NOTE: You may not need to enter information in every one of these lists.

6   Create a new record and complete the necessary fields.

 Some fields are described in the following table.

Field	Comments
Name	The name of the samples or promotional items dropped during the call. This field appears in the Call Products Detailed and Promotional Items Dropped lists.
Quantity	The quantity of samples or promotional items dropped during the call. This field appears in the Call Products Detailed and Promotional Items Dropped lists.

NOTE: To protect system integrity and to make sure users enter the correct information, users cannot enter dates and reference numbers for samples with Smart Calls. For more information on entering information on dropped samples, see "Recording and Submitting Contact Calls" on page 168 and "Recording a Contact Call for a Different Contact at the Time of Signature Capture" on page 170.

About Applying a Smart Call Template to a Call

End users apply a Smart Call template by making a selection from the Smart Call field in the Contact Call Detail and Account Call Detail views. For more information, see the field descriptions in "Creating a Contact Call (End User)" on page 117 and "Creating an Account Call (End User)" on page 119.

Once a user applies a Smart Call template to a call, the user can make additional edits to any fields in the current view.

If end users apply a Smart Call that contains samples, promotional items, or details that have not been set up in their personal lists, the smart call can still be applied, but only the samples, items, and details from the end users' personal lists can appear in the Call Detail view.

11 Managing Managed Care Accounts

This chapter covers the following topics:

About Managed Care in Siebel Life Sciences

Siebel Life Sciences has a number of features that help pharmaceutical and medical product companies maintain important data about MCOs (managed care organizations) and PBMs (pharmacy benefit management companies). Some of these features are listed here:

- **Account Data.** MCOs and PBMs are entered as accounts of type Managed Care. The fields in the managed care account form are designed to hold data relevant to these businesses, such as enrollment, prescription spending, and number of participating providers.

- **Health Plans.** Health plans are associated with managed care accounts. Health plan records contain information about the individual plans offered by MCOs, such as the plan name, size, utilization, co-payment.

- **Formulary.** Formularies are associated with health plans. Typically a unique formulary is set up for each therapeutic market, so that a plan has a list of formularies associated with it. Each formulary lists the individual drugs and products available for prescription on the health plan.

- **Contacts.** Two types of contact that are typically associated with health plans are the providers of health-care services (for example, physicians) and members of the P & T committee.

■ **Managed-Care Business Plans.** Managed-care account managers create business plans outlining how they can work with MCOs to promote the use of their company's products by members of the health plan. One way this is done is by influencing the P & T committee to add the products to formularies. Business plan records are associated with managed care accounts. Comprehensive data is contained in these business plans, including SWOT and business analysis views, key contact and account lists, formulary lists, and the objectives of the plan.

Table 20 on page 194 defines some terms that are used in this chapter and also in the application's user interface.

Table 20.　Terms Used in Managed Care

Term	Description
health plan	This is a health insurance option (or product) offered by an MCO. Variables in plans are premiums, choice of providers, out of pocket expenses, treatments covered, and so on. Large MCO's typically offer a selection of health plans.
MCO (Managed Care Organization)	Health care insurer where the insuring company is involved in the delivery of care. This is contrasted with the traditional indemnity plan where the insurer is not involved in care delivery. MCOs offer HMO, PPO, POS health plans.
Formulary	The list of products, usually drugs that are available to patients subscribing to the MCO. Formulary may be managed: ■ In-house by the MCO, or ■ Outsourced to a PBM
PBM (Pharmacy Benefit Manager)	These are organizations that contract with MCOs to administer pharmacy benefits to members. In many cases, the MCO delegates the pharmacy benefit management to the PBM. Large PBMs may have their own P & T committee who develop a universal formulary. Individual MCOs then appoint their own P & T committees who select products from the universal formulary to develop formularies for the MCO's health plans.
Managed Care Account Managers	These are the sales representatives who work for pharmaceutical and medical companies and who specialize in working with MCOs and in order to influence which products appear in the MCO's formularies.
HMO (Health Maintenance Organization)	In this type of health plan, members pay a fixed monthly premium and receive health care without charge or for a small fixed co-payment. There are several different types of HMOs and also hybrids of the different types available in the U.S.A. Some of these types are described in this table.

Table 20.   Terms Used in Managed Care

Term	Description
Staff Model HMO	In this type of health plan, the MCO employs salaried physicians and owns the medical facilities. Typically, the co-payment charge is minimal. Patients may only consult with the doctors in the HMO; though, in very rare cases these doctors refer patients to sub-specialists outside the network.
Group Model HMO	In this type of health plan, the MCO contracts with one or more large multi-specialty physician group practices to provide care. Doctors are not employed directly, instead the group practice employs the physicians.
IPA (Independent Practitioner Association Model)	In this type of health plan, a MCO contracts with many individual and group physician practices to form one or more associations of independent practitioners (IPAs). The IPA pays the physicians, but these physicians remain as contractors, not salaried employees, and maintain their offices independently.
POS (Point of Service)	This type of health plan is a mix of HMO and a traditional indemnity plan. When a patient stays in the HMO network of physicians and follows the referral path, care is fully covered (with the usual co-payment). When the patient seeks care outside the network specialist care without a primary care physician (PCP) referral within the network, the patient is covered at a lower level.
PPO (Preferred Provider Organization)	This type of health plan is similar to POS, except that a patient does not need a PCP referral to see a specialist within the network.
P & T (Pharmacy & Therapeutics) Committee	This committee is a group of health-care specialists, including physicians and pharmacists. The committee determine which products are in the MCO's or PBM's formulary.
SWOT analysis	This is a planning tool to help you evaluate the strengths, weaknesses, opportunities, and threats of your business and product in the marketplace. SWOT analysis is a component of a business plan.
Tiered Benefit	A tiered pharmacy benefit is one where the member's co-payments vary. For example, in a typical three-tiered system, generic drugs require the lowest co-payment, brand name drugs on the formulary require a higher co-payment, and brand name drugs off formulary require the highest co-payment.
Open Formulary	An open formulary is one where the MCO allows any drug to be prescribed.
Closed Formulary	A closed formulary is one where only the drugs on formulary may be prescribed. A closed formulary may be limited or unlimited.
Limited Formulary	A limited formulary is one where only a given number of drugs is allowed in each therapeutic class. In order for a new drug to be added, an existing drug must be removed from the formulary.
Unlimited Formulary	An unlimited formulary is one where there is no set limit on the number of drugs allowed in a therapeutic class.

Scenario for Managed Care

This scenario is an example process performed by a managed-care account manager and by a sales representative. Your company may follow a different process according to its business requirements.

The managed-care account manager and the sales representative are employees of a large pharmaceutical company.

Managed Care Account Manager Maintains HMO Account Data

The managed-care account manager is responsible for a nationwide HMO account. His job is to influence the HMO so that it buys more of his company's drugs.

His first task when he is assigned this account is to enter data about the account, such as enrollment and spending data, information about the individual health plans offered by the account, and formulary lists for each plan.

Of particular interest to him are the members of the P & T committee; these are contacts who he wants to influence.

Sales Representative Reviews and Enters HMO Account Data

The sales representative is responsible for detailing the company's drugs to physicians in her territory. She makes professional calls and influences the prescription habits of the physicians she calls on.

Before she meets with a physician, she wants to know about the health plans that the physician is affiliated with. Of particular interest to her is whether the drugs she details are on the plans' formularies. Furthermore, if the physician happens to be on the P & T committee, it is most important that she know this so that she can discuss her approach in advance with the account manager.

Managed Care Account Manager Prepares a Business Plan for the HMO Account

The account manager's relationship with the HMO can have significant impact on his company's sales revenues. The account manager plans his approach carefully. He creates a business plan for the account. It contains information about the account, including formulary, key contact, and associated account information, SWOT analysis, and finally his objectives with relation to the account for the coming year.

Process of Using Siebel Managed Care

This example process represents the tasks that are carried out in the "Scenario for Managed Care" on page 196.

■ "Associating Contacts and Accounts with Managed-Care Business Plans" on page 203

■ "Setting Objectives for the Managed-Care Business Plan" on page 204

Entering Health Plan and Formulary Information

Managed-care account managers can use the Account Plan Formulary view to enter and maintain information about health plan designs and formularies owned or administered by the account and about the products on those formularies. Account managers associate P & T committee members and track formulary review dates to be well prepared for calling on their contacts in the account.

Sales representatives, making professional calls may hear about contacts' roles in P & T committees. They also can review the Plan Formulary information and add their contacts to the P & T member list as appropriate.

This task is a step in "Scenario for Managed Care" on page 196.

Who Owns the Formulary?

There are two approaches to setting up formularies in Siebel Life Sciences. The formulary can belong to one of the following:

■ The MCO account

■ The PBM account

Before deciding which type of account should own the formulary, review "Indicating Affiliations Between a Contact and an Account" on page 55 and "Entering Formulary Information for Managed Care Business Plans" on page 201, and consider your own business process.

Procedure

To create health plan information for an account

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Plan Formulary view tab.

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

Some fields are described in the following table.

Field	Comment
Plan Type	See Table 20 on page 194 for definitions of the default values in this LOV.
No. of Lives	Number of lives in the health plan. This number cannot exceed the total lives entered for the account. **NOTE:** The Total Lives field must be completed in the Account form before you enter a value in this field. (Click on the show more button to see this field.)
% of Total Lives	Equal to [(Number of Lives at Plan Level) divided by (Number of Lives at Account Level)] multiplied by 100.
Utilization	Number of health plan members who are using health plan benefits. This number cannot exceed the number of lives in the health plan.
Utilization %	Equal to [(Utilization) divided by (Number of lives at Plan Level)] multiplied by 100.
Co-Payment	Typically, the co-payment amount for a member visit to a primary care physician. The pharmacy co-payment is entered separately for each product.
P & T Members Name	Names of contacts who are on the Pharmacy & Therapeutics committee.
Pharmacy Distribution	Type of distribution, such as in-house, contracted, or mail-order.

To create formulary information for an account

1 Navigate to the Plan Formulary view tab.

For information on how to navigate to the Plan Formulary view, see "To create health plan information for an account" on page 197.

2 In the Plan Design list, select a health plan.

3 In the Formularies list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comment
Type	See Table 20 on page 194 for definitions of the default values in this LOV.
Market	The option selected in this field determines which products are available in the formulary's Products list.

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

Some fields are described in the following table.

Field	Comment
Status	■ Off Formulary — Banned from the formulary.
	■ On Formulary — Approved by the formulary.
	■ On/Prior Auth — Physicians require MCO or PBM approval before prescribing.
	■ On/Restricted — One of the few drugs allowed its therapeutic class.
	■ On/Exclusive — The only drug allowed in its therapeutic class.
Tier	If the product is in a tiered formulary, indicate the tier.
Reimbursable	For example, if a product is off formulary, but can be reimbursed with prior authorization, select this check box.
Qty Limit	The quantity allowed per patient per year.
Competitor	This field is filled in automatically when the product's type is Competitive Product.

By adding a product to the Products list you indicate it is on formulary and can track its status.

NOTE: You cannot edit the Competitor field. A check mark appears in this field if the product you selected for the Name field is a competitor's product. For more information, see "Specifying a Competitor" on page 64.

5 Repeat Step 3 and Step 4 until you have created a record for every product on the formulary.

Associating Contact Information with Health Plans

Managed-care account managers can use the Contacts By Plan view (Accounts screen) to associate contacts (usually physicians) to health plans. This contact information may be typed in the UI as described here, but is more typically imported from external sources.

NOTE: Sales representatives use the Contact Affiliations view (Accounts screen) to track similar information about contacts. However, the Contact Affiliations view differs because it associates the contacts to the MCO *account* and not to the individual health plans.

This task is a step in "Scenario for Managed Care" on page 196.

To associate contacts with account plans

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Contacts By Plan view tab.

4 In the Plan Design list, select the plan to which you want to associate a contact.

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

Creating a Business Plan for a Managed Care Organization

The account manager creates a business plan for his MCO account. If the MCO contracts out its pharmacy formulary, the account manager may also choose to create a business plan for the PBM.

Typically business plans are created on a yearly basis, but the frequency varies according to business process. An account would have a number of business plans associated with it; each plan for a different period.

The first step in creating the business plan is creating the business plan record and entering overview information about the account.

This task is a step in "Scenario for Managed Care" on page 196.

To create an business plan for an account

1 Navigate to the Accounts screen > Accounts List view.

2 In the Accounts list, drill down on an account.

3 Click the Business Plans view tab.

4 Create a new record and complete the necessary fields.

5 Drill down on the business plan record.

6 Click the Account Overview view tab.

In the Account Overview form, enter information about the account that pertains to the business plan.

Some fields are described in the following table.

Field	Comments
Business Description	Use this text field to note general information about the MCO.
Regional Plans	Use this text field make note of other business plans related to this account. For example, if this is a national business plan, this field might contain the names of regional and local business plans that are related to this national plan.

Field	Comments
Contracts Process	Use this text field to note information about the contracts process.
	For example, notes about any contracts for rebates or discounts that the pharmaceutical company has with the account or with the account's PBM.
HMO Lives	This is the number of individuals enrolled in the HMO health plans offered by the account.
Total Lives	This is the number of individuals enrolled in all the health plans offered by the account. This field should equal the sum the other three lives fields (HMO Lives, PPO Lives, and POS Lives).
	This field is the same as the Total Lives field in the Accounts screen. (Click on the show more button to see this field in the Accounts form.)
Network Phy	This is the number of physicians participating in the insurance network.
	This field should contain approximately the same number as the Physicians field in the Accounts screen > More Info view.
Network Hosp	This is the number of hospitals belonging to the insurance network.
PPO Lives	This is the number of individuals enrolled in the PPO health plans offered by the account.
POS Lives	This is the number of individuals enrolled in the POS health plans offered by the account.
Medicare	This is the number of individuals who are enrolled both in Medicare and in the health plans offered by the account.
Medicaid	This is the number of individuals who are enrolled both in Medicaid and in the health plans offered by the account.

Entering Formulary Information for Managed Care Business Plans

The Pharmacy Benefit view allows the managed-care account manager to see, in a view list, all the products in all the formularies associated with a given business plan.

To add PBM and formulary information to a business plan for a managed-care account

1   Navigate to the Business Plans screen > Business Plan List view.

2   Drill down on a business plan record.

3   Click the Pharmacy Benefit view tab.

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

Some fields are described in the following table.

Field	Comments
Benefit Provider	Specify the account that owns the formularies that are relevant to the business plan. All products in all plans belonging to this account will be listed in the Formulary Status list in this Pharmacy Benefit view.
	Typically enter the name of the MCO account itself or of the PBM account. See note in "Entering Health Plan and Formulary Information" on page 197.
Tiered Benefit %	Indicate the approximate percentage of lives belonging to health plans with a tiered pharmacy benefit.
Open Benefit % Closed Benefit %	Indicate the approximate percentages of lives belonging to plans with open and closed formularies benefit.
Reimbursement Policy	Enter information about the benefit provider's reimbursement policy that is relevant to the business plan, for example, the co-payment rates, premium increases, or recent policy changes.
Formulary Approval Process	Enter information about the benefit provider's formulary approval that is relevant to the business plan, for example, how long it typically takes to have a new drug entered in the formulary.

5 Scroll down to the Formulary Status list and review the products in the formularies owned by the selected PBM.

Performing Business and SWOT Analysis for a Managed-Care Business Plan

When creating a business plan for managed care, the managed-care account manager needs to analyze both the market and the account. Two views in the business plan view that are useful during the analysis phase of preparing the business plan are:

■ Business Analysis view for reviewing syndicated prescription data:

- ■ Rx Trend by Plan - Volume

- ■ Rx Trend by Plan - Market Share

■ SWOT view for entering information about:

- ■ The account's (MCO's or PBM's) strengths and weaknesses

- ■ The opportunities and threats that the managed-care account manager needs to address in the business plan

To enter SWOT information for a business plan

1   Navigate to the Business Plans screen > Business Plan List view.

2   Drill down on a business plan record.

3   Click the Business Analysis view tab.

4   Use the Business Analysis view to review prescription trends for the market of interest.

For general information about analysis of syndicated data, see Chapter 13, "Analyzing Syndicated Data."

5   Click the SWOT view tab.

6   In the SWOT form, complete the fields.

Some fields are described in the following table.

Field	Comments
Strengths	For example, a recent study shows your drug is better tolerated by patients.
Weaknesses	For example, the MCO has very restrictive reimbursement policies for drugs in your market.
Opportunities	For example, a change of policy in the account makes it easier to get a drug added to the formularies.
Threats	For example, a study indicates that a competitor's product is as effective and less expensive than the product you are promoting.

Associating Contacts and Accounts with Managed-Care Business Plans

When creating a business plan for managed care, the account manager gathers information about accounts and contacts who are associated with the business plan.

Views in the business plan view that are useful for recording related accounts and contacts are as follows:

■   Account Coverage view: Use this view to list accounts associated with the business plan. For example, if the business plan is for a national account, add the names of the regional accounts associated with the national account.

■   Organizational Analysis view: Use this view to list key contacts for the business plan and to indicate the relationships between the key contacts.

■   Key Contacts view: Use this view instead of the Organizational Analysis view if you do not want to indicate the relationships between the contacts.

To associate accounts and contacts with business plan for a managed-care accounts

1 Navigate to the Business Plans screen > Business Plan List view.

2 Drill down on a business plan record.

3 Click the Account Coverage view tab and in the list, create new records and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Team	This field indicates which employees in your company are responsible for the account.
Coverage Level	For example, if the business plan is for a national account, the regional and local accounts associated with the national are listed. Use this field to indicate which account is regional or local.

4 Click the Organizational Analysis view tab.

5 Use the Organizational Analysis view to enter your list of contacts and to indicate relationships between them.

For general information about the organization analysis, see the *Siebel Applications Administration Guide.*

Setting Objectives for the Managed-Care Business Plan

The last but very important stage of creating a business plan is for the managed-care account managers to list what they are going to do to carry out the plan. These are their objectives.

These objectives are created in the Business Plans screen > Objectives view, but can also be viewed, created, and edited in the Objectives screen > Objective List > My Objectives view.

To create objectives for a business plan

1 Navigate to the Business Plans screen > Business Plan List view.

2 Drill down on a business plan record.

3 Click the Objectives view tab.

4 In the list, create new records and complete the necessary fields.

5 Drill down on the objective record to add activities to the objective.

For general information about objectives in Siebel Life Sciences, see Chapter 16, "Setting and Achieving Objectives."

12 Managing Accounts Contacts in Life Sciences

This chapter includes the following topics:

- ■ "About Japanese Pharmaceutical Market Features for Accounts Contacts" on page 205
- ■ "About Accounts Contacts" on page 206
- ■ "Configuring Workflows for Accounts Contacts" on page 207
- ■ "Managing Accounts Contacts" on page 208
- ■ "Creating Accounts Contacts Call Detail Records" on page 213
- ■ "Planning Calls in the Weekly Call Planning Screen (End User)" on page 214
- ■ "Reporting a Call in the Weekly Call Planning Screen" on page 216
- ■ "Deleting Multiple Calls in the Accounts Contacts Call Planning Screen" on page 216
- ■ "Switching to Reporting Mode in the Accounts Contacts Call Planning Screen" on page 217
- ■ "Displaying Calls Created by Other Representatives" on page 217

About Japanese Pharmaceutical Market Features for Accounts Contacts

The Japanese pharmaceutical market has some unique characteristics concerning the relationships of Hospitals and Physicians that influence how pharmaceutical companies conduct their Sales and Marketing activities in Japan. These market characteristics dictate how Sales Representatives engage with physicians and hospitals in their territories and how they plan future calls. For example Physicians always see patients at either large hospitals or small, private clinics. Therefore a contact call always takes place within the context of the Hospital (account) that the Physician (contact) is associated with.

Japanese Pharmaceutical companies also typically create and distribute large Targeting lists for each Sales Representative in their Sales Force which are based on the Hospital-Physician relationships and a series of Targeted Products. These Targeting lists are generally updated and distributed at the start of a new Targeting period, which is typically every quarter or half-year. The Hospital-Physician targeting lists include a number of targeting attributes (such as Call frequency) for one or more Products that are specific to each sales representative assigned to the specified Hospital-Physician. For example, one sales representative might be asked to make six visits to one account-contact during the quarter for Product A, but another sales representative might be asked to make only three visits to the same account-contact for the same Product A.

NOTE: Features specific to the call-planning features in the Japanese Pharmaceutical market are not covered in this section. For information about the call-planning features specific to the Japanese market, see "About Features for Call Planning Specific to the Japanese Pharmaceutical Market" on page 122.

The following Siebel Life Sciences features address the distinctive traits of the Japanese pharmaceutical market:

■ **Hospital-Physician relationships.** Sales representatives can visualize Hospital-Physician (that is account-contact) affiliations as a single record within a list. This feature provides an intuitive interface for users to retrieve customer information, create Siebel Target lists, and plan future calls.

■ **Hospital department support.** Affiliated Accounts can be displayed as Hospital Departments along with the corresponding Physicians who are affiliated to these departments.

■ **Hospital-Physician targeting information.** For a given targeting period (such as half year), Hospital - Physician targeting lists can be created by administrators and distributed to sales representatives for use within their targeting and call planning processes. Targeting information, such as call frequencies, detail frequencies and targeting flags, can be displayed for each hospital-physician record. Administrators can modify these attributes as business needs change and Sales representatives can plan their calls using these targeting attributes as guiding parameters.

■ **Weekly calendar with call-planning capabilities.** The application provides an intuitive and user-friendly Weekly call planning user interface which enables sales representatives to plan and visualize all the activities for their hospital-physician targets within a specific time period. New calls can be created by double clicking within the Call Planning screen. Sales representatives can also enter and report basic call data, (such as products detailed and samples dropped within the same screen), and submit the call if no additional information is required.

■ **Contact call with account information.** The standard contact call view has been enhanced to include account information. This feature allows sales representatives to capture detailed call data for a hospital-doctor record, such as promotional items dropped or decision issues.

About Accounts Contacts

The Siebel Pharma Accounts Contacts functionality supports the display of account-contact affiliations as a single record within dedicated Accounts Contacts List views, and also within an Accounts Contacts Weekly Call Planning screen. The Account-Contact records displayed in these screens are managed within the Siebel Pharma application as a set of separate Targeting records for each Sales Representative Position. These Targeting records store the relationship between the Account-Contact affiliation and Sales Representative Position. The records also have a series of Product Targeting attributes fields for each Account-Contact-Position relationship which store Product targeting information such as Detail Frequency targets.

The Targeting Period and related Accounts Contacts Targeting records needs to be created by an administrator, and then Targeting Period activated in order to make the Accounts Contacts Targeting records visible to end users. Administrators can create multiple Targeting Periods (and their related Accounts Contacts Targeting data) within the Siebel Pharma application, but only one Targeting Period can be active at any one time. The Targeting data can be manually created and setup through administration screens. However, a series of dedicated Siebel EIM tables are also provided to support the batch loading of the Targeting data. This method is the typical process for creating the data within the Siebel Pharma application.

Configuring Workflows for Accounts Contacts

The Siebel Pharma Accounts Contacts functionality utilizes Siebel Workflows in order to create and activate the Targeting lists. The application needs to be correctly configured to enable these workflows. The following topics describe how to configure and validate the Siebel Pharma application to enable Siebel Pharma Accounts Contacts functionality:

"Activating Workflows for Accounts Contacts" on page 207

"Enabling Server Components for Accounts Contacts" on page 207

Activating Workflows for Accounts Contacts

LS Pharma JPN Targeting Period Activation workflow must be activated to create and activate the Targeting periods and the Accounts Contacts lists. The administrator needs to set and activate this workflow process in order to enable the functionality.

To activate workflows for accounts contacts

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

2 Click Query and enter LS Pharma JPN* in the Name field.

The query returns LS Pharma JPN Targeting Period Activation.

3 Select the workflow and click Activate.

The selected workflow is added to the Active Workflow Processes view at the bottom of the screen.

NOTE: You only need to perform this procedure the first time you want to access the Accounts Contacts feature. The workflow remains activated the next time you use this feature.

Enabling Server Components for Accounts Contacts

The Accounts Contacts functionality also requires that a number of Siebel Pharma Application Server components be enabled to support the Workflows. These components are as follows:

■ Workflow Action Agent

■ Workflow Monitor Agent

■ Workflow Process Batch Manager

■ Workflow Process Manager

■ Workflow Recovery Manager

To activate workflows for accounts contacts

1 Navigate to the Administration - Server Configuration screen > Servers view.

2 Click the Components tab and Query Workflow* in the Components field.

The query returns the agent and manager records associated with the accounts contacts. All should have a status of Enabled.

3 Click Manual Start if any one of the components is Inactive.

NOTE: If you cannot view the Status field, select Columns Displayed from the Menu drop-down list and add the appropriate fields that you want displayed in the view.

Managing Accounts Contacts

The following topics describe the key tasks required to manage accounts contacts:

Loading and Distributing Accounts Contacts Targeting Data

When a new Targeting period begins, the administrator must load and distribute the Accounts Contacts Targeting data. The database administrator (DBA) then loads the new Target data into the Siebel Pharma application through Accounts Contacts Targeting EIM tables.

To load and distribute Accounts Contacts targeting data

1 Create a new Targeting Period record in the Accounts Contacts > Administration screen, and retrieve the Row Id for the new Targeting Period record.

2 Use the Row Id to create a set of Accounts Contacts Targeting Product records in a flat file that includes the following information:

Targeting Period Id

Account Id

Contact Id

Position Id (for Sales Representative)

Product Id

Product Targeting attributes.

3 Send the flat file to the database administrator (DBA) who loads the new Target data into the Siebel Pharma application through Accounts Contacts Targeting EIM tables.

4 Validate that the data is correct after the Targeting data is loaded into the application.

5 Use the Accounts Contacts Administration screens to set the Display Names for each of the Targeting Product Attributes.

6 Generate the corresponding column mappings for the Siebel Pharma Application to display the Product Attributes within the Accounts Contacts list screens.

7 Activate the current Targeting Period to create and distribute the Accounts Contacts Targeting lists to the end users.

Creating a New Targeting Period

In order to load and activate a new set of Accounts Contacts target lists and targeting information a new Accounts Contacts Period record must first be created by the administrator.

To set up the period for account-contact affiliation

1 Navigate to the Accounts Contacts screen > Administration view.

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

Some fields are described in the following table.

Field	Comments
Period	Select a target period from the Pick Period dialog and click OK.
Name	Enter a name for the contact.
Description	Enter a description for the accounts contact.
Status	(Read only) Indicate the status of this period. (In Progress, Lock, Active, Obsolete, Error).

Field	Comments
Request Id	(Read only) The activation process identification number. Drill down into the Process Information screen to check the status of the activation process.
Error Messages	(Read only) Displays an error message if the activation process fails.

3 Select Help > About Record and note the Record # (Row Id) of the new period.

This Row Id is used by the Administrator to create a flat file which maps the new Period to the new Accounts Contacts Target List and Targeting information so that the data can be loaded using the Accounts Contacts EIM tables. For more information about importing data with Siebel EIM, see "Importing Data with Siebel EIM" on page 262.

Creating Accounts Contacts Targeting Product Data

For each Targeting Period, a series of Targeting Product data records for each Account, Contact, and Sales Representative Positions needs to be created in order to generate the Targeting lists used by the end users. A Targeting Product is any Product being targeted to an Account Contact by a Sales Representative which needs to be tracked in terms of Targeting attributes (for example, Call Frequency targets) as part of the Sales Force's Targeting process. There are four Targeting Product attribute fields defined in the application which can be used to store and manage the Targeting Attribute values associated to a Target Product for a specific Account-Contact-Position (Sales Representative) relationship. By default, only the two numeric Targeting Attribute fields are enabled and are displayed in the Accounts Contacts list screens.

The steps below explain how to manually enter the Targeting Product records in the Accounts Contacts Administration screens. The values for each of the Account-Contact-Position Targeting Attributes fields can be loaded through the Accounts Contacts EIM tables.

To create targeting product data for account-contact-position relationship

1 Navigate to the Accounts Contacts screen > Administration view.

2 Select a period record from the list and drill down on the Period column.

3 In the Product Data applet, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Full Name	Select a name from the Pick Contact dialog box, and click OK.
Sales Representative	Select a position from the Pick Position dialog box, and click OK.
Product	Select a product from the Pick Product dialog box, and click OK.

Field	Comments
Numeric Attribute 1	Use the calculator to enter the first numeric attribute. For example, enter the numeric value for number of Sales Calls.
Numeric Attribute 2	Use the calculator to enter the second numeric attribute. For example, enter the numeric value for number of Product Details.
Text Attribute 1	Enter a text value to use as a product attribute.
Data Time Attributes 1	Enter a date value to use as a product attribute.

Generating Column Maps for Display of Product Attribute Fields

For each Product Attribute field, a common Display name value can be mapped to all the available Target Products. This Display name mapping is then used to automatically generate the Product Attribute Column labels displayed to the end users in the Accounts Contacts lists. The Display name for each of these Target Products' attribute fields is generated by combining the Product Name for each Targeting Product with the common Display name value defined by the administrator for the Product Attribute field. Once the Product Attribute labels are generated, an administrator can still edit the final display labels if minor updates are required before activating the Targeting Period.

The Targeting Product attributes used by the Sales Force may change from one Targeting Period to another. The application supports the ability to use the same attribute fields across all Targeting Periods, but define different labels for these fields for different Targeting periods. For example, a pharmaceutical company can decide to display the following information to the end users in the Accounts Contacts list screens:

■ In the first quarter, they might display the number of visits by product

■ In the second quarter, they might display the number of samples by product

■ In the third quarter, they might display the number of primary details by product

NOTE: While the labels can change, the underlying Targeting Product Attribute columns are the same. For this reason, it is important for the administrator to track how the attributes columns and labels are mapped for Targeting period.

Create column map for Accounts Contacts List

1 Navigate to the Product Attributes screen.

2 Check the Mapped Field column to select the field to be used to generate the column map.

3 Enter the Display Name as the postfix to the column display name.

4 Click the Generate button to generate column mapping in the Column Map view.

Some fields are described in the following table.

Field	Comments
Mapped Field	Check to select Product Data field used to display on Accounts Contacts List after activation.
Field	(Read only) Product data field column.
Display Name	Postfix of the Column Display Name in the Accounts Contacts List. This field will append to the product name in the generated column map.

5 Edit the Display Name in the Column Map view.

Some fields are described in the following table.

Field	Comments
Product	(Read Only) Product Name
Source Field	(Read Only) Product data field
Target Field	(Read Only) Mapped field in Accounts Contacts List view
Display Name	Column Display Name of this product attribute in Accounts Contacts List view

Activating the New Accounts Contacts Targeting Data

To allow end users to view and use the new Accounts Contacts Targeting data, the administrator must activate the Targeting Period. When a new Targeting Period is activated, the existing period becomes obsolete. Only the Targeting data for the active Targeting Period is visible to end users in the Accounts Contacts list screens. The activation process assigns an account-contact record to a Sales Representative's Position only if the Position is already part of both the Account and Contact teams. If this relationship already exists, then a targeting record is created for the Sales Representative's Position and all remaining targeting attributes are added to this record.

To activate a Targeting Period

1 Navigate to the Accounts Contacts screen > Administration view.

2 Select a period record from the list.

3 Select the Mapping and Activation view from the view toggle list.

4 Click the Activate button on the list.

The Server Request should be displayed in the Request Id field and the Status field should change to In Progress.

5 After a few minutes, refresh the screen to verify that Workflow processes have completed and the Period status has changed to Active.

6 Navigate to the Accounts Contacts List and toggle to the All Accounts Contacts Across Organization view.

7 Verify that the current Targeting Period's Accounts Contacts Targeting data has been created correctly.

Creating Account-Contact Target List Records Manually

Once a Target Period has been successfully activated, each Sales Representative will be able to view their list of Account-Contact-Targeting Product records for the current Targeting period in the Accounts Contacts list view. A user can also manually create new target list records for Account - Contact affiliations in the Accounts Contacts list.

To create a target list for account-contact affiliations

1 Navigate to the Accounts Contacts > Accounts Contacts List view.

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

Some fields are described in the following table.

Field	Comments
New	Indicates when a new Account Contact record is created for the current position.
Sales Rep	The sales representative to whom this account contact is associated.
Account Name	From the Pick Account Contact dialog, select the appropriate Account - Contact Affiliation. **NOTE:** Only affiliations where the Sales Representative's Position on both the Account and Contact teams will be displayed in this dialog.
Account Location	The location of the account contact.
Contact Primary Speciality	Primary speciality of the contact.

Creating Accounts Contacts Call Detail Records

The Accounts Contacts list displays the Account-Contact records with their targeting Product attributes for the current Targeting Period. The records in the list are limited to Account-Contact targeting records created for the current user's Position.

Users can create a Call record directly from the Accounts Contacts List applet. The New Call button
on the Accounts Contacts List applet creates an Account Contact Call record with both the Account
and Contact Ids populated. The created Call records are displayed in the Accounts Contacts Call
Detail view under Activities. Users can create records for the Products Detailed and Samples Dropped
based on the data setup in the user's Personal Lists.

To create Contact Call Details for a new Contact

1 Navigate to the Accounts Contacts List screen.

2 Select an Account - Contact record from the list.

3 Click New Call.

A new Contact Call Detail record is created and the Contact Call Detail view is displayed.

You can create records in the Products Details and Samples Dropped views with records based
on data setup in your Personal List.

4 Click Sign.

If all business rules are valid, signature capture window is launched. Verify the contact's name,
address, DEA number and license number displayed in the call header.

5 Click Submit to submit the call. If Samples were dropped a Signature will need to be entered
before the call can be submitted. For more information, see "Recording a Contact Call for a
Different Contact at the Time of Signature Capture" on page 170.

Planning Calls in the Weekly Call Planning Screen (End User)

Japanese sales representatives generally plan their Account Contact calls a week or more at a time.
For ease of viewing and editing, they prefer to use a calendar that displays Accounts Contacts on the
vertical axis and days of the week along the horizontal axis. The Weekly Account Contact Call
Planning screen enables sales representatives to easily view and plan their Account Contact calls.
Users can double-click any of the cells within the weekly calendar grid to easily and quickly create a
call record for an Account Contact on a given day of the week.

From this Weekly Call Planning screen, sales representatives can also see whether other sales
representatives have also scheduled calls for a particular Account-Contact which allows Sales teams
to plan their joint sales efforts more effectively. Managers can also view the planned and completed
Sales calls for all of their direct reports, allowing them to better monitor Sales Representatives'
activities and suggest any changes as needed.

When a sales representative creates a new activity, all other information, such as Products Detailed
and Samples Dropped, is automatically populated with the information previously entered on their
personal lists. For more information on personal lists, see the scenario "Scenario 1: Users Set Up
Personal Lists" on page 103 and "Creating a Personal List (End User)" on page 106.

The calls displayed on the Accounts Contacts Call Planning screen are color-coded, so that sales
representatives can monitor the status of a particular activity. When a call is submitted, the activity
color is automatically refreshed, and the record is locked.

To plan a call in the Weekly Call Planning screen

1 Navigate to the Calendar screen > Accounts Contacts Call Planning view.

2 In the Weekly Calendar grid, double-click the intersection cell corresponding to the Account Contact record on the Day for which you wish to create the Call record.

3 The application creates an Account Contact Call detail record and displays it in the view below the Weekly Call Planning Gantt chart.

A call created in this manner has the following characteristics**:**

■ **Account and contact name.** The account name and contact last name corresponding to the account-contact record selected.

■ **Start date and time.** The day corresponding to the day selected on the calendar. The time for all calls scheduled on this view is set to the start of the work day, as entered on the User Profile Calendar View.

Some of the fields displayed in the List portion on the left-hand side of the Gantt chart are described in the following table.

Field	Comments
Last Name	Displays the Last Name of the Contact as displayed in the Accounts Contacts list. (If you click the Last Name link, the Contact Details screen is displayed showing details of the call contact.
First Name	Enter first name for the contact.
Account	The name of the Account as displayed in the Accounts Contacts list.
Sales Rep	The Sales Representative position associated to the Account Contact record as displayed in the Accounts Contacts List.
Primary Speciality	Primary speciality of the contact.
Calls	A calculated field which displays the number of calls for the Account Contact record within a given period. The displayed value for this column is calculated when the user clicks the Calculate button on the Gantt chart and enters the Start and End Period for the calculation.

Button	Comments
Save Template	Saves all the calls to a template for all current Account Contact records between a Start and Finish date set by the user.
Apply Template	Applies a selected template from a start date set by the user.
5 Day Week	Displays all the days between Monday and Friday.

Button	Comments
7 Day Week	Displays all the days from Monday through Sunday.
Calculate	Calculates the number of calls for each of the current Account Contact records and displays values in the Call column in the Gantt chart's list. The calculation is based on the Start and End Period entered by the user.

Reporting a Call in the Weekly Call Planning Screen

Sales representatives can use the Weekly Call Planning screen to also report completed calls.
Information for Products Detailed and Samples Dropped is displayed below the Weekly Call Planning
Calendar for the currently selected Call record. A sales representative can quickly and easily update
this information before submitting the completed call all within the same Calendar Call Planning
screen.

To update call records in the Call Planning screen

1   Navigate to the Calendar > Accounts Contacts Call Planning screen.

2   In the Accounts Contacts Call Planning screen, single click on a previously created Call record in
    the Weekly Calendar grid.

3   The application displays the selected Call record in the form below the Weekly Calendar grid.

4   Update the fields in the form for the completed Call as necessary.

5   In the Products Detailed list below the form, enter a value in the Priority column for each Product
    detailed during the Call. All other Product Detailed records will be deleted when the Call is
    submitted.

6   If Samples were dropped during the call, then in the Samples Dropped list below the form,
    specify a lot number and quantity for the dropped samples.

7   If Samples were dropped, enter a Signature before you submit the call.

8   Click Submit to submit the call.

Deleting Multiple Calls in the Accounts Contacts Call Planning Screen

Sales representatives can use the Accounts Contacts Call Planning screen to delete multiple calls. A
sales representative can quickly and easily update this information in a weekly view for multiple
accounts.

To delete multiple calls

1   Navigate to the Calendar > Accounts Contacts Call Planning screen.

2 Press and hold the Ctrl key, and select the calls that you want to delete.

3 Click Delete.

Switching to Reporting Mode in the Accounts Contacts Call Planning Screen

Sales representatives can use the Accounts Contacts Call Planning screen to switch to reporting mode. A sales representative can quickly and easily switch modes by clicking one button.

To switch to reporting mode and submit calls

1 Navigate to the Calendar > Accounts Contacts Call Planning view.

2 Click Go to reporting mode.

3 Report the call information:

    a Select the call from the list.

    b Enter product details.

    c The Start Date field will be pre-populated with the current date. Change it to a different date, where appropriate.

    d Enter the number of minutes in the Duration field.

    e Enter any decision issues in the Decisions Issues field.

    f Select a status from the Status list.

    g Enter any additional comments in the Comments field.

4 Click Submit to submit the call.

Displaying Calls Created by Other Representatives

Sales representatives can use the Accounts Contacts Call Planning screen to display calls created by other representatives.

To display calls created by other representatives

1 Navigate to the Calendar > Accounts Contacts Call Planning screen.

2 Scroll through the calendar view.

All entries in grey represent calls created by other representatives.

13 Analyzing Syndicated Data

This chapter covers the following topics:

About Analyzing Syndicated Data

The views in the Analysis screen present sales, prescription, and call detailing data in an accessible format. These views allow you to evaluate your performance and determine where to focus your sales activities.

Much of the data displayed in these views derives from syndicated data.

NOTE: All the views in the Analysis screen are read-only.

The terms *direct sales* and *indirect sales* are used in some views of the Analysis screen as follows:

- **Direct sales.** Refers to product sales directly from your company to accounts.
- **Indirect sales.** Refers to product sales from wholesalers to accounts.

Scenario for Analysis

This topic outlines an example process performed by the Siebel administrator and end users. Your company may follow a different process according to its business requirements.

A pharmaceutical company has bought syndicated data concerning its retail product sales. This syndicated data is displayed in most of the Siebel Life Sciences Analysis views.

Periodically, the Siebel administrator extracts portions of the syndicated data and distributes it according to territory assignments. As part of this process, the Siebel administrator updates responsibilities, which affect the data that can be viewed by an individual, and updates payer and plan information.

In order to use the new information, the application user must download the syndicated data updates.

Process of Analysis

This topic details sample tasks often performed by administrators and end-users working with the Analysis screen. Your company may follow a different process according to its business requirements.

Administrator Procedure

The following administrative procedure is described in this topic:

■ "Defining Payer and Plan Information" on page 220.

Other administrator procedures, applicable to the data used in the Analysis screen, are described elsewhere:

■ "Loading Data into the Siebel Life Sciences Database" on page 270.

■ "To create a data extraction rule" on page 273. Extract portions of data according to territory assignments.

■ "To specify the data that is routed to mobile users" on page 274. Send the compressed data extracts to mobile users.

■ (Optional) Updating responsibilities. For general information about responsibilities, see *Siebel Security Guide*.

■ Associating positions to bricks. See "Administering Bricks" on page 50.

End-User Procedures

The following list shows tasks end users typically perform using the Analysis screens:

■ "Importing Syndicated Data Files (End User)" on page 221.

■ "Analyzing Brick-Level Syndicated Data (End User)" on page 222.

■ "Working with Sales, Rx, and Call Data (End User)" on page 223.

Defining Payer and Plan Information

You can use the Payer Administration view to define payer and plan information. This information appears in the plan and payment type–based views in the Analysis screen.

To create a payer

1 Navigate to the Administration - Application screen > Payer view.

2 Click the New button and complete the fields in the new record.

Some of the fields are described in the following table.

Field	Comments
Type	Three types are supported: Total, Plan, and Payer.
Name	Enter the name of the payer, plan, or payment type. If you selected Plan in the Type field, enter the plan name.
Account Name	If relevant, select the payer account, or create a new account for the payer in the Pick Account dialog box.
Account Site	The location of the plan.
IMS Id	The identifier assigned to the plan by the syndicated data provider.

Importing Syndicated Data Files (End User)

If data extracts have been routed to the end users by the Siebel administrator, the end users receive notification when they synchronize your local database. During synchronization, the data extracts are downloaded to their hard drives (as attachments), where they are stored until you import them. After they import the data into their local databases, the files are deleted from their hard drives.

NOTE: If you want to postpone receiving data extracts until a later time, turn off the Retrieve Published Files option in your synchronization setup. To find this option, choose File > Synchronize, and then click Setup in the Siebel Remote dialog box.

To import syndicated data extracts

1 Navigate to the Syndicated Data Files screen.

NOTE: Even if you postponed receiving data extract files by turning off the Retrieve Published Files option in your synchronization setup, this view displays records for all the files routed to you. Although the files are listed here, you *cannot* import them until you have received them during a subsequent synchronization.

2 Select one or more files and click Import.

The Syndicated Data Files view is cleared, and the data extract files that you received during synchronization are deleted from your hard drive.

Analyzing Brick-Level Syndicated Data (End User)

End users can analyze syndicated data that is associated with a brick. They can also analyze activities, such as calls, associated with an account or contact within a brick. Using the brick-level analysis views, end users can correlate those activities with prescription or sales trends.

The data that appears in the Analysis screen > Bricks is determined by the user's position and the bricks that the administrator has associated with that position. For more information, see "Administering Bricks" on page 50.

To display all contacts associated with a brick

1   Navigate to the Analysis screen > Bricks Analysis List view.

2   From the Show drop-down menu, select Bricks Rx Analysis.

3   Select a brick in the Bricks list.

4   Click on the Contacts view tab.

The Contacts list displays all contacts associated with the selected brick.

To correlate actual calls made with indirect sales by brick

1   Navigate to the Analysis screen > Bricks Analysis List view.

2   Select a brick in the Bricks list.

3   Click on the Indirect Sales by Brick view tab.

4   Select a record and click the actual calls button.

The list shows the number of account calls submitted for the selected product and period. Remember to select a record that contains your company's product in order to see the activity data.

To correlate actual calls made with prescription trends by brick

1   Navigate to the Analysis screen > Bricks Analysis List view.

2   Select a brick in the Bricks list.

3   Click on the Rx Trend by Brick view tab.

4   Select a record and click the actual calls button.

The list shows the number of account calls submitted for the selected product and period. Remember to select a record that contains your company's product in order to see the activity data.

Working with Sales, Rx, and Call Data (End User)

The views in the Analysis screen display prescriber, account, plan, payer, and territory level sales and Rx data, as well as call data. These views provide the capability to view data in both list and chart formats.

To access any of the views listed in , navigate to the Analysis screen default Analysis view, select the appropriate market in the All Markets list, and then select the desired view from the view tabs.

A list format appears by default when you select a view from the Analysis view tabs. You can view your sales and Rx data numbers in a chart format by clicking the toggle button.

The data in the Analysis screen must be updated periodically. Mobile users must download files that have been extracted and sent by the Siebel administrator and then import the new data into their local databases. For more information, see .

To display data with the views in the Analysis screen

1 Navigate to the Analysis screen.

2 Select the appropriate market (therapeutic class) in the All Markets list.

   NOTE: You can select a different market at any time in all views in the Analysis screen, except in the Activities subviews (the Account Detailing Analysis and Contact Detailing Analysis views).

3 Click a category from the view tabs.

4 Display only the sales, Rx, or call data you want to view using query by example or targeting.

   See Chapter 7, "Planning Calls in Pharma," for information on targeting.

   NOTE: By default, Siebel Pharma displays (and charts) all available data appropriate to the selected Analysis view. It is recommended that you always filter your data lists to make the displayed data more meaningful. The charts in the Account Detailing Analysis and Contact Detailing Analysis views display all calls, regardless of status, unless you filter the data in the upper list.

5 Select a chart type from the drop-down list to specify which type of chart you want to use for viewing the selected data.

   Examples of available chart types include 3D stacked bar, 3D bar, and 2D bar.

6 Zoom in on data or limit the chart to particular data points by hovering the mouse cursor over the chart element (a bar or pie segment) to see the data only for that chart element. To return to the complete set of data for the original chart, execute a new query.

Views in the Analysis Screen

In Siebel Life Sciences, the availability of certain views can be limited according to each user's responsibilities. Therefore, the views you see may differ from those shown and described in Table 21.

NOTE: Analysis data is read-only. Data refresh cycles are determined by your company's business process and data availability.

Table 21 describes the functions of the views in the Analysis screen. Your responsibilities determine which views are available to you.

Table 21.   Views Available from the Analysis Screen

View	Functions
All Markets > Direct Sales Trend by Territory - Volume	For managers, displays internal product sales data at the territory level over a selected period of time. Displays direct sales data for areas covered by their sales representatives.
All Markets > Direct Sales Trend by Account - Volume	For representatives, displays internal product sales data at the account level over a selected period of time.
All Markets > Indirect Sales Trend by Territory - Volume	For managers, displays product sales data at the territory level over a selected period of time. Allows managers to see indirect sales data for the areas covered by their sales representatives.
All Markets > Indirect Sales Trend by Territory - Share	For managers, displays product sales data at the territory level over a selected period of time.
All Markets > Indirect Sales Trend by Brick - Volume	For representatives, displays product sales data at the brick level over a selected period of time.
All Markets > Indirect Sales Trend by Brick - Share	For representatives, displays market share data at the brick level over a selected period of time.
All Markets > Indirect Sales Trend by Postal Code - Volume	For representatives, displays product sales data at the ZIP Code level over a selected period of time.
All Markets > Indirect Sales Trend by Postal Code - Share	For representatives, displays market share data at the ZIP Code level over a selected period of time.
All Markets > Indirect Sales Trend by Account - Volume	For representatives, displays product sales data at the account level over a selected period of time.
All Markets > Indirect Sales Trend by Account - Share	For representatives, displays market share data at the account level over a selected period of time.
All Markets > Rx Trend by Territory - Volume	For managers, displays product Rx trends in a territory. Allows managers to see Rx trends for the areas covered by their sales representatives.
All Markets > Rx Trend by Territory - Share	For managers, displays product Rx trends in a territory.

Table 21.   Views Available from the Analysis Screen

View	Functions
All Markets > Rx Trend by Prescriber - Volume	For representatives, displays product Rx trends by prescriber.
All Markets > Rx Trend by Prescriber - Share	For representatives, displays product Rx trends by prescriber.
All Markets > Rx Trend by Plan and Territory - Volume	For managers, displays product Rx trends by plan and territory.
All Markets > Rx Trend by Plan and Territory - Share	For managers, displays product Rx trends by plan and territory.
All Markets > Rx Trend by Plan and Prescriber - Volume	For representatives, displays product Rx trends by plan and prescriber.
All Markets > Rx Trend by Plan and Prescriber - Share	For representatives, displays product Rx trends by plan and prescriber.
All Markets > Rx Trend by Payment Type and Prescriber	For representatives, displays product Rx trends by the payment types associated with prescriptions and prescribers.
All Markets > Rx Trend by Payment Type and Territory	For both representatives and managers, displays product Rx trends by the payment types associated with prescriptions.
Activities > Account Detailing	For both representatives and managers, shows the number of times a product was detailed during account calls, as well as the priority, or order, of the product details. Use this view to assess your product emphasis and plan your account calls.
Activities > Contact Detailing	For both representatives and managers, shows the number of times a product was detailed during contact calls, as well as the priority, or order, of the product details. Use this view to assess your product emphasis and plan your contact calls.
Bricks > Bricks Rx Analysis > Rx trend by brick	For representatives, displays product prescription trends by brick. This data is for the entire brick that is selected in the Bricks list and is not related to any contact.
Bricks > Bricks Rx Analysis > Rx trend by brick-Product NRx	For representatives, displays new prescriptions for a given product by brick. This data is for the entire brick that is selected in the Bricks list and is not related to any contact.
Bricks > Bricks Rx Analysis > Rx trend by brick-Product TRx	For representatives, displays total prescriptions for a given product in a given period by brick. This data is for the entire brick that is selected in the Bricks list and is not related to any contact.

Table 21. Views Available from the Analysis Screen

View	Functions
Bricks > Bricks Sales Analysis > Indirect sales by brick	For representatives, displays indirect sales data at the brick level for the brick selected on the Bricks list.
Bricks > Bricks Sales Analysis > Indirect sales trend by product value	For representatives, displays indirect sales data at the brick level for the selected product and for the brick selected on the Bricks list.
Bricks > Bricks Sales Analysis > Indirect sales trend by product units	For representatives, displays indirect sales data at the brick level for the selected product unit and for the brick selected on the Bricks list.

14 Tracking Time Off Territory

This chapter covers the following topics:

About Tracking Time Off Territory

In order to better manage their sales and field personnel, pharmaceutical companies need a way to measure and track the amount of time individuals take off.

A time off territory is any block of time during normal business hours in which sales representatives are out of their territories. Examples of time off territory include field trainings, national sales meetings, sick leave, vacation, or personal activities such as doctor's appointments.

Companies can use time off territory information to track the time that remote sales and field personnel spend on activities that do not directly relate to accounts, contacts, or opportunities. Companies can use this information to:

- Maintain a record of field employee time such as vacation and sick days
- Evaluate market penetration based on territory coverage and to assess the effectiveness of field personnel

Using the views in the Time Off Territory screen, users can record blocks of time that should not be included in call-frequency reporting. In addition, they can enter and record past and future time off information, including the duration, reason, date, and description of the time off territory event.

Because time off territory is actually a type of activity in Siebel Pharma, time off territory records appear in the Activities screen and in views that display activities. For more information about activities, see *"About Creating Activities"* on page 112.

Scenario for Time Off Territory

This scenario is an example process performed by two types of end users, a field sales representative and his or her regional sales manager. Your company may follow a different process according to its business requirements.

A sales representative for a pharmaceutical company has been invited to a two-day, out of town seminar. She speaks to her manager and they decide she should attend it. The sales representative then uses Time Off Territory to record why her territory will not be worked on the days on which the seminar will take place. Once she submits the information, her manager has a record of where she is and why she is gone.

Process of Tracking Time Off Territory

This topic details sample tasks often performed by end-users when tracking time off territory. Your company may follow a different process according to its business requirements.

When tracking time off territory, end users typically perform the following tasks:

■ "Creating a Time Off Territory Record (End User)" on page 228. Typically, the sales representative creates a record for all of the days she will be attending the seminar.

■ "Submitting a Time Off Territory Record (End User)" on page 229.

The regional sales manager uses Siebel Time Off Territory to:

■ "Viewing Time Off Territory Charts (End User)" on page 229. The regional sales manager can review the time off territory records that have been submitted to the system.

Once the sales representatives submit time off territory records to the system, Siebel Pharma:

■ Creates a new time off territory record in the Activities list.

■ For each time off territory record, creates an all-day appointment in the calendar.

NOTE: Siebel Time Off Territory includes two filters for displaying time off territory records: My Time Off Territory and My Team's Time Off Territory. Each user's responsibilities determines which of these views are available.

Creating a Time Off Territory Record (End User)

End users must create at least one time off territory record for business days that they spend on activities not directly related to an account, contact, or opportunity. A single time off territory record can represent one or many days. Multiple time off territory records can represent different activities performed on a single day. For example, a user could create one record for a conference attended in the morning and another for vacation time taken in the afternoon.

To create a time off territory record

1 Navigate to the Time Off Territory screen.

2 Create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Description	The reason for the time off.
Hours	Represents duration of the time off request. The application automatically calculates this value when you enter or update the Start Time and End Time fields.
Status	The status of a time off request. End users cannot select Submitted. For more information on changing the status of a record to Submitted, see "Submitting a Time Off Territory Record (End User)" on page 229.

The new time off territory record appears in the Activities lists and in the calendar.

Submitting a Time Off Territory Record (End User)

End users must submit a time off territory record for the information to be included in ROI (return on investment) analyses and expense reports. Once a time off territory record has been submitted, it can no longer be modified or deleted.

To submit a completed time off territory record

1 Navigate to the Time Off Territory screen.

2 Select the record you want to submit.

3 Click Submit and then OK.

The status of the time off territory record changes to Submitted and the record becomes read-only.

Viewing Time Off Territory Charts (End User)

Managers and end users can view graphical charts of time off territory information by clicking the Charts view tab. Using these charts is an effective way see trends and patterns.

For Siebel Mobile Web Client: If your routing rules are not configured to route employee time off territory records to managers, employees can give calendar access to their managers so that managers working remotely can view their teams' time off territory records.

NOTE: Routing rules can no longer be edited in the Administration - Siebel Remote screen. For help with editing routing rules, contact your Oracle sales representative for Oracle Advanced Customer Services to request assistance from Oracle's Application Expert Services.

To view time off territory charts

1 Navigate to the Time Off Territory screen.

2 From the visibility filter, select My Team's Time Off Territory.

3 On the link bar, click Charts.

4 From the drop-down list, select how you want the information to be displayed:

- **TOT by Reason.** Displays the number of hours spent off territory each month, by reason.

- **TOT by Creator.** For managers. Displays the aggregate and incremental number of hours spent off territory.

5 From the By drop-down list, select how you want the information to be displayed.

Configuring Time Off Territory

Most of the procedures in Siebel Time Off Territory are end-user related. However, the Siebel administrator may want to:

- Create an approval process and develop alerts so that managers will be notified when sales representatives submit Time Off Territory records. For more information, see the message broadcasting chapter in *Siebel Applications Administration Guide*.

- Enter additional selections to the Reason drop-down list. For more information about Lists of Values, see *Siebel Applications Administration Guide*.

15 Managing MedEd Events

This chapter covers the following topics:

About Managing MedEd Events

This chapter describes how a pharmaceutical company can use Siebel Pharma Medical Education (Siebel MedEd) to plan all aspects of a medical education event. A medical education event can be as simple as a "lunch-and-learn" in a physician's office or as complex as a seminar series or national sales meeting.

Using the procedures given in this chapter you will be able to perform the administrator tasks of setting up funding for MedEd plans, creating templates for activities, making literature selections available to end users, and designating contacts as MedEd speakers. After these administrative tasks have been completed, end users can then use Siebel MedEd to define MedEd plans, set up MedEd events and sessions, and invite and register event attendees.

Siebel MedEd provides a single repository of medical event information to allow administrators and end users to:

■ Plan and execute events

■ Track allocated event budgets

■ Compare allocated budgets to actual event costs

For more information on the differences between administrator and end-user tasks see "Scenario for MedEd Events" on page 233.

MedEd Terminology

Before reading further, you should understand the terminology specific to the Siebel MedEd application. This chapter includes the following MedEd-specific terminology:

■ **Event or MedEd event.** Refers to a promotional or educational event attended by physicians or medical professionals. An event may consist of single or multiple-sessions and functions as a forum for exchanging information on a particular disease, illness, therapeutic class, or product.

■ **Session.** Refers to a single class or meeting attended by one or more participants as part of a particular MedEd event.

■ **MedEd Team.** Refers to a group of people from various departments or sales teams who are primarily responsible for the planning, execution, and funding of a MedEd event.

■ **Plan.** Refers to a hierarchical collection of MedEd events focused on delivering a specific set of objectives and sharing common funding. For example, the objective might be promotion of a new indication, to gain awareness and increase market share for a particular product. A plan may display aggregated actual cost and attendee information related to every event associated with that plan.

About MedEd Event Types

A MedEd event can be any type or promotional or education event attended by physicians or medical professionals. From a corporate perspective, MedEd event types include:

■ **Sales Representative Level**. Executed by a manager or one or many sales representatives in the field.

■ **Corporate or National Level**. A national training or meeting targeted at a specific group of medical professionals.

Depending upon the needs of their environment, users can plan events at the national level for either a specific product or time period and then allocate resources by region, district, or sales representative.

Scenario for MedEd Events

This topic outlines an example process performed by a Siebel MedEd administrator and end users. Your company may follow a different process according to its business requirements.

A product manager at a pharmaceutical company is responsible for increasing the market share of a new product. To accomplish this objective, he uses Siebel MedEd to plan various dinners, symposiums, and lunch-and-learn meetings to communicate the budgets and objectives. In Siebel MedEd, he creates a MedEd plan and then defines how much money each sales representative will be given to drive events within the district. In the process of creating sub plans, the product manager allocates a budget and assigns the teams who will be responsible for event planning and execution.

Sales representatives in the field use Siebel MedEd to see the events and plans to which they have been assigned, itemize the tasks they need to accomplish, invite various contacts, record expenses, develop the meetings agendas, associate speakers, add materials, and manage the overall calendar of events in his or her territory. Over time, the product manager can closely monitor whether his team is executing on-time and within budget by comparing each event's allocated budget with the actual costs.

In this scenario, the product manager is responsible for administrating Siebel MedEd so that end users can plan, track, and execute medical events. As the MedEd administrator, he requires administrative responsibilities in Siebel MedEd to:

■ Establish funds for a MedEd plan

■ Create MedEd activity templates

■ Add MedEd literature items to the application

■ Designate a contact as a MedEd speaker

The end users are the sales representatives and managers who execute MedEd events in the field. They enter information to:

■ Set up a MedEd plan

■ Set up MedEd events

■ Track the MedEd event costs

■ Set up sessions within an a MedEd event to track speakers and associate literature and materials with the event

■ Designate a contact as a MedEd speaker

■ Invite and register MedEd event attendees

Process of Managing MedEd Events

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

Administrator Procedures

The following list shows tasks administrators typically perform to manage MedEd events. The administrator may be the product manager who is responsible for using Siebel MedEd to plan a variety of events that feature the new product. These tasks are typically performed in the following order:

End-User Procedures

The following list shows tasks end users typically perform when managing MedEd events. These tasks are typically performed in the following order:

Establishing Funds for MedEd Plans

A MedEd plan is a database record in which you specify common funding for a group of MedEd events that share a common objective. Each MedEd event can be funded by up to one MedEd plan for each event team member who is responsible for each event. Using the MedEd Activities view, you can track costs associated with each event. Because these events are automatically aggregated by plan, you can compare actual expenditures with MedEd plans across sales divisions.

Figure 8 shows the possible relationships between MedEd funds, master plans, subplans, events, sessions, activities, and invitees.
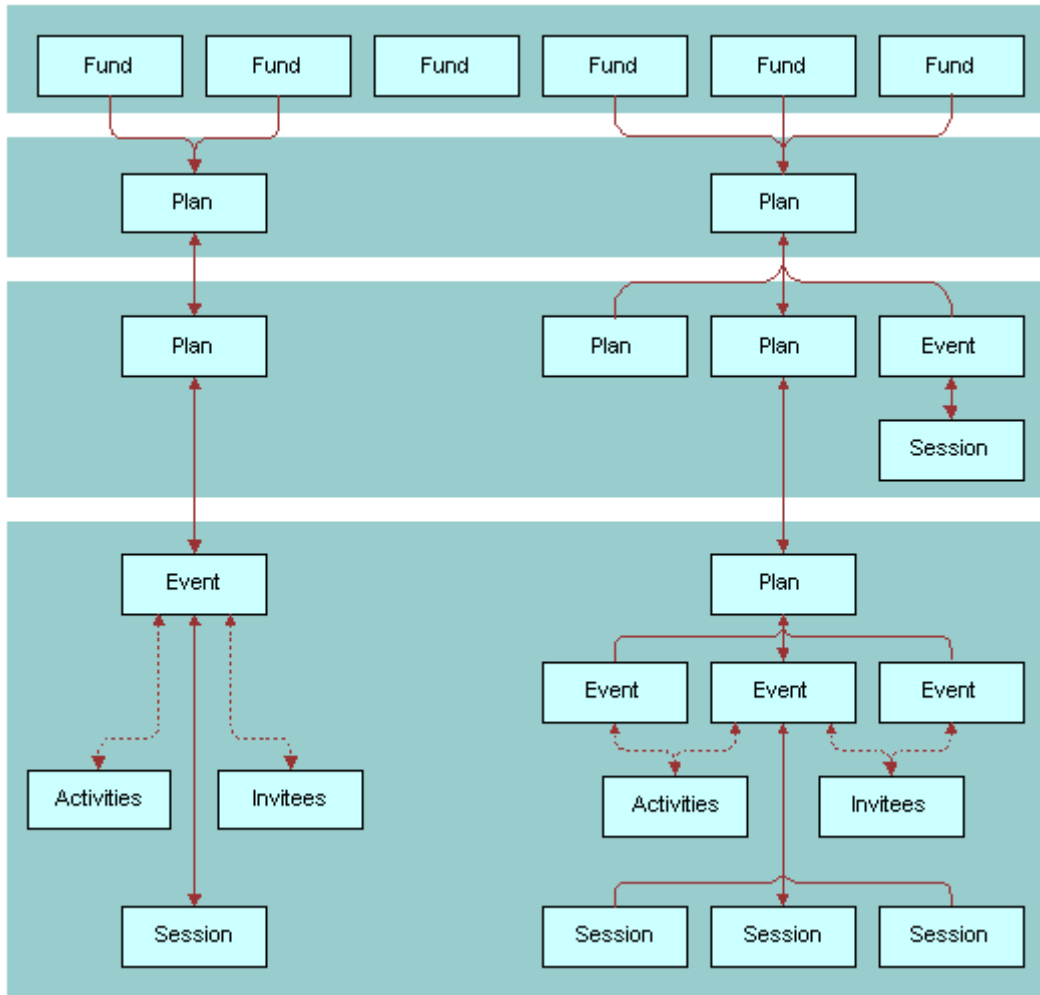
Figure 8.   Relationships Between Funds, Plans, Events, Sessions, Activities, and Invitees

To establish a fund and associate it with a MedEd plan, you must:

■ **Define an active period for the fund.** Define an active period that can be assigned to a fund. For more information on defining periods, see *Siebel Applications Administration Guide*.

■ **Establish the fund.** Establish the fund by loading fund information into the database using Siebel Enterprise Integration Manager (EIM). To perform this task, you must consult *Siebel Enterprise Integration Manager Administration Guide* to determine which columns are included in the database table EIM_MDF and how those columns map to the columns in the base table S_MDF. Then, use a standard SQL utility to place information about the fund you are establishing in the EIM_MDF table.

NOTE: If you want the fund to be active immediately, make sure that the current date falls between the start date and end date that you specify for the fund.

For more information on using EIM, see *Siebel Enterprise Integration Manager Administration Guide*.

■ **Verify fund availability.** Verify that the fund has been successfully established and is available for association with a MedEd plan. For more information, see the procedure "To verify that a fund is available for association with a MedEd plan" on page 236.

To verify that a fund is available for association with a MedEd plan

1 Navigate to the Administration - Data screen > MedEd Planning view.

2 In the Plans list, select a plan.

3 In the Plan Administration form, click the select button in the Funds field.

All active funds listed in the S_MDF table appear.

4 Verify the fund you want is available and then close the dialog box.

Creating Master MedEd Plans

Administrators and managers create master MedEd plans to allocate funding resources and spending privileges to end users who perform tasks associated with a MedEd event. Each person who receives a funding allocation from a specific MedEd plan can create one or more subplans to further specify how the funds will be allocated. For more information on creating MedEd plans and subplans, see "Setting Up a MedEd Plan (End User)" on page 240.

To create a MedEd master plan

1 Navigate to the Administration - Data screen > MedEd Planning view.

2 In the Plan Administration form, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Assigned To	Person responsible for carrying out the plan. Defaults to the current user name.
Budget	Amount of money authorized for spending under the plan.
Funds	One or more funds (cost centers) associated with the plan.

Field	Comments
Objective	One or more purposes to be accomplished by holding MedEd events associated with the plan.
Period	Time period during which the plan is to be used.
Plan ID	An unique alphanumerical value identifying the plan. The application automatically assigns this value when you create the plan record.
Plan Name	Name for a plan that you want others to associate with MedEd events.
Products	Products to be promoted with the funds supplied under this plan.
Status	Indicates whether the plan is currently active or inactive.

Creating a MedEd Activity Template

Activity templates let you provide your MedEd event team with a list of standard activities required to successfully complete a particular type of event. Each activity plan for an individual event depends upon an activity template. Activity plans assist you in scheduling and assigning activities.

To create an activity template for a MedEd event
■ Create an activity template of type Pharma ME Event.

For information about how to create activity templates, see *Siebel Applications Administration Guide*.

NOTE: Lead times for MedEd activities are defined as the amount of time between the start date for an activity plan and the date that the selected activity should start.

MedEd Lists of Values

As you work with various MedEd records, you will find a number of fields that require you choose values from drop-down lists. Table 22 lists the locations, field names, and values types of some MedEd drop-down lists.

Table 22.   Lists of Values for MedEd Settings

Views	Field Name	List of Values Type	Comments
MedEd Events > More Info view tab	Accreditation	LS_ME_EVT_ACCREDT_CD	Organizations that give Continued Medical Education (CME) credits for attending MedEd events.
	Dress Code	LS_ME_EVT_DRESS_CD	Appropriate types of dress for MedEd events.
	Status	LS_ME_EVT_STAT_CD	Status of MedEd events. Note: When the status is Completed, the event and its children records—such as Invitees, Sessions, Material, Activities, and Activity Plan—are locked. The status can only be unlocked by the administrator using the Administration - Data screen > MedEd Event Details.
	Type	LS_ME_EVT_TYPE_CD	Types of MedEd events.
MedEd Events > Invitees view tab	Role	LS_ME_INV_ROLE_CD	Roles that invited contacts or employees may fill for MedEd events.
MedEd Events > Event Details view tab MedEd Events > Invitees view tab	Invitee Status	LS_ME_INV_STAT_CD	Status of invitees for MedEd events. When the status is Completed, the event and its children records—such as Invitees, Sessions, Material, Activities, and Activity Plan—are locked.

Table 22.   Lists of Values for MedEd Settings

Views	Field Name	List of Values Type	Comments
MedEd Events > Invitees view tab > Sessions MedEd Events > Sessions view tab	Registration Status Status	LS_ME_SES_REG_STAT_CD	Status of invitees for individual sessions within MedEd events.
MedEd Events > Sessions view tab > Drill down on Session Name > Contacts list	Email	LS_ME_REG_EMAIL_CD	Status of email registration for an attendee.
MedEd Events > Event Details > Materials list	Item	LS_ME_SES_MAT_CD	Materials or equipment that may be needed for MedEd sessions.
MedEd Events > Sessions view tab > Sessions list	Status	LS_ME_SES_STAT_CD	Status of individual sessions within MedEd events.
MedEd Plans > More Info view tab MedEd Plans > Plan Explorer view tab	Plan Status	LS_ME_STAT_CODE	Status of a MedEd funding plan.

If you need to create a new value in the list of values, follow the procedures on modifying a list of values in *Siebel Applications Administration Guide*.

Administering MedEd Literature

You can associate a literature item with one or more MedEd sessions when it meets two conditions:

■ The literature item is stored in the Siebel Life Sciences repository

■ The Literature Type of the item is set to Sales Tool

For information about how to associate the literature item with a MedEd session, see .

To add a literature item to the application

■ Follow the procedure for adding literature records in the *Siebel Applications Administration Guide*.

Designating MedEd Event Speakers

Both administrators and end users may designate a contact as a speaker. In order to associate a speaker with a MedEd session, you must include the speaker as a Contact in the S_CONTACT table and select the Speaker flag.

For more information on working with contacts, see Chapter 4, "Managing Contacts in Life Sciences."

To designate a contact as a MedEd speaker

1   Navigate to the Contacts screen > Contacts List view.

2   From the Show drop-down list, select All Contacts.

   NOTE: Depending on your responsibilities, you may also be able to use the My Contacts, My Team's Contacts, or the All Contacts Across Organizations filters.

3   In the Contacts list, select the Speaker field for the contact you want to designate as a speaker.

   The application lists the contact as a possible speaker for MedEd sessions.

Setting Up a MedEd Plan (End User)

A MedEd plan is a database record that lets end users specify common funding for a group of medical education events that have a common objective. A subplan allocates a specific amount of the parent plan's funding to a given user in order to help accomplish the parent plan's objectives.

End users can compare aggregated actual costs of event activities with the MedEd plan budget at any time. For information on tracking costs, see "Tracking Costs of MedEd Activities (End User)" on page 244.

To create a MedEd plan

1   Navigate to the MedEd screen > MedEd Plans view.

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

   Some fields are described in the following table.

Field	Comments
Assigned To	Person responsible for carrying out the plan.
Budget	Amount of money that the plan authorizes the responsible person to spend.
Parent Plan Name	Blank for master plans. For subplans, the application automatically provides the name of the associated parent plan.
Periods	Time period during which the plan is to be used.
Plan Name	The name of the MedEd plan for which team members can associate event costs with a given fund.

Field	Comments
Products	Products to be promoted with the funds supplied under this plan.
Status	Status of the plan. Defaults to Active.

3 In the form, enter any additional details.

The application automatically creates an unique alphanumeric value for the Plan ID.

Specify the details of the new MedEd Plan by creating subplans as described in the next procedure.

To create a subplan

1 Navigate to the MedEd screen > MedEd Plans view.

2 In the Plans list, drill down on the Name of the plan for which you want to specify a subplan.

3 In the Sub-Plans list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Assigned To	Person responsible for carrying out the subplan.
Budget	Amount of money that the subplan authorizes the responsible person to spend. If you wish to keep some funding in reserve, do not allocate the entire amount of the parent plan to the subplans.
Name	Name of the subplan.
Objective	One or more purposes to be accomplished by holding the MedEd events associated with the subplan.
Period	Time period during which the subplan is to be used. For more information on defining periods, see *Siebel Applications Administration Guide.*
Products	Products to be promoted with the funds supplied under this subplan.
Status	Status of the subplan. Defaults to Active.

The application automatically populates the subplan Plan Status and Assigned To fields.

4 Scroll down to the Events list.

In this view, the Events list is read-only.

When you create an event, you associate the event with a funding plan by assigning fractions of the event cost to specific end users. Once an event has been associated with an end user, that user designates which MedEd plan will be charged for his or her share of the total event costs. For more information, see the next topic,

Setting Up MedEd Events (End User)

A MedEd event is a database record that describes an educational event attended by physicians or medical professionals. An event may consist of single or multiple-sessions and functions as a forum for exchanging information on a particular disease, illness, therapeutic class, or product.

The cost of a MedEd event can be allocated across multiple products and across team members. Users who have purchased and installed the optional Pharma Sales Analytics product can use cost allocations as input when creating return on investment (ROI) analysis reports.

NOTE: Users who have purchased and installed the optional MedEd for Customers module can also display MedEd event information to selected professionals on their Physician Portal Web site. For more information, see *Siebel Life Sciences Portals Guide*.

To create a MedEd event

1   Navigate to the MedEd screen > MedEd Events view.

2   Create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Accreditation	The organization that will be giving Continued Medical Education (CME) credits for attending the event.
Budget	The amount of money budgeted for the event.
CME Credit	Number of CME (Continued Medical Education) credits that can be earned at the event. For MedEd for Customers, this field appears on the Physician Portal Web site.
Confirm Date	Date on which MedEd team members should send any confirmation reminder messages to registered invitees.
Confirmation	Indicates whether MedEd team members should send messages to registered invitees prior to the event reminding them to attend and asking them to reconfirm their attendance.
Created By	User name for the person who created the MedEd event.
End	Date and time that the event ends. Set the time fields before clicking a calendar day. For MedEd for Customers, this field appears on the Physician Portal Web site.
Fee Required	Indicates whether the event requires an attendance fee.
Location	City and address or venue where the event is to take place. For MedEd for Customers, this field appears on the Physician Portal Web site.
MedEd ID	The application automatically creates this alphanumeric value when you create the event.

Field	Comments
MedEd Team	A group of employees who will be responsible for planning, managing, and carrying out the MedEd event. Event costs may be allocated across team members as well as across product lines. For more information, see "To allocate event costs across team members" on page 243.
Name	The name of the event. If you are using MedEd with MedEd for Customers, this field appears to selected contacts on your Physician Portal Web site.
Objective	The overall goal for the people attending the event. For MedEd for Customers, this field appears on the Physician Portal Web site.
Products	One or more products targeted for discussion at the event.Event costs may be allocated across products. For more information, see "To allocate event costs across product lines" on page 244.
Registration Fee	The amount of any fee required for attending the event.
Start	Date and time that the event starts. Set the time fields before clicking a calendar day. For MedEd for Customers, this field appears on the Physician Portal Web site.
Status	Indicates whether the event is active, cancelled, completed, in progress, inactive, or planned. For MedEd for Customers, this field appears on the Physician Portal Web site. **NOTE:** When the status is Completed, the event and its children records—such as Invitees, Sessions, Material, Activities, and Activity Plan—are locked. If the event status needs to be changed, the administrator can make changes in Data Administration > MedEd Event Details.
Type	The category of medical education event being offered. For MedEd for Customers, this field appears on the Physician Portal Web site.

3 In the MedEd Team field, click the Select button.

All available team members appear in the Event Team dialog box.

To allocate event costs across team members

1 Navigate to the MedEd screen > MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Cost Allocation view tab.

4 For each team member, enter the percentage of the event costs that will be charged to that team member.

For example, if an event team consists of three employees, one employee might be allocated 40% of the cost and the remaining two employees might be allocated 30% of the cost.

NOTE: The total of the values you enter for Cost Allocation across team members should equal 100%.

5 Select your own record, specify a plan, and click OK.

Each MedEd Team member must log in to Siebel Life Sciences, and specify which MedEd plan will be charged for his or her portion of the event's costs.

To allocate event costs across product lines

1 Navigate to the MedEd screen> MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 In the Product field, click the Select button, and the Products dialog box appears.

4 Add one or more products that will be discussed at the event.

5 In the Cost Allocation field for each product, enter the percentage of the event costs that will be charged to each product.

NOTE: The total of the values you enter for Cost Allocation across products should equal 100%.

Tracking Costs of MedEd Activities (End User)

In order to compare MedEd costs with the amount of funds budgeted in MedEd plans, event team members must:

■ List task activities associated with MedEd events

■ Enter the costs incurred for each activity

Siebel MedEd aggregates the line item activity costs against the MedEd plans specified by team members. For increased efficiency in planning event activities, users can create a MedEd activity template for each type of MedEd event that they commonly host.

An activity template allows common recurring tasks to be associated with a given event without having to enter each task manually. Such tasks might include renting a venue, hiring a caterer, obtaining equipment, printing literature, and arranging for other materials to be available for the event. For more information on creating activity templates, see "Creating a MedEd Activity Template" on page 237.

The following procedure describes how to create an activity plan for an individual MedEd event, where the plan contains a combination of tasks derived from an activity template and tasks that are specific to the given event.

To create an activity plan for a MedEd event

1 Navigate to the MedEd screen > MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Activity Plans view tab.

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
Lock Assignment	Determine whether the Assigned To field should be locked. If the activity is locked, Assignment Manager does not access it. If it is unlocked, Assignment Manager can reassign it.
Planned Start	Refers to the date that planning and preparation for an event starts, rather than the date that the MedEd event starts. Changing the value of Planned Start in an activity plan automatically changes the value of all Due dates for activities that are a part of that plan. In contrast, changing the value of an individual activity's Due date does not affect the values of Due dates for other activities or the Planned Start date for the activity plan.
Template	Select an activity template from the drop-down list. Individual activities from the selected template appear in the Activities list. For more information on creating activity templates, see *Siebel Applications Administration Guide*.

5 If this event involves activities that are not included in the selected activity plan template, click the Activities subview tab.

6 In the Activities list, create a new record, and complete the necessary fields.

Many activity fields are not applicable to MedEd events and can be left blank.

Some fields are described in the following table.

Field	Comments
Employees	User name of the person who is to perform the activity. Leave this field blank for the activity to be assigned to the active user.

7 Repeat Step 6 until all activities have been specified.

To record the cost of an activity

1 Navigate to the MedEd screen> MedEd Events view.

2 In the MedEd Events list, drill down on the Name hyperlink for the event for which you want to record the cost.

3 Click the Activities view tab.

4 In the Activities list, select the activity for which you want to supply cost information, and then scroll to the right until the Cost field appears.

5 Enter the cost of the activity in the Cost field.

To view aggregated activity costs for a MedEd plan

1 Navigate to the MedEd screen > MedEd Events view.

2 Drill down on the Name hyperlink for the plan for which you want to view aggregated costs.

3 In the Plans form, click Actual Cost in the upper-right corner.

The Actual Cost and Remaining Budget fields are updated in the form.

About Designating MedEd Event Speakers (End User)

Both administrators and end users may designate a contact as a speaker. In order to associate a speaker with a MedEd session, users must include the speaker as a Contact in the S_CONTACT table and select the Speaker flag. For more information, see "Designating MedEd Event Speakers" on page 240.

You can review a list of all designated speakers.

To review all available speakers

1 Navigate to the MedEd screen.

2 On the link bar click All Speakers.

The Speakers list shows all contacts who have been designated as speakers. This is a read-only list.

3 In the form, click the show more button to see more details about the speakers.

Setting Up Sessions Within a MedEd Event (End User)

A MedEd event can be a single presentation, such as a lunch-and-learn where participants listen to a single speaker, or it can be composed of multiple individual sessions covering different subject areas. A session consists of a single class or meeting attended by one or more participants of a MedEd event. Because certain types of information are only associated with sessions, users must create at least one session for an event if they want to:

■ Track speaker participation

■ Associate one or more literature items with the event

■ Associate materials or equipment items with the event

■ Register participants for the event using their Physician Portal Web site and MedEd for Customers software

MedEd is designed to allow participants to register for individual sessions, whether at one-session or at multiple session events.

NOTE: MedEd event participants can use the optional MedEd for Customers module to register for MedEd sessions at your Physician Portal Web site. However, participants can only register at the session level. For reasons of configuration flexibility, event-level registration must be entered manually in the Invitee Status field of the Invitee view tab.

The following procedure describes how to create a session for a MedEd event. Repeat this procedure for each required session.

To create a session for a MedEd event

1 Navigate to the MedEd screen > MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Sessions view tab.

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

Some fields are described in the following table.

Field	Comments
CME Credit	Number of Continued Medical Education Credits (CME) that can be earned by attending the session. This field is not typically displayed on the Physician Portal Web site, but can be configured to do so as an implementation detail.
End Date	Defaults to end date and time for the event that includes the session. However, for multiple session events, each session's end date and time can differ from the end date and time of the event. Typically, the time is the most important part of this setting. For MedEd for Customers, this field appears on the Physician Portal Web site.
Location	Describes where the session will be held. Typically used to indicate a room name or number within a hotel, conference center, or other venue.
Max Attendees	Indicates the maximum number of attendees for the session.
Products	One or more products targeted for discussion during the session.
Session Name	Name of the session within a multiple-session event. For single-session events, simply repeat the event name. For MedEd for Customers, this field appears on the Physician Portal Web site.
Session Objective	Overall goal for the participants attending the session. For MedEd for Customers, this field appears on the Physician Portal Web site, but the field name is changed from Objective to Description.

Field	Comments
Speaker First Name	The application automatically supplies this value if a Speaker Last Name is selected. For MedEd for Customers, the value of this field combined with the value of the Speaker First Name and appears on the Physician Portal Web site.
Speaker Last Name	Select the last name of the person giving a presentation during the session. For more information on managing contacts, see "Creating a Contact (End User)" on page 52.
	For MedEd for Customers, the value of this field combined with the value of the Speaker First Name and appears on the Physician Portal Web site.
Start Date	Defaults to start date and time for the event that includes the session. However, for multiple-session events, each session's end date and time can differ from the end date and time of the event. Typically, the time is the most important part of this setting. For MedEd for Customers, this field appears on the Physician Portal Web site.
Status	Indicates whether the session is active, canceled, completed, in progress, or inactive. For MedEd for Customers, this field appears on the Physician Portal Web site.
	Note: When the status is Completed, the event and its children records—such as Invitees, Sessions, Material, Activities, and Activity Plan—are locked.

To provide literature to event attendees, end users can associate literature with each session of an event. The MedEd administrator can also create an item in an activity template directing an event team member to make sure that there is adequate stock of the required literature items available. For more information about adding a literature item to the database, see "Administering MedEd Literature" on page 239.

To specify literature for a MedEd session

1 Navigate to the MedEd screen> MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Sessions view tab.

4 Drill down on the Session Name hyperlink for the session for which you want to specify literature.

5 Scroll down to the Literature list, and create a new record.

In addition to literature, each session can require certain equipment and other materials, such as flip charts, markers, projectors, and screens. You may wish to create an item in an activity template directing an event team member to make sure that the required materials will be available.

To specify materials for a MedEd session

1 Navigate to the MedEd screen > MedEd Events view.

2   In the MedEd Events list, drill down on an event.

3   Click the Sessions view tab.

4   Drill down on the Session Name hyperlink for the session for which you want to specify materials.

5   Scroll down to the Materials list, create a new record, and complete the necessary fields.

   The new items appear in the Materials list.

For more information about adding a materials item to the drop-down list of available items, see "MedEd Lists of Values" on page 238. Drop-down values are normally added and maintained by an administrator.

Inviting and Registering Prospective MedEd Attendees (End User)

After an end user has scheduled a MedEd event and decided what sessions will be offered, the next step is to invite participants.

End users who have purchased and set up the optional MedEd for Customers module can also use this procedure to let each invited contact view information about an event on their Physician Portal Web site. For those users who are not using MedEd for Customers, the Invitee information indicates that the call center agents or sales representatives need to convey the invitation to the invitee.

To invite a contact or an employee to a MedEd event

1   Navigate to the MedEd screen > MedEd Events view.

2   In the MedEd Events list, drill down on an event.

3   Click the Invitees view tab.

4   In the Invitees list, create a new record.

5   In the Role field of the Invitees list, select the value that best describes each individual's role at the session.

6   In the Comments field, enter any additional information.

   As soon as you leave the current record, information about the selected session becomes available to the designated invitee at the Physician Portal Web site.

   NOTE: When the event status is Completed, the event and its children records—such as Invitees, Sessions, Material, Activities, and Activity Plan—are locked and become read-only lists.

The following procedure describes how to register a contact or employee for a MedEd session by using the dedicated client software. This procedure can be used whether or not you are using the optional MedEd for Customers module for the Physician Portal Web site.

To register an invitee for a MedEd session

1 Invite the contact or employee to the MedEd event as described in "To invite a contact or an employee to a MedEd event" on page 249.

2 In the Invitees list, select the invitee to be registered.

3 Scroll down to the Sessions list and create a new record.

4 In the Registration Status field, change the status to Confirmed.

Repeat Step 3 through Step 4 for each additional session the invitee will attend.

Generating Correspondence for MedEd Event Invitees (End User)

End users can send electronic correspondence, such as an agenda, brochures, or a list of hotels, to all event invitees.

To generate correspondence to multiple invitees

1 Navigate to the MedEd Screen > MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Invitees view tab.

4 Perform one of the following:

■ Query for the invitees to whom you wish to send correspondence.

■ From the application-level menu, select Edit > Select All to select all the people invited to the MedEd event.

5 From the application-level menu, select File > Send Letter.

The Correspondence Recipients list shows all the invitees you selected in Step 4.

6 In the Correspondence List, select a correspondence template and complete the necessary fields.

Scheduling Calls to an Invitee (End User)

End users can schedule calls to invitees. These calls appear in the Contacts screen.

To automatically schedule a call to an invitee

1 Navigate to the MedEd screen > MedEd Events view.

2 In the MedEd Events list, drill down on an event.

3 Click the Invitees view tab.

4 Query for the invitees with whom you wish to schedule a call.

5 Click the Schedule button.

6 In the Auto Schedule dialog box, review the displayed values, make any needed changes, and click OK.

The auto-scheduling function does not check for scheduling conflicts. Therefore, users need to verify that automatically scheduled calls do not conflict with other activities in their calendar.

16 Setting and Achieving Objectives

This chapter covers the following topics:

About Setting and Achieving Objectives

An *objective* is usually a sales or marketing goal, assigned to a particular individual or team, and targeted at a particular set of accounts or contacts. It includes one or more recommended activities to be performed by sales representatives as they visit the target contacts and accounts to which the objective is applied.

Ideally, objectives should be implemented at the beginning of a planning cycle.

Objectives can have child objectives associated with them. For example, an overall objective of increasing prescriptions of a particular product might have associated sub-objectives of increased calls to certain contacts or accounts and improved education on product issues.

Structuring Objectives

Managers typically define objectives for their teams, but individual users can also define personal objectives for themselves or create child objectives of larger objectives that have been defined for them. If there is general information about the objective that all team members need to know, include it in the Summary text. If there are electronic versions of documents or graphics that are related to the objective, add them as attachments.

The process of associating accounts and contacts with objectives is an excellent candidate for using target lists. After creating target lists of contacts and accounts at whom you will direct your sales efforts, you can apply those lists in the Objective Targets view.

Scenario for Objectives

This scenario is an example process performed by a pharmaceutical district manager and sales representatives to create and fulfill sales objectives. Your company may follow a different process according to its business needs.

Your company, a large pharmaceutical manufacturer, has received approval for a new indication for one of your products. The district manager is responsible for making sure that the sales representatives reporting to her take the actions necessary to have a successful launch of this product for the new indication.

The district manager begins by creating an objective. Next, she creates three recommended activities that she wants each member of her sales force to carry out in order to meet this objective: to attend a training program, to attend a team meeting to outline tactical aspects of promoting the new indication, and to conduct contact calls. In order to communicate the importance of these activities to her sales force, she assigns the priority "1-ASAP" to all three recommended activities. She also adds a product insert to the objective as a literature item. Her sales representatives can use this product insert to gain valuable information about the new indication prior to visiting contacts. Finally, she adds every targeted contact in each territory to the objective, adds each sales representative as an objective team member.

As the sales representatives check their calendars, they will see that the district manager has scheduled a series of calls for them to complete. As they prepare for each of these calls, they can review the objective and the recommended activities she has created and the product insert she added. Later, as the new indication launch is in progress and the sales representatives are performing sample drops, the district manager and sales representatives can review the objective.

Process of Objectives

This topic details sample tasks often performed by administrators and end users when working with objectives. Your company may follow a different process according to its business requirements.

Administrator Procedures

The following list shows tasks typically performed by district managers or marketing administrators. Although some companies choose to allow sales representative to create their own objectives.

1 "Creating an Objective" on page 255

2 "Creating Recommended Activities for an Objective" on page 256

3 "Targeting Accounts to an Objective" on page 258

4 "Loading Actual Amount Fields Using EIM" on page 258

End-User Procedures

The following list shows tasks end users typically perform when managing their objectives:

1 "Reviewing Objectives (End User)" on page 258

2 "Creating an Objective" on page 255

3

Creating an Objective

You must complete this task before performing the remaining tasks in this chapter. If you need an objective to recur, see .

To create an objective

1 Navigate to the Objectives screen.

2 Create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Parent Objective	If this objective is a subgoal of another objective, select the parent objective.
	The parent objective defines some of the criteria for all of its child objectives. For example, child objectives are constrained to the products associated with the parent objective, if any.
	You can create parent objectives without completing the Parent Objective field. You *must* complete the Parent Objective field when creating child objectives.
	Parent-child relationships between objectives can be viewed in the Objectives Explorer view. Note that child objectives are not constrained by the organization or team definitions of the parent objectives.
Type	The type of objective being created; for example, a promotion or a marketing type of objective. Selecting the type of objective does not drive any other functionality within the product.
Description	A few words which describe the purpose of the objective.
Start Date	The start date of an objective. It must fall within the objective's time period. This field is automatically updated if the Period field is changed.
End Date	The ending date of an objective. It must fall within the objective's time period. This field is automatically updated if the Period field is changed.
Period	The period of time during which an objective must be completed.
Actual	This data must be imported by the Siebel administrator using EIM. You cannot manually edit this field.

Field	Comments
Last Actual Update	This date must be added by the Siebel administrator using Siebel EIM, after the Actual data has been updated. You cannot manually edit this field.
Organization	The organization will constrain the target accounts that will be available to associate with the objective.
Team	Multiple people can be assigned to the objective's team.
Business Plan	If this objective is associated with a business plan for a managed-care account, enter the plan name.

Creating Recurring Objectives

At some time you may wish to create recurring objectives. You can:

■ Change the period of an existing objective

■ Copy an existing objective and apply a new period to it

■ Use a workflow to schedule monthly calls. For general information about workflows, see *Siebel Business Process Framework: Workflow Guide.*

NOTE: Deleting an objective completely removes the objective from the system. If you are unsure about whether the objective is still active (and therefore should not be deleted), you can remove yourself from the objective's team instead of deleting the record.

Creating Recommended Activities for an Objective

You can create one or more recommended activities for an objective. These recommended activities are a guide for sale representatives. Sales representatives can review this list and create similar activities for their accounts and contacts targeted for the objective.

To create recommended activities for an objective

1 Navigate to the Objectives screen.

2 In the Objectives list, drill down on the objective for which you want to create an activity.

3 Click the Activities view tab, in the Activities list, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Fields	Comments
Type	The type of activity to be performed; for example, an assessment or presentation.
Assessment Template	If the recommended activity requires an assessment to be carried out, the relevant assessment template should be added here.
Products	Each activity can have one or more products associated with it. The choice of products is restricted to products that are already associated with the objective. To add products to an objective, see "Creating an Objective" on page 255.

Targeting Accounts to an Objective

You can apply objectives to one or more target accounts. The target accounts that will be available are those that belong to the organization of which the user is an account team member.

In the Objective Targets view, add and view accounts and contacts targeted for an objective. You can display charts of progress toward a quantified goal for target accounts or target contacts. A variety of chart formats can be selected from the drop-down menu in the chart view.

NOTE: For general information on creating and applying target lists, see *Siebel Applications Administration Guide*.

To specify target accounts or contacts for an objective

1 Navigate to the Objectives screen.

2 Drill down on an objective, and click the Targets view tab.

3 Create new records in the Target Accounts and the Target Contacts lists.

You can select multiple records in the Add Accounts and Add Contacts dialog boxes.

NOTE: You can also add accounts through the Target Accounts view (click Commit) and the Account Status view. You can also add contacts through the Contacts Status view.

4 In the form, click Schedule to automatically create and schedule calls to the targeted accounts and contacts.

The account calls and contact calls are scheduled for the current date and time.

5 Navigate to the Calendar screen > Daily view and edit the start and end times for the account and contact call records.

NOTE: Data for the Actual Amount fields in the Target Accounts and Target Contacts lists must be imported by the Siebel administrator. You cannot manually edit these fields. For more information, see Chapter 17, "Importing Data into Life Sciences."

Loading Actual Amount Fields Using EIM

You must load data into the Actual Amounts fields of Target Accounts and Target Contacts using Siebel Enterprise Integration Manager (EIM). Once loaded, this data becomes read-only. Refer to *Siebel Enterprise Integration Manager Administration Guide*.

Reviewing Objectives (End User)

When end users navigate to the Objectives screen, the default filter used on the Objectives list is My Objectives. The availability of the other view, My Team's Objectives, can be limited by the user's responsibilities.

The remaining view tabs and fields visible to the end users in the Objectives screen are identical to those available to the administrator.

To review objectives

1 Navigate to the Objectives screen.

2 From the Show drop-down list, select the appropriate filter:

■ My Objectives: Objectives for which the user is assigned to the team

■ My Team's Objectives: All objectives within a manager's team, including their own

■ All Objectives: If available, the list of objectives for the default organization, such as department, business unit, or sales force

■ All Objectives Across Organization: If available, the most comprehensive list of objectives

3 Drill down on an objective.

4 Use the view tabs to review recommended activities, target accounts, and other information about the objectives.

Charting Objectives

During the campaign, managers and sales representatives can graph objective data.

To chart objectives

1 Navigate to the Objectives screen.

2 Select the objective whose status you want to review.

3 On the link bar, click Charts.

Choose from the charts available using the Charts view Show drop-down list.

17 Importing Data into Life Sciences

This chapter covers the following topics:

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In this chapter, you will learn how to import data into your Siebel Life Sciences database.

There are two general categories of data: proprietary data and syndicated data. These two types of data possess different characteristics and should generally be loaded into Siebel base tables using different processes.

NOTE: Loading data directly into Siebel base tables is not supported. Because of the complexity of table relationships and Mobile Web Client requirements, and the risk of loss of data integrity, Siebel Enterprise Integration Manager (EIM) must be used to import data into Siebel base tables. Do not attempt to modify data directly in the physical tables.

- **Proprietary data.** This is data that resides in an existing database and must be imported into the Siebel Life Sciences database during initial implementation or on an ongoing basis.

  For proprietary data, Siebel Enterprise Application Integration (EAI) is used. Siebel Enterprise Integration Manager, one method of EAI, is a subsystem in the Siebel Life Sciences software that manages the exchange of data between Siebel Life Sciences database tables and other corporate databases. It includes a number of data integrity features, such as generation of foreign-key references and case adjustment.

- **Syndicated data.** This is read-only data about sales, Rx, and profitability that is provided periodically by third-party vendors. Once delivered, this data must be loaded into the Siebel Life Sciences database and made available to users in a timely fashion. Although you can use Siebel EIM (with transaction logging turned off) to import syndicated data, direct loading with a database utility (such as SQL* Loader) is faster for importing the large volumes of syndicated data typically loaded by pharmaceutical companies.

  The Siebel Life Sciences views and business components that require data import, and the data values for those views, are shown in .

Scenario for Importing Data

This scenario is an example of the tasks performed by the database administrator, the application administrator, and the sales representatives. Your company may follow a different sequence according to its business requirements.

The database administrator (DBA) transfers company data into the Siebel Life Sciences interface data tables. The Siebel EIM transfers the data to the Siebel Life Sciences base tables.

Later, the DBA receives syndicated data from a data provider (for example, IMS Health) and transfers this data to a staging table.

The application administrator uses administrative views to map EIM_SYND_DATA fields to S_SYND_DATA, to load the data from the staging table into the application base tables.

After loading a syndicated data update, the application administrator extracts portions of the data according to territory assignment and sends a compressed version of the data extracts to mobile users in the field.

The sales representatives download the data extracts and import them into their local databases. Using the imported data in the Analysis views, they can evaluate their performance and determine where to focus their sales activities.

Process of Importing Data

This topic details sample tasks performed by database and application administrators and end users when importing data.

Administrator Procedures

The following list shows tasks administrators typically perform to import data:

1 "Importing Data with Siebel EIM" on page 262

2 "Importing, Extracting, and Routing Syndicated Data" on page 269

3 "Extracting Data for Mobile Users" on page 272

End-User Procedure

■ "Importing Syndicated Data Files (End User)" on page 284

Importing Data with Siebel EIM

Siebel EIM manages the exchange of data between Siebel database tables and other corporate databases. This topic provides information specific to Siebel Life Sciences and supersedes information in *Siebel Enterprise Integration Manager Administration Guide*. For general information on Siebel EIM, read *Siebel Enterprise Integration Manager Administration Guide*.

Stages of the Data Import Process

The data import process with Siebel EIM uses two stages, as shown in Figure 9.

1 The data is first copied from external data tapes (or other provided media) into the interface tables for the Siebel Industry Application (SIA), using a native database data-loading utility (such as SQL* Loader).

For information about the interface tables and their relationships to base tables in the Siebel application database, read "Data and Related Interface Tables" on page 264. For further details on Siebel Industry Application interface tables, such as the contents of each table, read *Siebel Enterprise Integration Manager Administration Guide*.

2 Using EIM, you transfer the data from the interface tables to predefined destination columns in the base tables of the Siebel Life Sciences database. The EIM process uses a configuration file (defaul t. i fb).

For general information about defaul t. i fb and instructions on using Siebel EIM, read *Siebel Enterprise Integration Manager Administration Guide*.
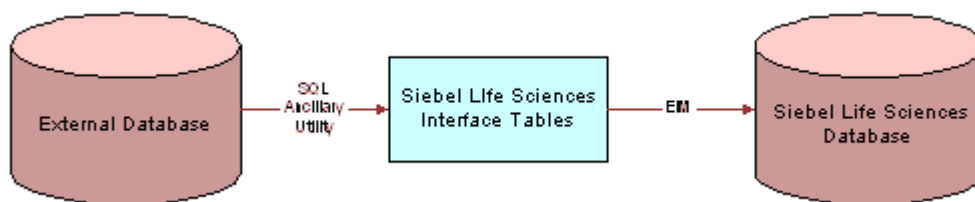
Figure 9.   Process Flow From an External Database to the SIA Database

Recommended Import Order

To correctly establish the relationships between dependent data elements, the data should be imported in the order recommended below. In general, reference data such as therapeutic classes, competitive metrics, and competitive issues should be imported first, followed by employee and product data (internal products, external products, and medical specialties), followed by contacts data. Syndicated data should be loaded last.

The following list shows the recommended import order for all data types specific to Siebel Life Sciences:

1 Reference data (therapeutic classes, competitive metrics, and so on)

2 Employees

3 Broadcast messages

4 Products (both internal and external)

5 Leads

6 Medical specialties

7 Insurance plans

8 Accounts

9 Opportunities

10 Formularies

11 Contacts

12 Contact ratings and rankings

13 Quotes

14 Documents

15 Proposal templates

16 Forecasts

17 Fulfillment data

18 Call lists

19 Objectives

20 Marketing campaigns

21 Product consumption

22 Service requests

23 Product defects

24 Activities and appointments

25 Notes

26 File attachments

27 Syndicated data

Data and Related Interface Tables

The process for importing syndicated data takes advantage of the fact that syndicated data is read-only. Because the row ID on the S_SYND_DATA table is never referred to anywhere else in the Siebel data model, it can be populated with dummy values that differ from usual row IDs. The application administrator uses SQL*Loader to populate the ID field with a unique sequential value, a process which provides either full or partial table-level extraction. Using views in the Administration - Syndicated Data screen, you can define complex routing rules for syndicated data.

Table 23 shows the relationships between the data, interface tables, and base tables.

Table 23.   Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
Accounts Contacts	EIM_TGT	S_TGT	Accounts Contacts Targeting List
	EIM_TGT_ADMIN	S_TGT_ADMN	Targeting Period
		S_TGT_ITM_ADMN	Accounts Contacts - Targeting Products
		S_GT_COL_MAP	Targeting Product Column Mappings
Account Details	EIM_ACCNT_DTL	S_ORG_EXT	Organization
		S_ORG_EXT_LSX	1:1 Extension table for Account Types
		S_ORG_EXT_X	1:1 Account Best Times to Visit
Activities	EIM_ACTIVITY	S_EVT_ACT	Activities
	EIM_ACTIVITY1	S_EVT_ACT	Activities Only User Key
		S_ACT_SIGN	Signatures
	EIM_ACTIVITY2	S_EVT_ACT	Activities Only User Key
		S_ACT_PRDINT	Activity Products
		S_ACT_ISS	Activity Issues
		S_ACT_PROD_ISS	Issues for Activity Products
Addresses	EIM_ADDR_ORG	S_ADDR_ORG	Account Addresses including Bricks
Agreements and Contracts	EIM_AGREEMENT	S_DOC_AGREE	Agreements and Contracts
	EIM_AGREE_LS	S_DOC_AGREE	Contracts
		S_AGREE_PAY	Contract Payments
	EIM__ENTLMNT	S_ENTLMNT	Entitlements and Contract Price Group
		S_ENTLMNT_ITEM	Price Group Products
		S_ENTLMNT_FEE	Nonproduct Fees
		S_ENTLMNT_ITEM_FEE	Product Fee Price Group
Brick	EIM_AREA_LS	S_AREA_LS	Bricks

Table 23.   Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
Chat and Discussions	EIM_DISCN_LS	S_TOPIC_LS	Chat/Discussion Topics
		S_TOPIC_CON_LS	Chat User Registration
		S_MESG_BRD_LS	Message Board
Clinical	EIM_CL_ACT_LS	S_EVT_ACT	Clinical Activity Columns
	EIM_CL_DSGN_LS	S_CL_DSGN_LS	Clinical Designs
	EIM_CL_PGM_LS	S_CL_PGM_LS	Clinical Programs
		S_CL_PGM_ATT_LS	Clinical Program Attachments
		S_CL_PGM_APP_LS	Clinical Program Applications
	EIM_CL_PTCL_LS	S_CL_PTCL_LS	Clinical Protocols
		S_CL_PTCL_LSXM	1:M Protocol Extension Table
		S_CL_PTL_ATT_LS	Clinical Protocol Attachments
		S_CL_PTL_POS_LS	Clinical Protocol Positions
		S_CPTCL_DSGN_LS	Clinical Protocol Designs
	EIM_CL_SUBJ_LS	S_CL_SUBJ_LS	Clinical Subjects
		S_CL_SUBJ_ST_LS	Clinical Subject Status
		S_CL_SJ_CSNT_LS	Clinical Subject Consent
		S_CL_SBJ_ATT_LS	Clinical Subject Attachments
	EIM_PTL_SITE_LS	S_PTCL_SITE_LS	Clinical Protocol Sites
		S_PTL_ST_POS_LS	Clinical Protocol Site Positions
		S_PTL_ST_ATT_LS	Clinical Protocol Site Attachments
		S_PTL_ST_CON_LS	Clinical Protocol Site Contacts
		S_PS_STMPVER_LS	Clinical Protocol Site Template Versions
		S_CL_ACT_EXC_LS	Clinical Protocol Site Activity Exceptions
		S_CL_PYMNT_LS	Clinical Payments
	EIM_SBJ_TMPL_LS	S_SUBJ_TMPL_LS	Subject Templates
		S_SBJTMP_VER_LS	Subject Template Versions
	EIM_TMPL_PLNITM	S_TMPL_PLAN_ITEM	Subject Template Visits

Table 23.   Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
Companies	EIM_ACCOUNT	S_ORG_EXT	Organization
		S_ACCNT_POSTN	Position for Account
		S_ADDR_ORG	Account Addresses
		S_ORG_REL	Account Affiliations
	EIM_ACCOUNT1	S_ORG_EXT	Organization Only User Key
		S_ACCNT_CLS_RNK	Account Ratings and Rankings
		S_ACCNT_MED_PROC	Account Medical Procedures
		S_ACCNT_MED_SPEC	Account Medical Specialties
Contacts	EIM_CONTACT	S_CONTACT	Contacts
		S_ADDR_PER	Contact Addresses
		S_CONTACT_REL	Contact Affiliations
		S_PER_ORG_UNIT	Contact to Account Affiliations and Roles
		S_STATE_LIC_LS	Contact State Licenses
	EIM_CONTACT1	S_CONTACT	Contacts Only User Key
		S_POSTN_CON	Contact Positions
		S_CON_ADDR	Contact Address Usage
	EIM_CON_DTL	S_CONTACT	Contacts Only User Key
		S_CONTACT_LSX	1:1 Contacts Extension Table
		S_CONTACT_LSXM	1:M Contacts Extension Table
		S_ACCNT_CON_ATT	Accounts Contacts File Attachments
		S_NOTE_ACCT_CON	Accounts Contacts Notes
Formularies	EIM_FRMULRY_LS	S_FORMULARY	Formulary Opportunities
		S_FRMULRY_PROD	Formulary Products
Industry	EIM_INDUSTRY	S_INDUST	Account and Contact Types
Insurance Plans	EIM_INS_PLAN_LS	S_INS_PLAN	Insurance Plans

Table 23.   Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
Medical Education	EIM_ME_EVT_LS	S_ME_EVT_LS	MedEd Events
		S_ME_EVT_POS_LS	MedEd Event Positions
		S_ME_EVT_PRD_LS	MedEd Event Products
		S_ME_EVT_INV_LS	MedEd Event Invitees
	EIM_ME_PLN_LS	S_ME_PLN_LS	MedEd Plans
		S_ME_PLN_MDF_LS	MedEd Plan Funds
		S_ME_PLN_PRD_LS	MedEd Plan Products
	EIM_ME_SES_LS	S_ME_SES_LS	MedEd Sessions
		S_ME_SES_PRD_LS	MedEd Session Products
		S_ME_SES_INV_LS	MedEd Session Invitees
		S_ME_SES_LIT_LS	MedEd Session Literature
		S_ME_SES_MAT_LS	MedEd Session Materials
Medical Procedures	EIM_PROC_LS	S_MED_PROC	Medical Procedures
Medical Specialties	EIM_SPEC_LS	S_MED_SPEC	Medical Specialties
Objectives	EIM_ACCT_SRC	S_ACCNT_SRC	Target Accounts for Objectives
	EIM_CONTACT2	S_CONTACT	Contacts Only User Key
		S_CAMP_CON	Target Contacts for Objective
	EIM_SRC	S_SRC	Objectives
		S_SRC_POSTN	Objective Positions
Products	EIM_PROD_INT	S_PROD_INT	Products-Details, Samples, Markets, Lots, and Promotional Items
	EIM_PROD_INT1	S_PROD_INT	Products
		S_PROD_POSTN	Personal Product List
		S_PROD_REL	Product Relations

Table 23.   Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
Samples	EIM_SAMPLE_LS	S_SAMPLE_TXN	Sample Transactions
		S_MPL_TXN_ITEM	Sample Transaction Item
	EIM_POSITION	S_POSTN	Positions
		S_STOCK_POSTN	Stock Inventory by Position
		S_STOCK_PERIOD	Stock Period
Signature Disclaimers	EIM_SIGNDIC_LS	S_SIGN_DISC_LS	Signature Disclaimers
Syndicated Data	EIM_SYN_DATA_LS	S_SYND_DATA	Syndicated Data

For further information, see *Siebel Enterprise Integration Manager Administration Guide*, which lists the contents of each table referred to in Table 23 on page 265:

■ Specific data and file attachments that Siebel EIM can process.

■ Names of the interface tables.

■ Target base tables mapped to the interface tables.

■ Any secondary tables associated with the target tables (where data from the interface tables might ultimately reside).

Importing, Extracting, and Routing Syndicated Data

The process described here for importing syndicated data takes advantage of the fact that syndicated data is read-only. Because the row ID on the S_SYND_DATA table is never referred to anywhere else in the Siebel data model, it can be populated with dummy values that differ from usual row IDs. The application administrator uses SQL*Loader to populate the ID field with a unique sequential value, a process that allows either full or partial table-level extraction. Using views in the Administration - Syndicated Data screen, you can define complex routing rules for syndicated data.

NOTE: Routing rules are used by Siebel Remote and Replication Manager to determine what data and transactions are routed to mobile client databases and regional databases. For more information on routing rules, see *Siebel Remote and Replication Manager Administration Guide*.

The views that require syndicated data import are shown in Table 26 on page 279.

The general steps for loading syndicated data and distributing it to mobile users are:

1 Load the data into the base tables of the Siebel Life Sciences database.

 If you choose to use EIM to load the data, turn off transaction logging.

2 Extract the data required by mobile users.

3 Transfer the extracted data files to mobile users.

Loading Data into the Siebel Life Sciences Database

Before you can view syndicated data in Siebel Applications, you must first populate the foreign keys fields in the S_SYND_DATA table. These keys are populated from the sales representative (POSITION_ID), territory (TERR_ID), product group (MARKET_ID), product (PROD_ID), contact (CON_ID), area (AREA_ID), and period (PERIOD_ID) fields. Each of these is a key to a record in another Siebel application table. Therefore, these fields need to be populated with valid row IDs for the corresponding position, territory, product group, product, and period business components.

To load syndicated data, the application must have the row IDs for the foreign key data that is stored in the S_SYND_DATA table. The data files used to load syndicated data are supplied in a format in which any key information is supplied as a textual description. This means that unless EIM is used to load the data, the textual descriptions need to be converted into their Siebel application table row ID equivalents.

Different data types need to be supplied to make a record visible in S_SYND_DATA. The only compulsory foreign key field is the PERIOD_ID. However, there is a unique index on the table that comprises all of the foreign key fields: S_SYND_DATA_U1. Table 24 lists all of the foreign key fields, their foreign key table, and a description of what the field contains for Siebel Life Sciences.

Table 24.   Foreign Key Fields in Syndicated Data Loading

Field	Table	Description
AREA_ID	S_AREA_LS	Brick/Mini Brick Id
CON_ID	S_CONTACT	Contact for this sales data
MARKET_ID	S_PROD_INT	Product Group
OU_EXT_ID	S_ORG_EXT	Account
PERIOD_ID	S_PERIOD	Period
PLAN_ID	S_INS_PLAN	Plan
POSITION_ID	S_POSTN	Person who owns the data (for example, a sales representative)
PRDINT_ID	S_PROD_INT	Product
TERR_ID	S_ASSN_GRP	Territory

Use a native data loader (recommended method) such as SQL*Loader in Oracle or BCP in SQL Server. For the purposes of example, Oracle is used as the target database, although the technique applies equally to SQL Server. Alternatively, you can use Visual Basic and Com.

Using SQL*Loader to Load the Data

Data records in Siebel applications do not refer to the row ID field in the S_SYND_DATA table. You can insert any value in this field if it is unique in the record. Therefore, you can use a native database utility to populate this table. This method discusses the use of the Oracle SQL*Loader utility. As with the Visual Basic and COM method, using SQL*Loader requires that you resolve the foreign key references either before or after the data has been loaded into the table.

To use SQL*Loader to load the data

1 Resolve the foreign keys before loading.

Process the input file one line at a time and convert each foreign key value into a row ID. To save time, first load the data directly into the table as it is stored in the flat file, then update the foreign key fields using SQL statements.

2 Load the data file using a .ctl format file.

The following is an example of loading a data file:

```
options (rows=100)
load data
infile 'c:\myfile.txt'
badfile 'c:\myfile.bad'
append
into table S_SYND_DATA
fields terminated by ","
trailing nullcols
(ROW_ID SEQUENCE (MAX,1),
CREATED SYSDATE, CREATED_BY CONSTANT "1-0",
LAST_UPD SYSDATE, LAST_UPD_BY CONSTANT "1-0",
MODIFICATION_NUM CONSTANT 0,
CONFLICT_ID CONSTANT "0",
POSITION_ID, TERR_ID,
PERIOD_ID, DATA_SRC_CD CONSTANT "RXTer",
MARKET_ID, PRDINT_ID, ATTRIB_01)
```

3 Run the SQL*Loader utility from the command line using the following syntax:

```
SQLLDR73.EXE database/userid@pw control=c:\my.ctl log=c:\my.log
```

NOTE: The exact file name and syntax of the Loader utility is determined by the version of Oracle being used.

4 When the data has been loaded, resolve the foreign key references for each field. This step makes the data visible to the users, as in the following example.

```
UPDATE s_synd_data
FROM s_period p
SET s_synd_data.period_id=p.id
WHERE p.name=s_synd_data.period_id ;
```

This code updates the Period field in the Syndicated Data Table to the ID of the Period rather than to the textual description of the period. You must modify and run this code for each foreign key field referred to in . The code only needs to be run for each field that you load, not for all of the fields.

Alternative Method: Using Visual Basic and COM to Load the Data

Use Visual Basic and the Siebel COM interface to retrieve the Siebel table row ID information by searching for the field that contains the text and return the ID field.

About Summary Records

Sales forces are frequently hierarchically organized, with a sales representative being the lowest level of the hierarchy, rising through various managerial levels. It is possible that someone at the top of the hierarchy needs to see all of the syndicated data in the system. This may be practical if the particular user is connected to the database. However, if the managerial levels are remote users, they will have visibility on a very large number of records; their synchronization times will be extremely long.

A solution to this problem is to store summary records in the S_SYND_DATA table. Summary records are totals of the sales data for territory, region, division, and other groupings, stored with a type flag in an extension column that indicates the level of summarization is being stored. The summary records can be created by SQL scripts or with a database package such as Microsoft Access. They can be loaded using the two methods described in the previous topics.

In addition to loading summary records, you also must configure the table using Siebel Tools, to make sure that a manager-level user sees only summary records, rather than detail records, on the sales data views. Using this technique, you can also implement drill-down functionality for connected managers so that they can start at top level data and work down.

Extracting Data for Mobile Users

Once the data is in the database, it needs to be made visible to the users. The data is visible by position and can be viewed on many chart and analysis views in Siebel Life Sciences. This is fine for connected users, but the typical user of such data will be the sales rep or sales manager of a particular territory, who are likely to be remote users, synchronizing with the database using Siebel Remote. Therefore, the data needs to be extracted from the database.

The application administrator extracts syndicated data according to data-routing (visibility) rules that the administrator defines. When you do this, a full export-process audit trail is generated through log files.

NOTE: Insurance plan data (S_INS_PLAN table) might not be extracted for a specific mobile if syndicated data (S_SYND_DATA table) is loaded to the server at the same time a database extract component is running for the mobile client. In addition, if there is no account associated to the insurance plan data, then insurance data for a specific mobile can not be extracted. The data extraction rule, (dock object MedicalInsPlan, rule # 3) controls how insurance plan data is routed. If an account is associated to an insurance plan record and mobile has visibility over that account, the insurance plan data is successfully extracted.

You can run multiple instances of the extraction process on each Siebel Server to maximize hardware capacity. The resulting output files are written in a compressed form and then zipped again to minimize file transfer time.

The general steps for data extraction are:

1 Create a data extraction rule.

2 Associate the necessary nodes of mobile users with the rule.

3 Define the portion of the data you want to extract and specify whether any deletions should be performed on the extracted data.

4 Set the environment by running the siebenv.bat file at the command prompt under the Siebel Server bin directory.

5 Run the Syndexp.exe executable file to perform the extraction.

These general steps are detailed in the following procedures.

To create a data extraction rule

1 Navigate to the Administration- Syndicated Data screen > Export Rules view.

2 Click to select the Rules list and create a new record.

3 Complete the fields described in the following table.

Field	Comments
Name	A descriptive name for the rule.
Outfile Id	Enter a unique, three-character ID. This ID will be used as the name of a temporary data file created by the extraction process.
Active	If the rule is not active, it will not be processed by the extraction process.

You can create multiple rules for different types of extractions. For example, you could create one rule for Rx data and another rule for Outlet Level data. You can also extract data by multiple criteria (for example, sales force or position).

The WHERE part of a SQL SELECT statement specifies the rows of the S_SYND_DATA table that should be exported. In most cases, this WHERE clause is

    WHERE T.POSITION_ID = [Position Id]

When you specify the users to extract, it will match their position ID to the position ID on the syndicated data table and extract only the data that is visible to them.

To associate nodes with an extract rule

1 In the Syndicated Data Export Rules view, select the correct extract rule.

If a different view is currently displayed, navigate to Data Administration > Export Rules and select the appropriate rule.

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

Some fields are described in the following table.

Field	Comments
Name	You can select multiple nodes in the Add Nodes dialog box.
Group Code	A code used for the grouping of nodes within the same extraction rule. You can specify the Group Cd value as an argument for the extraction process that is run with the Syndexp.exe executable file. With this group code, multiple Syndexp.exe processes can be run for the same extraction rule on the same Siebel Server.
Node Type Code	An attribute column for the nodes, used to identify the remote nodes. (The Syndexp.exe process services only remote nodes.)
Active	Only nodes specified as active will be processed.

To specify the data that is routed to mobile users

1 In the Syndicated Data Export Rules view, select the correct extract rule.

If a different view is currently displayed, navigate to Data Administration > Export Rules and select the appropriate rule.

2 Click in the Tables list and create a new record.

3 Complete the fields. The fields are described in the following table.

Field	Comments
Table Name	Generally, this value should be S_SYND_DATA. The exception to this general rule is if you have created an extension table or if you are using another table to store syndicated data.

Where String	Enter a string that defines the data to be extracted. Generally, these strings use standard SQL WHERE statements to build the extraction scripts. In addition to using static column values and column names to specify the data to be extracted, you can use two case-sensitive variables, [Position Id] and [Employee Id].
	
	An example WHERE string definition that uses the Position Id variable is provided below. This example extracts data where the position ID in the syndicated data is equal to the position ID of the user.
	
	Example:
	
	    `WHERE T.POSITION_ID = [Position Id]`
	
	A second example, provided below, extracts data for all positions assigned to an employee. Note that <TableOwner> in the example should be replaced with the appropriate Siebel database TableOwner value.
	
	Example:
	
	    `WHERE EXISTS (SELECT 1 FROM <TableOwner>.S_PARTY_PER R WHERE`
	    `R.PARTY_ID = T.POSITION_ID  AND R.PERSON_ID = [Employee Id])`

Sequence	Enter a numeric value that defines the order in which tables will be extracted.
Active	Only tables specified as active will be processed.

4 In the Administration - Syndicated Data screen, from the Show drop-down list, select SQL Statements.

5 Click in the Pre SQL Statements list and create a new record.

6 Complete the fields described in the following table.

Field	Comments
SQL Text	This SQL statement cleans up the data in the remote database in preparation for importing newer data, by deleting the existing data that will be replaced by newer data. If the entire syndicated data table is to be extracted, use the DELETE FROM table function. If only a subset of the data is to be extracted (for example, the latest month's data), use a where clause to specify the data subset. **NOTE:** Each SQL statement must be prefixed with the table owner SIEBEL. If you do not include the table owner, the syndicated data import process fails.
Comments	Optional description of statement's purpose; for example, describe the portion of the data you want to extract.
Sequence	Enter a numeric value that defines the order in which SQL statements will be executed.
Active	Only statements specified as active will be processed.

You can refresh the entire syndicated data table, or you can refresh only certain specified data periods.

NOTE: Do not use the TRUNCATE function. Use the DELETE FROM function instead.

To set the environment

1 In a DOS window, navigate to the *siebel_server*\BIN directory.

2 Run the siebenv.bat file.

CAUTION: If you do not run siebenv.bat, you may encounter the following error message: "Unable to start common api. Error in DATAExpStartApis function."

3 Set the environment variables.

NOTE: Syndexp.exe will not detect nodes in a clustered environment successfully unless you manually set CLUSTER_NETWORK_NAME in either siebenv.bat or syndexp.bat.

Refer to the command line arguments listed in Table 25 for multiple variables that are specific to the user environment. For more information on administering data extracts, see *Siebel Remote and Replication Manager Administration Guide*.

NOTE: Arguments that contain path names or spaces should be enclosed in double quotes ("").

Table 25. Command Line Arguments for Environment Variables

	Argument and Meaning	Comments
/A	Create Attachment	Default: Y
/C	ODBC Data Source	Default Environment Variable: SIEBEL_DATA_SOURCE
/D	Siebel Table Owner	Required
/E	Extract Rule Name	Required
/F	File Server Directory	Default Environment Variable: SIEBEL_FSRV_ROOT. This File System parameter can use the absolute path to the \att directory or the Universal Naming Convention (UNC). Examples: ■ syndexp /f "d:\Siebel\FS\att" ■ syndexp /f \\MACHINENAME\FS\att
/G	Group Code	Required
/L	Log File	Default: syndexp.log
/N	Repository Name	Default Environment Variable: SIEBEL_REPOSITORY
/P	Password	Required
/Q	Log Frequency	Default: -1
/R	Read Consistency	Default: N
/S	Use Sequence Number	Default: N
/T	Data File Type	Default: compressed
/U	Username	Required
/V	AppServer name	Required. This is the logical name of the Siebel Server (not the host name).
/X	Appserver Home Directory	Default Environment Variable: SIEBEL_HOME

To perform the data extraction

1 In the *siebel_server*\BIN directory, run the Syndexp.exe executable file.

Use the command line arguments listed in Table 25 on page 277 to define multiple variables that are specific to the user environment. For example:

```
syndexp /U sadmin /P sadmin /D phdemo /E "Rule One" /C siebsrvr_siebel
```

NOTE: Interruption of the extraction process at any point causes the system to fail and necessitates restarting the data extraction from the beginning.

2 If an interruption occurs, you must go into the Pharma Node Attachment Administration view (navigate to the Syndicated Data Files view) and delete the previously generated data files. You also must go into each node and delete the latest file that was created in the previous run.

After the program executes the Syndicated Data Loading (SDL) process, it displays the name of the user whose data is being extracted. This process continues until it has completed the extraction process for each user defined in the Syndicated Data Export Rules.

3 After you successfully complete the extraction process, you may want to create a batch file for use with subsequent extractions.

The extracted files are output in a compressed form to minimize file transfer time. Files are transferred using Siebel Remote, which is described in *Siebel Remote and Replication Manager Administration Guide*. After mobile users receive their extracted files, they must import the data into their local databases.

Full and Partial Data Extracts

Because syndicated data loading does not use EIM to maintain synchronization between the server and the remote databases, you must force a resynchronization step at the end of each direct load. Force resynchronization either by re-extracting an entirely new remote database for each mobile user or by performing a partial extract that includes only the refreshed syndicated data. A new, full database extract creates a database snapshot file for a given mobile user. A partial extract contains only S_SYND_DATA table data.

Some users receive syndicated data updates once a week, while some may receive syndicated data updates monthly or quarterly. Therefore, partial extract is preferred.

Possible Data Loss

Sometimes remote users connect to Siebel Server using unstable dial-up connections that prevent the data file from being transferred correctly, so that the data file does not reach the remote server. Siebel Server does not verify that the data file reached its destination successfully. At the end of the transfer step, Siebel Server removes the data file from the server.

In the case in which a data file is lost and removed from the server, you must extract a new data file for users.

CAUTION: The loss of data or files may occur without warning. You might not be able to automatically determine the success or failure of a particular transfer. As a result, sales representatives may be using incorrect data for up to several months without realizing it.

Troubleshooting Syndicated Data Loading

If the Siebel application client session freezes or terminates during a syndicated data file import, do the following procedure.

To fix a session freeze or termination

1 In a DOS window, navigate to the *siebel_server*\FS folder.

2 Copy S_NODE_ATTxxx.SAF (containing S_NODE_ATTxxxx.dat) to CLIENT\LOCAL\FILES.

3 Navigate to the CLIENT\LOCAL\FILES folder.

4 Delete S_NODE_ATTxxxx.dat.

5 Restart the Life Sciences client.

6 Click Import.

Views Requiring Syndicated Data Import

This topic lists the Siebel Life Sciences views and business components that require data import and indicates which data values must be loaded into the syndicated data table.

Table 26 lists the views that require data import.

Table 26.   Views and Business Components Requiring Data Import

Screen	View	Business Component
Accounts	Charts > Sales	Pharma Sales Consumption
	Charts > Profitability	Pharma Consumption

Table 26.   Views and Business Components Requiring Data Import

Screen	View	Business Component
Analysis	Direct Sales Trend by Territory - Volume	Pharma GA Sales Consumption
	Direct Sales Trend by Account - Volume	Pharma GA Sales Consumption
	Indirect Sales Trend by Territory - Volume	Pharma GA Sales Consumption
	Indirect Sales Trend by Territory - Share	Pharma GA Sales Consumption
	Indirect Sales Trend by Zip - Volume	Pharma GA Sales Consumption
	Indirect Sales Trend by Zip - Share	Pharma GA Sales Consumption
	Indirect Sales Trend by Brick - Volume	Pharma GA Sales Consumption
	Indirect Sales Trend by Brick - Share	Pharma GA Sales Consumption
	Indirect Sales Trend by Account - Volume	Pharma GA Sales Consumption
	Indirect Sales Trend by Account - Share	Pharma GA Sales Consumption
	Rx Trend by Territory - Volume	Pharma GA Rx Consumption
	Rx Trend by Territory - Share	Pharma GA Rx Consumption
	Rx Trend by Prescriber - Volume	Pharma GA Rx Consumption
	Rx Trend by Prescriber - Share	Pharma GA Rx Consumption
	Rx Trend by Plan and Territory - Volume	Pharma GA Rx Consumption
	Rx Trend by Plan and Territory - Share	Pharma GA Rx Consumption
	Rx Trend by Plan and Prescriber - Volume	Pharma GA Rx Consumption
	Rx Trend by Plan and Prescriber - Share	Pharma GA Rx Consumption
	Rx Trend by Payment Type and Prescriber	Pharma GA Rx Consumption
	Rx Trend by Payment Type and Territory	Pharma GA Rx Consumption
	Rx Trend by Brick	Pharma GA Rx Consumption
	Indirect Sales by Brick-Share	Pharma GA Markets
	Indirect Sales by Brick-Volume	Pharma GA Sales Consumption
Contacts	Rx Trend > Rx Trend by Product	Pharma GA Rx Consumption
		Pharma Consumption
	PreCall > Rx Trend	Contact BC
	PreCall > Rx Trend and Formulary	Pharma GA Rx Consumption
	PreCall > Rx Trend by Plan	

Table 26.   Views and Business Components Requiring Data Import

Screen	View	Business Component
Objectives	My Objectives My Team's Objectives	Pharma Campaign The Actual and Last Actual Update fields are the only fields in the business component that require data import.
	Targets (The Actual Amount fields in the Target Accounts and Target Contacts lists)	Pharma Campaign Target Account Pharma Campaign Target Contact The Actual Amount field is the only field in each business component that requires data import.

Data Loading Matrix for Syndicated Data

The Data Loading Matrix, shown in Table 27, and the Attribute by Data Source Matrix, shown in Table 28 on page 283, are provided to facilitate loading sales, Rx, profitability, and influence data. Table 27 indicates, by view, the combination of data source, mandatory ID, and plan type values a record must have to be displayed in the view. The following list explains the table headings:

■ **View.** Name of the Analysis, Contacts, Accounts, or Products view.

■ **Data Source.** Value that determines which view will display the data stored in the record. The valid values are SlsDirAct, SlsDirBrk, SlsDirTer, SlsDirZip, SlsIndAct, SlsIndBrk, SlsIndTer, SlsIndZip, RSPT, RXBrk, RXEVM, RXSMI, RSXMM, RXPrf, RXTer, RXXPT, RXZip, Anlsys ROI, and Anlsys EvsR.

■ **Mandatory Id.** Value that indicates the ID field that must be non-NULL for a database record to be displayed in the corresponding view. There are four key ID fields: Account Id, Contact Id, Territory Id, and Zip Id. For each view listed in the table, one of these ID fields is required and the other three must be NULL.

■ **Plan Type.** Value that indicates the type of plan ID a database record must have to be displayed in the view.

Table 27.   Data Loading Matrix

View	Data Source	Mandatory ID	Plan Type
Accounts > Charts > Sales	SlsIndAct	Account Id	Total
Accounts > Charts > Profitability	Anlsys ROI	Account Id	Total
Analysis > Direct Sales Trend > by Territory - Volume	SlsDirTer	Territory Id	Total
Analysis > Direct Sales Trend > by Account - Volume	SlsDirAct	Account Id	Total
Analysis > Indirect Sales Trend > by Territory - Volume	SlsIndTer	Territory Id	Total

Table 27.   Data Loading Matrix

View	Data Source	Mandatory ID	Plan Type
Analysis > Indirect Sales Trend > by Territory - Share	SlsIndTer	Territory Id	Total
Analysis > Indirect Sales Trend > by Zip - Volume	SlsIndZip	Zip Id	Total
Analysis > Indirect Sales Trend > by Zip - Share	SlsIndZip	Zip Id	Total
Analysis > Indirect Sales Trend > by Brick - Volume	S1sIndBrk	Area Id	Total
Analysis > Indirect Sales Trend > by Brick - Share	S1sIndBrk	Area Id	Total
Analysis > Indirect Sales Trend > by Account - Volume	SlsIndAct	Account Id	Total
Analysis > Indirect Sales Trend > by Account - Share	SlsIndAct	Account Id	Total
Analysis > Rx Trend > by Territory - Volume	RXTer	Territory Id	Total
Analysis > Rx Trend > by Territory - Share	RXTer	Territory Id	Total
Analysis > Rx Trend > by Prescriber - Volume	RXPrf	Contact Id	Total
Analysis > Rx Trend > by Prescriber - Share	RXPrf	Contact Id	Total
Analysis > Rx Trend > by Plan and Territory - Volume	RXTer	Territory Id	Plan
Analysis > Rx Trend > by Plan and Territory - Share	RXTer	Territory Id	Plan
Analysis > Rx Trend > by Plan and Prescriber - Volume	RXPrf	Contact Id	Plan
Analysis > Rx Trend > by Plan and Prescriber - Share	RXPrf	Contact Id	Plan
Analysis > Rx Trend > by Payment Type and Prescriber	RXPrf	Contact Id	Payer
Analysis > Rx Trend > by Payment Type and Territory	RXTer	Territory Id	Payer
Contacts > Rx Trend > Rx Trend by Product*	RXPrf	Contact Id	Total
Contacts > Profitability	Anlsys ROI	Contact Id	Total
Contacts > Sample Influence	Anlsys EvsR	Contact Id	Total
Products > Product Profitability > Sample ROI*	Anlsys ROI	Territory Id	Total
Products > Sample Influence	Anlsys EvsR	Territory Id	Total
* Fourth level menu			

Table 28 indicates, by data source, the data values that should be loaded into the syndicated data table (S_SYND_DATA) attribute fields.

Table 28.   S_SYND_DATA Attribute by Data Source

Data Source	Attribute 1	Attribute 2	Attribute 3	Attribute 4	Attribute 5
Anlsys EvsR	TRx	Number of Calls	Number of Samples	Number of Details	
Anlsys ROI	Revenue	Samples Cost	Promotion Cost	Call Expenses	Other Expenses
RSPT	Product NRx	Product TRx	Market NRx	Market TRx	None
RXBrk	Product NRx	Product TRx	Market NRx	Market TRx	None
RXEVM	Product NRx	Product TRx	Market NRx	Market TRx	None
RXPrf	Product NRx	Product TRx	Market NRx	Market TRx	None
RXSMI	Product NRx	Product TRx	Market NRx	Market TRx	None
RXSMM	Product NRx	Product TRx	Market NRx	Market TRx	None
RXTer	Product NRx	Product TRx	Market NRx	Market TRx	None
RXXPT	Product NRx	Product TRx	Market NRx	Market TRx	None
RXZip	Product NRx	Product TRx	Market NRx	Market TRx	None
SlsDirAct	Product Sales $	Product Sales Units	None	None	None
SlsDirBrk	Product Sales $	Product Sales Units	None	None	None
SlsDirTer	Product Sales $	Product Sales Units	None	None	None
SlsDirZip	Product Sales $	Product Sales Units	None	None	None
SlsIndAct	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	None
SlsIndBrk	Product Sales $	Product Sales Units	Market Sales	Market Sales Units	None
SlsIndTer	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	None
SlsIndZip	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	None

Importing Syndicated Data Files (End User)

Extracted files are transferred using Siebel Remote (as described in *Siebel Remote and Replication Manager Administration Guide*). After mobile users receive their extracted files, they must import the data into their local databases.

The process is described in the following procedure.

To import syndicated data files

1 Using Siebel Remote, synchronize your local database with extracted data files that have been routed to you. Extracted data files are received as attachment files.

2 Click the Import button and the extracted data files are downloaded to the \LOCAL\FILES folder of your hard drive.

3 After importing the extracted data files into your local database, delete the downloaded files from the \LOCAL\FILES folder.

NOTE: Users may postpone downloading of extracted data files by turning off the Retrieved Published Files option in their synchronization setup. Whether or not the extracted data files are downloaded, header information is transferred to the mobile client during the synchronization session. This information appears in the Syndicated Data Files view.

For further information, see *Siebel Remote and Replication Manager Administration Guide*.

18 Setting Up and Carrying Out a Clinical Trial

This chapter covers the following topics:

About Setting Up and Carrying Out a Clinical Trial

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

- 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 enrollment rates
- Review payments made to the protocol

Figure 10 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 10. Siebel Clinical Hierarchical Relationships

Scenario for Clinical Trials

This scenario is an example process performed by the director of clinical trials, clinical study manager, and the clinical research associates (CRAs). Your company may follow a different process according to its business requirements.

In this scenario, the clinical director and the study manager, working for a clinical research organization, or pharmaceutical, biotech, or medical device company, have administrator responsibilities in Siebel Clinical to:

■ Set up a new treatment study program.

■ 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 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 visit schedules for subjects, may also be performed by the site personnel using Site Portal Web site. 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 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 may follow a different process according to its business requirements.

In the following examples, tasks are carried out 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. These tasks are typically performed in the following order:

1 "Creating a Clinical Program" on page 288.

2 "Setting Up a Protocol" on page 289.

3 "Tracking and Revising Team Assignment History" on page 291

4 "Creating and Revising Protocol Versions" on page 292.

5 (Optional) "Setting Up Regions" on page 293.

6 "Defining a Subject Visit Template" on page 295.

End-User Procedures

The following list shows tasks end users typically perform when managing a clinical trial. The procedures are performed by the CRA at the site level and are typically performed in the following order:

1 (Optional) "Creating an Account and Contacts (End User)" on page 298.

Creating a Clinical Program

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.

To create a new clinical program

1 Navigate to the Clinical Programs screen > Program List view.

2 In the Clinical Programs 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 Chapter 6, "Managing Products for Life Sciences."

Some fields are described in the following table.

Field	Comments
Application	A multi-value field containing details of the application.
	Filed. Whether the application has been filed with the specified regulatory agency.
	Indication. The clinical indication for the application.
	Number. The number assigned to the application when submitted to the regulatory agency, for example the (A)NDA or IND number.
	Product. This field must be completed before a protocol can be created for the program.
	Sub-Type. Who filed the application. For example, a company or an investigator.
	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 new record and associate files with the clinical program.

Setting Up a Protocol

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

To create a protocol record

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

2 In the Protocols list, create a new record, and complete the necessary fields. (To access more fields, drill down on the name field of the protocol and select the More Info tab view.)

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.
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.
Design	Information about the type of study.
Phase	Phase of clinical trial such as Phase II, or III.
Product	Only products that have been associated with the clinical program, through the Application field in the Clinical Programs view, can be selected from the Clinical Product and Indication dialog box. For more information about creating a clinical program, see "To create a new clinical program" on page 288.
Program	Name of the clinical trial program.
Protocol #	Identifying number assigned to the protocol.
Regions Required	Flag to indicate the sites for this protocol must belong to a region. For information on regions, see "Setting Up Regions" on page 293. When this flag is selected, you cannot create sites directly under protocols. You must create regions first and then create sites that are associated with regions.
Status	Protocol status such as planned, in progress, completed.
Team	Enter the names of those who need access to the protocol, the study manager and others who monitor the clinical trial.
Title	Descriptive title for the protocol.
Type	Purpose of the protocol.

Field	Comments
Withholding Amount	The amount to be withheld from each of the payments to the investigators until the trial is complete. This may be overwritten at the Region and Site levels.
Withholding Percentage	The percentage to be withheld from each of the payments to the investigators until the trial is complete. This may be overwritten at the Region and Site levels.
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). **NOTE:** It is important to specify the Currency Code for the protocol.
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.

3 To add team members to the protocol, click the Select button in the Team field to open the Team dialog.

4 Select a name in the Team picklist, and click Add to move the member to the Selected pane.

5 Click Position Rolldown.

Multiselected team members are added to the protocol as well as to all regions and sites belonging to the protocol.

6 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 "Automatically Assign Team Members to a Protocol Using the Position Rolldown Button" on page 291. If a member is removed from the team of a protocol, the end date of this record will be automatically filled in. For more information, see "Remove Team Members from the Team of a Protocol" on page 292.

7 Click the Team History tab to view the details of the team member that was automatically added to the protocol in the previous step.

From the Team History tab 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 291.

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 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.

To manually create protocol assignment team history

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

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

3 In the Team History tab view, create a new record, and complete the necessary fields.

Field	Comments
Role	Select the value that best describes each individual's role.
Start Date	If a team member is added from the Team of a Protocol (either manually or by using the Position Rollup mechanism), the start date defaults to the system date, and the end date is blank.
End Date	If a team member is removed from the Team of a Protocol (either manually or through reverse of Position Rollup mechanism), 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.

Automatically Assign 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 enable 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.

Remove 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 of the team member's record, if present, is overridden with the system date. However, if the record is already read-only, the initial End Date is not updated. The Position Rolldown mechanism automates the update of the End Date of the assignment records as if they are manually removed from the Team of the sites and regions.

NOTE: The system prompts whether to remove the member from only the Protocol or from All (Protocol, Region, and Sites belonging to the Protocol).

Creating and Revising Protocol Versions

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.

To create a new protocol version

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

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

3   In the Protocol Versions tab view, 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, check this field. If this field is checked, the Amendment Version field becomes read-only.
Amedment 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.

Setting Up Regions

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

Regions are optional for protocols. However, if you choose to use regions, by flagging 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 flag has been selected for the protocol. See "Regions Required" on page 289.

To create region records for a protocol

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

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

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).
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. This date may 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	Check this flag when there is no site information available under a region. Only summary information on enrollment is available for such a region. For more information, see "About Subject Enrollment Information Roll-Up" on page 310.
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.

Field	Comments
Team	Team members associated with the protocol to which the region belongs. See Step 3 for information on entering.
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 Protocol Withholding Amount. However, the Protocol Withholding Amount may be overwritten here at the Region level.
Withholding Percentage	The percentage to be withheld from each of the payments to the investigators until the trial is complete. The default value is the Protocol Withholding Amount. However, the Protocol Withholding Percentage may be overwritten here 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.

4 Select a name in the Team picklist, and click Add to move the member to the Selected pane.

5 Click Position Rolldown.

Multiselected team members are automatically added to all the site teams of this region.

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

6 Click Position Rollup.

Multiselected team members are automatically 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 291.

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

8 (Optional) Drill down on the region field and add extra information using the More Info tab view.

NOTE: It is important to specify the Currency Code for each region if multiple currencies will be used for the trial.

Automatically Assign 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 Site Team History and Protocol Team History views as if they had been assigned manually.

To remove a team member from the Protocol, see "Remove Team Members from the Team of a Protocol" on page 292.

Creating Region Assignment Team History

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

To manually create region assignment team history

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

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

3 In the Team History tab view, create a new record, and complete the necessary fields.

Defining a Subject Visit Template

Subject visit templates allow you to set up a template schedule based on the 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.

About Subject Visit Templates

Figure 11 and Figure 12 illustrate the relationship between the subject visit template and the visit schedule created for a given subject.

For example, if the subject visit template in Figure 11 is applied to a subject with a screen date of 11/20/2006, a rescreen date of 11/22/2006, and an enrollment date of 11/27/2006, the resulting visit schedule is displayed in Figure 12.

Figure 11. Visits List

Figure 12. Subject Form and Visits List in the Visit Plans View

The first screening visit takes place on the screen date because the lead time for this visit is 0. But this visit can be rescheduled to 11/21/2002 because the allowed variation for this visit is two days after the lead date (Max = 2 days). If you enter a date before the 11/20/2002 or after the 11/21/2002, an alert message appears, warning you that the entered date is outside the allowed range.

Similarly, the first enrollment visit takes place on 12/03/2001 because the lead time for this visit is 1 week after the enrollment date of 11/26/2001.

If the protocol is amended, you will need to create new versions of the subject visit template to reflect the modifications made to the protocol. See "Tracking and Revising Team Assignment History" on page 291.

Creating a Subject Visit Template

The following procedure describes how to create a subject visit template.

To create a subject visit template

1 Navigate to the Administration - Clinical screen > 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 list of existing protocols in the Pick Protocol dialog box.
Title	Tied to the Protocol # field.

3 For the new subject visit template, in the Template Versions list, create a new template version record or select a version that you have created using the Versions view. For more information, see "Tracking and Revising Team Assignment History" on page 291.

4 For the new template version record, in the Visits list, create a visit record for each visit (screening, rescreening, and enrollment) that a subject is to make to the site.

Some fields are described in the following table.

Field	Comments
Lead	■ For Screening visits, this is the time from the screen date. For example, in Figure 11 on page 296 the Lead value for the screening visit is 0. ■ For Rescreening visits, this is the time from the rescreen date. ■ For Enrollment visits, this is the time from the enrollment date. The Lead value for an enrollment visit taking place 1 week after enrollment would be 1, assuming the Lead Unit is weeks.
Lead Units	Units for lead time.
Max	The time after the lead time that the visit may take place. For example, if Max=2 and Min/Max Units = days, the visit may take place up to two days after the scheduled visit. Do not leave this field blank.
Min	The time before the lead time that the visit may take place. For example, if Min=1 and Min/Max Units = days, the visit may take place one day before the scheduled date. Do not leave this field empty.
Min/Max Units	Units for the Min and Max values. Do not leave this field empty.

Field	Comments
Name	Name of the visit; for example, screening or baseline.
Sequence	Sequence number of the visits. Typically, the first visit that will be made has order number 1.
Visit Type	Screening, Rescreening, or Enrollment. If Screening is selected, the visit due date will be based on the screen date. If Rescreen is selected, the visit due date will be based on the rescreen date. If Enrollment is selected, the visit date will be based on the enrollment date.
# CRF Pages	Number of CRF pages.

5 For each visit record, in the Activities record, create a set of activity records 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 may be adjusted on a per site or per individual basis.
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 20, "Setting Up and Making Subject Activity Payments."

Creating an Account and Contacts (End User)

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 may 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 may 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 may create and modify these records as needed. (See Chapter 17, "Importing Data into Life Sciences.")

To create an account

1   Navigate to the Accounts screen > Accounts List view.

2   In the Accounts list, create a new record, and complete the necessary fields. (To access more fields, click the more info 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" or "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.
	When you search for an account or enter an account in another part of your Siebel 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   Use the views tabs to access other views such as Account Team, Activities, Addresses, and so on to add more information to the account record.

For more information about creating and maintaining account affiliations, see Chapter 5, "Administering and Managing Accounts in Life Sciences."

To create a contact record

1   Navigate to the Contacts screen > 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 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's 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 Chapter 4, "Managing Contacts in Life Sciences."

Creating a Site (End User)

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 protocol, account, and principal investigator.

To create a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites 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.
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. This date may 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*.
No Subject Info	Check this flag when there is no subject information available for a site. Only summary information on subject enrollment is available for such a site.
PI Last Name	Last name of the principal investigator.
	If an account has already been specified for the site, use Affiliated Contacts in the Pick Contacts dialog box to view only those 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, enter a region name.

Field	Comments
Site #	The number that is to be assigned to the site. The Site # field is not required when the site status is Planned or Not Initiated. The Site # 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 flag defaults to the creator of the site record. The flag can only be changed by the manager of the team through the My Team's Sites view. This is consistent with the best practice because resource management is normally a manager's responsibility. See Step 3 for information on entering.
Versions	See Step 4 for information on entering.
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 Percentage	The percentage of the total payment to be withheld from the investigators until the trial is complete. The default value may 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, then if the region required flag is checked, 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 MVG Version field and do the following:

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

The template versions are filtered to display only those related to your protocol.

b Enter the IRB Approval Date for the selected version.

The template version cannot be activated without the IRB approval date.

c Click 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.

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

For more information about protocol versions, see "Tracking and Revising Team Assignment History" on page 291.

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

For information, see "To associate contacts with a site" on page 319.

6   (Optional) Drill down on the Site # field, and add extra information using the More Info tab view.

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 a Site" on page 317.
# 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.

Automatically Assign 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 set to the system date by default, and with the End Date displayed as blank.

To remove a team member from the Protocol, see "Remove Team Members from the Team of a Protocol" on page 292.

Creating Site Assignment Team History

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

To manually create site assignment team history

1   Navigate to the Administration - Clinical screen > Site List view.

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

3   In the Team History tab view, create a new record, and complete the necessary fields.

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 of the team member's record, if present, is updated with the system date. However, if the record is already read-only, the initial End Date is not updated. The Position Rollup mechanism automates the update of the End Date of the assignment record as if it was manually removed from the Team.

NOTE: The system prompts whether the member should be removed from only the Site or from ALL (Sites, Region and Protocol) Sites including both these particular sites as well as all other sites within this protocol that this user is a team member.

Creating a Subject and Setting Up Visits and Visit Activities (End User)

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

Screening a Subject

It is possible to enter and screen subjects for clinical trials using the Subjects view tab.

To enter and screen a subject

1   Navigate to the Site Management screen > Protocol Site List view.

2   In the Sites list, drill down on the site for which you want to add subjects.

3   Click the Subjects view tab.

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

   Some fields are described in the following table.

Field	Comments
Enrollment Id	This is the principal ID number for the subject. The value is entered when you click the Enroll button (Step 8 on page 308).
Informed Consent	An informed consent date must be entered before a subject can be enrolled in the protocol. See Step 4 on page 305.
Randomization Id	An ID number for the subject, which can be used in studies where both an enrollment ID and a randomization ID are required.

Field	Comments
Screening #	This field is based on the subject's initials and date of birth. It is automatically populated after Subject Initials and Date of Birth fields are entered and the record is saved.
Status	A multi-value field that contains a history the subject's status. **Primary.** This flag sets the current status, which displays in the Status field of the Subjects view. **Status.** The status of the subject, for example, screened, enrolled, or re-screened. **Date.** The date the status was changed or updated. **Comments.** Comments about the subject's status.

5 Click the hyperlink in the Screening # field of the subject.

The Visits view of the Subjects screen appears.

6 To generate screening visits and activities:

a Click Screen in the Subject form.

b Enter the screen date in the Screening dialog box.

Screening visits and activities to take place in those visits appear in the Visits and Activities lists.

NOTE: A subject can be screened only once for each visit template. After screening visits have been generated, clicking the Screen button again and changing the screen date reschedules the screening visits according to the new screen date. (If the subject visit template has been updated since the last time the screen button was clicked, new screening visits are generated.) See "Applying Protocol Amendments (End User)" on page 307.

7 (Optional) Edit subject visits dates.

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, the application displays a warning message, but *still reschedules the visit* according to the new date.

8 (Optional) Create or modify subject visits or activities.

Rescreening a Subject

A subject who initially fails screening can be rescreened. The rescreen date must be greater than or equal to the screen date and rescreening cannot happen if the subject has not already been screened (that is, if the screen date is null).

To rescreen a subject

1 Navigate to the Subjects screen.

2 Select the subject who is eligible for the study. (The subject must have already been screened.)

3 Click Rescreen in the Subject form and enter a rescreen date.

The rescreen visits and activities are automatically created in the subject's schedule.

4 (Optional) Edit subject visits dates.

5 (Optional) Create or modify subject visits or activities.

6 (Optional) Rescreen multiple times.

A subject can be rescreened more than once. Each time the Rescreen button is clicked and the rescreen date entered, a new set of the rescreening visits and activities is generated and appended to the existing ones. This applies even though the subject visit template has not been changed.

Enrolling a Subject

A subject who has successfully passed screening or rescreening is then enrolled in the study.

To enroll a subject

1 Navigate to the Subjects screen.

2 Drill down on the Screening # for the subject.

3 Click the Visits view tab.

4 Enter the informed consent date:

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

   b Click New.

      The versions of the subject visit template appear in the drop-down list of the Add Informed Consent dialog box. Make sure to select the version before entering the informed consent date.

   c Click Add.

   d In the Informed Consent Dates dialog box, enter an informed consent date for the subject and close the Informed Consent Dates dialog box.

      NOTE: Enrollment activities cannot be generated without an informed consent date for the active version of the protocol.

5 Click the Enroll button in the Subject form.

6 Enter the enrollment date and the enrollment ID in the Enrollment dialog box.

The enrollment date must be greater than or equal to the screen date.

7 (Optional) Edit subject visit dates.

See Step 7 on page 304 for more information about editing visit dates.

8 (Optional) Create or modify subject visits or activities.

Creating an Unscheduled Subject Visit

On occasion, it may be necessary to create an unscheduled subject visit. This can be done in the
Subjects screen, or in the Site Calendar.

To create a subject visit from the Subjects screen

1 Navigate to the Subjects screen > Subject List view.

2 In the Subjects list, drill down on the screening number of the subject for whom you want to add
an unscheduled visit.

3 Click the Visits View tab.

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.

To create a subject visit from the Site Calendar

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the site for which you want to add subject visits.

3 Click the Calendar view tab.

4 Click New Subject Visit to create a new record, and complete the necessary fields.

The Calendar details view is displayed.

Some fields are described in the following table.

Field	Comments
Assigned To	Person to whom the subject visit is assigned.
Completed	Indicates whether or not the visit has taken place.
Completed Date	Indicates the date on which the visit took place.
Due	Date on which the subject visit is due.
Lock Assignment	Determine whether the Lock Assignment field should be selected. If the activity is locked, Assignment Manager will not access it. If it is unlocked, Assignment Manager can reassign it.

Terminating a Subject's Trial Early

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

To terminate a subject's trial early

1 Navigate to the Subjects screen > Subject List view.

2 In the Subjects list, Drill down on the Screening # of the subject whose trial you wish to terminate.

3 Click the Select button in the MVG Status field.

4 In the Subject Status dialog box, click the Status field and do one of the following:

To	Select
Indicate that the trial was terminated early	Early Terminated
Indicate that the subject failed the screening	Screen Failure

When either of these two events occur, all remaining visits for the subject are deleted.

Applying Protocol Amendments (End User)

When a protocol is revised mid-study, you need to 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.

To apply a new version of a subject visit template to a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, select the site for which you want to apply a new version of the visit template.

3 Enter the new version of the subject visit template in the Version field.

Make sure that the new version is active by entering the IRB Approval Date for the version and checking the Active flag.

For instructions on editing the MVG Version field, see Step 4 on page 301.

To apply a new version of the subject visit template for an enrolled subject

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # for which you want to update subject visits.

3 Click the Subjects view tab.

4 Click Apply Active Version.

This creates new records for the new version of the template in the Informed Consent Dates field for all subjects in this site except for those whose status is "Early Terminated" or "Completed."

5 Navigate to the Subjects screen and drill down on Screening # of the enrolled subject whose schedule you want to update for the revised subject visit template.

6 Click the Visits view tab.

7 Enter the informed consent date for the newer version as described in .

8 In the Subjects form, click Enroll and click OK in the Enrollment dialog box.

A dialog box is displayed asking you if you would like to delete non-applicable visits. 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.

9 Do one of the following:

■ Click OK. If you click OK, the non-applicable visits are deleted.

■ Click Cancel. If you click cancel, the new visits for the new protocol version are appended to the existing Visits list. No visits are deleted. Typically, if you select this option, you may return at a later stage to the Visits list and delete:

❑ Future-scheduled visits from the original subject visit template version.

❑ Past-scheduled visits from the new subject visit template version.

See for more information.

NOTE: Screening and rescreening schedules are revised in the same way, except that informed consent dates are not necessary for these types of visit.

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, the application creates a new set of visits, and adds them on top of the visits already created from prior versions.

If you choose OK, the application creates a new set of visits, compares the two sets of visits, and deletes the non-applicable visits when the following conditions are satisfied:

1 The application uses the Subject's Informed Consent date 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 < 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 > or = Informed Consent date, there the following rules apply:

❑ If the Due date of the corresponding new visit is < Informed Consent date, 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 > or = Informed Consent date, 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 children 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 the application 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 visit that does not have the Completed date filled in:

a If the Due date is > or = Informed Consent date, the visit generated form the old version 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 < Informed Consent date, 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 < Informed Consent date, the new visit is deleted.

b If the Due date is > or = Informed Consent date, the new visit is left intact, although it could still be deleted based on other rules specified above.

Rules for Deleting Visits Deemed Non-applicable by Early Termination

In addition to automatically deleting non-applicable visits per protocol amendments, the application applies the following automation rules 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 > 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 > Screen Failure date.

About Subject Enrollment Information Roll-Up

One of the key capabilities of Siebel Clinical is supporting clinical organizations to better manage their trials in real-time enrollment status tracking. This is implemented though rolling-up subject information from Site to Region and then to protocol or directly from Site to Protocol. 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 it is not always possible for the clinical organization to receive subject level information. The enhanced subject roll-up functionality allows accurate subject enrollment data to be available at 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.

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

■ Subject enrollment information is automatically rolled-up from Subject to Site, from Subject to Region, and from Subject to Protocol.

■ 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.

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

■ Sites that do not have subject-level information available may be check-marked as having No Subject Info.

■ The following information may be entered by CRAs for sites that do not have subject or site level information:

■ # Subjects Screened

■ # Subjects Re-screened

■ # Subjects Screen Failure

■ # Subjects Enrolled

■ # Subjects Completed

■ # Subjects Early Terminated

■ First Subject Enrolled Date

■ Last Subject Off Study Date

- ■ Site Initiated Date

- ■ Site Terminated Date

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

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

■ Regions that do not have site-level information available should be check-marked as having No Site Info. You do not need to check-mark No Subject Info.

■ The following information may be entered by CRAs for regions that do not have site-level information:

- ■ # Subjects Screened

- ■ # Subjects Re-screened

- ■ # Subjects Screen Failure

- ■ # Subjects Enrolled

- ■ # Subjects Completed

- ■ # Subjects Early Terminated

- ■ First Subject Enrolled Date

- ■ Last Subject Off Study Date

- ■ Site Initiated Date

- ■ Site 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 that for regions with subject data.

Monitoring Subject Status and Enrollment Rates (End User)

You can view charts of:

■ Subjects by status

■ Enrollment rates

These charts can be displayed by protocol, region, or site. Charts can be displayed in a variety of formats.

To create graphical charts

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 On the link bar, click the Charts view tab.

4 To display a subjects-by-status chart:

    a From the Show drop-down menu, select Subject Accruals.

    b From the second drop-down menu, select Subject Status Analysis.

5 To display an enrollment rate chart:

    a From the Show drop-down menu, select Subject Enrollment.

    b From the second drop-down menu, select Subject Enrollment Analysis.

19 Managing Sites and Clinical Contacts

This chapter covers the following topics:

About Managing Sites and Clinical Contacts

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

- Clinical trial sites
- 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:

- Site activity plans

- Account and contact assessments

Scenario for Managing Sites and Clinical Contacts

This scenario provides an example of a process performed by the administrator and the clinical research associates (CRAs). Your company may follow a different process according to its business requirements.

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

When the CRAs begin work on a new clinical trial, they must set up a number of site visits that will 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 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 need to plan how the protocol will be carried out at the site. This is done by creating a site activity plan, which determines how the trial is conducted. The CRAs use the clinical protocol site template that has been created by the administrator. CRAs may also track any number of extra documents that are associated with a site. This may 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 have those accounts and contacts deleted. CRAs do not have the permissions needed 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. Please obtain legal advice before using the contact assessment feature in Siebel Clinical.

Process of Managing Site and Contact Information

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

NOTE: 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 site activity plan can be created.

Administrator Procedures

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

■ "Creating a Clinical Protocol Site Template" on page 316. 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 316. The administrator or the study manager creates assessment templates that define weighted attributes for assessing a contact or account.

■ "Maintaining Contact and Account Information" on page 317. An administrator maintains records of contact license numbers and deletes erroneous or obsolete account and contact data.

■ "Associating Contracts with a Site" on page 317. The administrator or a study manager enters details about the contracts for a site and the payment details for each contract.

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 318. CRAs create site visits to evaluation, initiate, monitor, and close-out sites.

■ "Creating and Updating Site, Contact, and Account Records (End User)" on page 319. CRAs record details about contacts, accounts, and sites.

■ "Assigning Employees to the Site Team (End User)" on page 320. Managers or CRAs add employees to the team associated with the site.

■ "Creating Site Activity Plans (End User)" on page 321. CRAs use the clinical protocol site template that has been created by an administrator to plan a list of activities for each site.

■ "Tracking and Adding Documents at Sites (End User)" on page 323. CRAs and regional study managers post clinical trial and regulatory documentation for review at site, region, and protocol levels.

■ "Creating Documentation Tracking Activities" on page 324. Documents can be attached and tracked at the protocol, region, and site levels, or for accounts or contacts.

■ "Assessing Investigators and Hospitals or Other Contacts and Accounts (End User)" on page 329. CRAs score contacts and accounts, based on the attributes defined in an assessment template.

Creating a Clinical Protocol Site Template

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

The clinical site protocol template is one of a number of activity templates used in Siebel Clinical. Others are subject visit templates ("Defining a Subject Visit Template" on page 295), trip report templates ("Creating a Trip Report Template" on page 341), contact and account assessment templates ("Creating Contact and Account Assessment Templates" on page 316).

When an activity template is of type, Clinical Protocol Site, and is not associated with a Protocol Title, the template can be applied to all sites in the Clinical Protocol Site Activity Plan View (Site Management > Activity Plans).

If an activity plan of type, Clinical Protocol Site, is associated with a Protocol Title, the activity plan can be applied only to sites under this Protocol.

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

To create a clinical protocol site template
■ Create an activity template of type 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*.

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.

To create an assessment template

■ Follow the procedure for creating an assessment template in the *Siebel Applications Administration Guide*. For contact assessment templates, make sure to set the template type to Contact. For account assessment templates, make sure to set the template type to Account.

Maintaining Contact and Account Information

The end users are responsible for much of the day-to-day maintenance of their account and contact data. However, there are a few tasks for which the administrator is responsible. These are:

■ Entering data into the primary specialty field for contacts. See *"Setting Up Primary Specialties" on page 48*.

 NOTE: If the specialty type you need is not available, enter it by following the procedure, *"To define a specialty" on page 49*.

■ Deleting contact and account records that were created in error or are obsolete. See *"To delete a contact" on page 50* and *"To delete an account" on page 65*.

Associating Contracts with a Site

Contracts that define the total payments that are to be made to a site can be associated with each site. Some sites may only need one contract that will govern the entire payment for the site. However, depending on the site in question, it may be necessary to associate multiple contracts with the site. There may 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 tab in the Site Management screen.

To associate a clinical contract with a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 Drill down on the Site # of the site with which you wish to associate a contract.

3 In the Contracts view tab, create a new record, and complete the necessary fields.

 Some fields are described in the following table.

Field	Comments
Contract Number	The number assigned to this contract. This field is automatically populated.
Type	The type of contract that is to be associated with the site.

Field	Comments
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 can be seen 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 to be made. This is a multi-value field and multiple payees for the contract may be entered using the multi-value picklist.
Address	The address associated with the payee.

Creating and Managing Site Visits

CRAs typically need to carry out five types of visits to a site as follows:

■ **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 case report forms (CRFs)

■ **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 may wish to carry out

CRAs need to 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 Site Management > Protocol Site List view. 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 in the system and follow-up activities associated with these visits. Study managers can also filter site visits to see what visits are assigned to their teams and view follow-up activities in order to assess what the most pressing issues are.

Depending on the type of site visit you choose, the drill down views vary. If the site visit type is Site Initiation or Site Evaluation, then the drill down view does not contain the CRF Tracking tab. If the site visit type is Site Monitoring or Site close-out, the drill down view contains the CRF Tracking tab. For more information, see "Defining a Subject Visit Template" on page 295.

To create a site visit

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # for the site with which you want to create a visit and click the Site Visits tab.

Some fields are described in the following table.

Field	Comments
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. For more information on Trip Reports, see Chapter 21, "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	Not Stated, In Progress, Completed, Submitted, Approved, and Rejected. A state model is preconfigured to allow for structured state transition.

Monitoring Site Visits Using the Calendar

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

Creating and Updating Site, Contact, and Account Records (End User)

It is important to maintain accurate information in the Siebel Clinical database. End users need to 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 the following topics:

■ "To create an account" on page 299

■ "To create a contact record" on page 299

■ "To create a site" on page 300

■ "To indicate an affiliation between contacts" on page 55

■ "To indicate an affiliation between an account and a contact" on page 71

■ "To indicate an affiliation between accounts" on page 72

To associate contacts with a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # for the site with which you want to associate contacts.

3 Click the Contacts view tab.

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	Affiliated Contacts filters the names in the Pick Contacts dialog box, displaying only those contacts associated with the site's account.

Capturing Different Types of Addresses for Each Site (End User)

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

To add an address type for a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Protocol Site list, drill down on the Site # of the protocol site for which you want to add an address type.

3 In the Addresses tab view, 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.

Assigning Employees to the Site Team (End User)

CRAs 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, 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 44.

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*.

To assign employees to the site team

1 Navigate to the Site Management screen > Protocol Site List view.

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

3 In the list, edit the Team field.

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

NOTE: You can also automatically assign an employee to the site team using the Position Rollup button or Position Rolldown button. For more information, see "Automatically Assign Team Members to a Site Using the Position Rollup Button" on page 302. For more information about removing employees from the site team, see "Removing Team Members from the Team of a Site" on page 303.

Creating Site Activity Plans (End User)

A site activity plan 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 here makes creating site activity plans more efficient.

For information on creating templates, see "To create a clinical protocol site template" on page 316.

To assign activities to a site using a template

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site to which you want to assign activities.

3 Click the Activity Plans view tab.

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 the Lock Assignment field should be selected. If the activity is locked, Assignment Manager will not access it. If it is unlocked, Assignment Manager can reassign it.
Template	Only templates whose type is Clinical Protocol Site and whose protocol matches the protocol at the site are displayed.
	Only activities with type Document or Site Initiation are shown in the document tracking views.

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

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.
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.

NOTE: To view additional fields in this list, click the menu button and select Columns Displayed.

Applying Protocol Site Activity Templates

You can simultaneously apply one or multiple site-activity templates across one or multiple sites for a study. Activity records of type, document and site initiation, are displayed in the Site Management > Document Tracking view. Correspondence activity types are displayed in the Site Management > Activities view.

The templates applied through this action are also displayed in the Site Management > Activity Plans view for each of the sites selected.

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

1 Navigate to the Regions screen > Region List view.

2 In the Regions list, drill down on the Region for which you want to apply an activity template.

3 In the Sites tab view, select the sites for which you want to apply an activity template.

4 Click Apply Template and from the Templates dialog, select one or multiple activity templates that you want to apply to the selected site.

5 Click OK.

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

1 Navigate to the Protocol screen > Protocol List view.

2 In the Protocols list, drill down on the Protocol for which you want to apply an activity template.

3 In the Sites tab view, select the sites for which you want to apply an activity template.

4 Click Apply Template and from the Templates dialog, select one or multiple activity templates that you want to apply to the selected site.

5 Click OK.

Tracking and Adding Documents at Sites (End User)

During the life of a clinical trial, CRAs need to 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.

To track documentation milestones

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to track documentation.

3 Click the Document Tracking view tab.

A list of documents associated with the clinical trial appear.

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.
Lock Assignment	Determine whether the Lock Assignment field should be selected. If the activity is locked, Assignment Manager will not access it. If it is unlocked, Assignment Manager can reassign it.

Field	Comments
Name	The name of the document. This field is a hypertext link to the Attachments tab.
Received Date	The date that the signed document returns from the site.
Sent Date	The date that the document is sent to the site.

To add a document to a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to track documentation.

3 Click the Document Tracking view tab.

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 have just added and drill down on the Name hyperlink.

The Attachment view appears.

6 Create a new record and in the Name field specify the file name or URL.

7 Check the Auto Update flag if you want to have the file automatically updated during synchronization.

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

Creating Documentation Tracking Activities

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.

To create documentation tracking activities

1 Navigate to the Document Tracking screen.

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

NOTE: A document tracking activity 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. This is a hyperlink to the associated Attachment view.
Site, Region, Protocol, Contact, or Account	Delegate the document to one of these fields. The field you select determines how the hyperlink in the Name field operates. This field is a hyperlink to the associated Activities view.

To review, update, and add existing documentation for tracking

1 Navigate to the Document Tracking screen.

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

3 Click the document name hyperlink.

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, region, protocol, contact, or account field.

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

Creating CRF Tracking Activities

Numerous case report forms (CRFs) 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, protocols, contacts, or accounts.

CRF Tracking records are created when you apply a subject visit template in addition to subject visit records. You can also create a CRF Tracking Activity from the Protocol Site CRF Tracking View.

To view CRF tracking activities

1 Navigate to the Document Tracking screen.

2 Click CRF Tracking and in the CRF Tracking list you can view all tracking records in the system.

NOTE: A CRF tracking activity 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 CRF name.
	This is a hyperlink to the associated Attachment view.
Site, Region, Protocol, Contact, or Account	Delegate the CRF to one of these fields. The field you select determines how the hyperlink in the Name field operates.
	This field is a hyperlink to the associated Activities view.

To review, update, and add existing CRFs for tracking

1 Navigate to the Document Tracking screen.

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, region, protocol, contact, or account field.

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

Tracking Case Report Forms (CRFs)

Users can create and track CRFs 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 children activities records as existed in the current product, a duplicate set of visit records with Type = Case Report Form are created (with # Pages as specified in the template).

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

To monitor and retrieve case report forms

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Protocol Site list, drill down on the Site # of the protocol site for which you want to track CRFs.

3 In the CRF Tracking tab view, click New to 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	Defaults to CRF activity type. Only activity records with CRF activity type are displayed in this view.
# CRF Pages	Number of pages contained in the CRF.
Retrieved	Checked if the CRA 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.
Source Verified Date	The date when the CRF was source verified.
Comments	Enter a relevant comment about the CRF.

Creating Site Correspondence Activities

You can track all correspondence (phone, fax, email, and letters delivered by the postal service) between a site and a study team member as site correspondence activities. 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 clinical research organization, or central lab.

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

To create a correspondence activity for a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Protocol Site list, drill down on the Site # of the protocol site for which you want to create a correspondence activity.

3 In the Activities tab view, create a new record, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Activity	Defaults to Correspondence activity for the site.
Activity Type	Select from one of the following activity types: ■ Case Report Form ■ Email ■ Fax ■ Mail ■ Phone
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 filed.

To create a new role correspondence for a site

1 Navigate to the Protocol screen > Protocol List view.

2 In the Protocols list, drill down on the Protocol # of the protocol for which you want to create a new role.

3 In the Sites tab view, select one or multiple sites for which you want to apply a new role for the correspondence.

4 Click New Correspondence and from the Roles of Contacts dialog box, select the role or multiselect the roles that best describe the individual's role, and click OK.

Tracking Business Partner Correspondence

You can track all correspondence (phone, fax, email, and letters delivered by the postal service) between business partners, such as a CRO, or Central Lab.

To create a correspondence activity between business partners

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Protocol Site list, drill down on the Protocol # of the protocol site for which you want to create a business partner correspondence activity.

3 In the Activities tab view, create a new record, and complete the necessary fields.

Adding Notes to a Site

When you are working with site records, you often find that you need 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.

To add private and public notes to a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Protocol Site list, drill down on the Site # of the protocol site for which you want to add notes.

3 Click the Notes view, and select Private Notes or Public Notes

4 Click New, and complete the fields for the new record.

The Created By Name and the Created Date fields are automatically completed with the creator's 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 Use the Check Spelling button to make sure your note has no spelling errors.

Assessing Investigators and Hospitals or Other Contacts and Accounts (End User)

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 may be assessed to determine competence to carry out a large scale phase III clinical trial or a hospital may be assessed to determine suitability to carry out a similar trial. The results of this assessment help CRAs find suitable investigators and hospitals for subsequent trials.

NOTE: The application automatically updates the score values in the Assessment Attributes list and the (total) score value in the Assessments list.

For information on creating templates, see .

To assess a contact or account

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

■ Navigate to the Contacts screen > Contacts List view. In the Contacts list, drill down on the contact whom you want to assess.

■ Navigate to the Accounts screen > Accounts List view. In the Accounts list, drill down on the account that you want to assess.

2 Click the Assessments view tab.

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 316.)

The application fills in other fields in the record 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.

20 Setting Up and Making Subject Activity Payments

This chapter covers the following topics:

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About Setting Up and Making Subject Activity Payments

Payments to investigators and sites are set and adjusted at three 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 may be a subject activity for which the site is not paid, but a site would be 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.)

In addition to subject activities, sites can be paid on other activities created at the site level, such as IRB fees and equipment costs. Those activities can be flagged as payable to the site with the Payment Flag.

NOTE: For information about managing budgets at the protocol level, see Chapter 22, "Managing Clinical Projects."

You can use multiple currencies for a protocol. Currencies and exchange rate dates are set at three 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, you should 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.** You should 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.

For more information on setting up currency conversions, see *Siebel Applications Administration Guide*.

Scenario for Payments

This scenario is an example process performed by the financial administrator for your company. Your company may follow a different process according to its business requirements.

Based 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 will guarantee that investigators are motivated to carry out all activities so that they get paid in full.

The CRAs 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 will be paid the full amount for all activities including the amount or percentage withheld.

Occasionally, the sponsor or CRO (clinical research organization) needs to make an additional payment to a site, a payment which is not directly associated with subject activities. These are ad hoc 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 the Site Portal application. For more information about Siebel Site Portal, see *Siebel Life Sciences Portals Guide.*

Process of Setting Up and Making Payments

This topic details sample tasks often performed by administrators and end-users when setting up and managing subject activity payments, performed by study managers and CRAs. Your company may follow a different process according to its business requirements. The tasks are generally carried out in the order presented, although ad hoc payments can be made any time.

Administrator Procedures

1 "Setting Up Standard Payment Amounts in the Subject Visit Template" on page 333.

2 "Adjusting Payment Amounts and Generating Payments for Sites" on page 336. This task is generally performed after the End-User Procedures have been carried out.

End-User Procedures

The following list shows tasks end users typically perform when managing subject activity payments. These tasks are typically performed in the following order:

1 "Setting Payment Exceptions for a Site (End User)" on page 334. Adjust payment amounts for individual sites.

2 "Marking Subject Activities Completed (End User)" on page 335.

3 (Optional) "Generating Ad Hoc Payments for Sites (End User)" on page 335.

4 "Generating Final Payments for Sites (End User)" on page 337.

Setting Up Standard Payment Amounts in the Subject Visit Template

Payment amounts can be set up when the subject visit template is created (as described in "Defining a Subject Visit Template" on page 295) or may be added later following the procedure described here.

Payments at the site level may 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, payment amounts at the site level are rolled up into the currency that is designated for the protocol.

To set up standard payment amounts for subject activities

1 Navigate to the Administration - Clinical screen > 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 will be paid for:

a Set the Payment Flag.

If the Payment Flag is not selected, the activity will 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 a Site (End User)

The amount paid to individual sites for a particular procedure may differ from the standard amount set in the subject visit template ("Setting Up Standard Payment Amounts in the Subject Visit Template" on page 333), or the currency used at the site might differ from the currency used for the standard amount.

The procedure below explains how to use payment exceptions to change the standard amount paid for a payment subject activity for an individual site.

Once 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 will show the site-specific amount.

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

To set site-specific payment amounts for subject visit activities

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to set up payment exceptions.

3 Click the Payment Exceptions view tab.

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 subject payment activities with Payment Flag 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 may 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.

Marking Subject Activities Completed (End User)

Usually the site personnel will use the Site Portal Web site to enter when subjects complete activities. However, this task can also be performed by the CRA using Siebel Clinical, as shown in "To mark subject activities as completed" on page 335.

To mark subject activities as completed

1 Navigate to the Subjects screen > Subjects list.

2 Drill down on Screening # of the subject whose activities have been completed.

3 Click the Visits view tab.

4 In the Visits list, select the visit that has just been completed and click Check All.

   This marks the selected visit and all of its activities as completed:

   ■ The Completed flag is selected.

   ■ The Completed Dates of all activities of the selected visit are also filled in with the same Completed Date as that of the parent visit.

   ■ The Status is set to Done.

5 If necessary, edit the fields for the visit in the Activities list.

Generating Ad Hoc Payments for Sites (End User)

Ad hoc payments not associated with subject activities can be created for sites.

To generate an ad hoc payment

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to generate a payment.

3 Click the Payment Activities view tab.

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.
Completed	This field must be selected.
Standard Amount	The payment amount.

5 Click Generate Payment.

The application removes the completed payments from the Payment Activities list.

6 To complete the payment, follow Step 6 on page 336 to Step 8 on page 337 in the procedure "To make final adjustments to the payment amounts and generate payments,".

Adjusting Payment Amounts and Generating Payments for Sites

Although payments are generally set on per-site basis ("Setting Payment Exceptions for a Site (End User)" on page 334), occasionally the financial administrator may want to make additional adjustments to the amount paid for a given payment activity.

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.

To make final adjustments to the payment amounts and generate payments

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to generate payments.

3 Click the Payment Activities view tab.

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 + Deviation Amount = Actual Amount

5 Check Completed and click Generate Payment.

The application removes the completed payments from the Payment Activities list.

6 Click the Payments view tab.

The payment generated in Step 5 appears in the Payments list.

7 Complete the fields in the Payments record.

Some fields are described in the following table.

Field	Comments
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. 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. The sum of all values in the Earned Amount column equals the Earned to Date value of the site.
Payment #	The application automatically generates this unique number.
Requested Amount	The requested amount of payment for the payment activities carried out at this site. This field is calculated as follows: `Requested Amount = Earned Amount X [(100 - Withholding Perentage/100) - Withholding Amount]`
Type	For payment subject activities that are generated from the Generate Payment button, this field defaults to Interim Payments. For payment subject activities that are generated from a back office system, this field defaults to 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.

Information may also be automatically loaded from a back-office finance system.

8 (Optional) Click the hyperlink in the Payment # field to view the payment activities associated with this payment.

Generating Final Payments for Sites (End User)

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 in the system before new final payments can be generated.

To generate final payments for a site

1 Navigate to the Site Management screen > Protocol Site List view.

2 In the Sites list, drill down on the Site # of the site for which you want to generate a payment.

3 Click the Payments view tab.

4 Make sure that all Check Amounts for past payments are up to date.

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

Some fields are described in the following table.

Field	Comments
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.
Check Date	The date on which the check was issued.
Check Number	The number assigned to the check.
Status	This field defaults to To Be Processed.
Type	You must set this field to Final Payment. When this field is set, the Requested Amount for the final payment is automatically calculated as equal to the Earned to Date Amount minus the Paid to Date Amount for the site.

When you step-off and save the record, the requested amount field is automatically updated, by subtracting the site's total Paid Amount to date (that is, Check Amount) from it's total Earned Amount to date. For more information on these values, see .

21 Administering and Using Clinical Trip Reports

This chapter covers the following topics:

- "About Administering and Using Clinical Trip Reports" on page 339
- "Scenario for Managing Clinical Trip Reports" on page 339
- "Process of Administering Clinical Trip Reports" on page 340
- "Creating a Trip Report Template" on page 341
- "Selecting a Trip Report Template Before a Site Visit (End User)" on page 341
- "Completing a Trip Report After a Site Visit (End User)" on page 343
- "Approving Trip Reports" on page 345

About Administering and Using Clinical Trip Reports

This chapter describes how to set up and use trip reporting in Siebel Clinical.

The study managers or clinical administrators can set up templates for trip reporting. These templates are then used by the clinical research associates (CRAs) 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 for all trip reports

Scenario for Managing Clinical Trip Reports

This scenario is an example process performed by the clinical administrator and the clinical research associates (CRAs). Your company may follow a different process according to its business requirements.

The Clinical Administrator

In this scenario, a clinical administrator prepares a set of trip report templates for the CRAs to use when preparing for and writing up their visits to clinical sites.

The clinical administrator prepares four templates, one for each type of site visit the CRAs are typically required to perform:

■   Site evaluation

■   Site initiation

■   Site monitoring

■   Site close-out

For more information about site visits, see "Creating a Subject and Setting Up Visits and Visit Activities (End User)" on page 303.

The CRAs

The CRA is the end user of the Siebel Clinical product. Before visiting a site, the CRA uses the trip report feature to prepare for the visit. The follow-up items list reminds the CRA of the open activities arising from previous visits that need to be closed.

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, it is then locked to prevent the CRA from making any further changes. If the trip report is not satisfactory, the manager may reject the report and return it to the CRA for further attention.

Process of Administering Clinical Trip Reports

This topic details sample tasks often performed by administrators and end-users when administering clinical trip reports. Your company may follow a different process according to its business requirements.

Administrator Procedures

1   "Creating a Trip Report Template" on page 341. Create a template for each type of site visit.

2   "Approving Trip Reports" on page 345. Approve or reject trip reports submitted by CRAs.

End-User Procedures

The following list shows tasks end users typically perform when administering clinical trip reports. These tasks are typically performed in the following order:

1 "Selecting a Trip Report Template Before a Site Visit (End User)" on page 341. Before a visit, use a trip report template to prepare an activities checklist and follow-up items.

2 "Completing a Trip Report After a Site Visit (End User)" on page 343. After visiting a site, use the Trip Report view to record activities accomplished, site personnel met, and follow-up items. Distribute and archive the completed trip report.

Creating a Trip Report Template

Typically, the clinical administrator prepares a number of generic trip report templates, perhaps one designed for each of the different stages in the study. (See "The Clinical Administrator" on page 340.)

The trip report template is an activity template of type Clinical Trip Report. This is one of a number of activity templates used in Siebel Clinical.

Other activity templates used in Siebel Clinical are subject visit templates ("Defining a Subject Visit Template" on page 295), clinical site templates ("Creating a Clinical Protocol Site Template" on page 316), and contact assessment templates ("Creating Contact and Account Assessment Templates" on page 316).

To create a trip report template

■   Create an activity template of type Clinical Trip Report.

For information about how to create activity templates, see *Siebel Applications Administration Guide*.

In the Activity Template Details list, create new records that describe activities for trip or follow-up items to be carried out after trips.

Selecting a Trip Report Template Before a Site Visit (End User)

Although a trip report is designed to be written after a site visit, it can be used during a site visit to guide the CRA through a list of required activities. The report contains different lists depending on the Visit Type.

The Trip Reports view contains two lists for Pre-Study and Site Initiation visit types:

■   **Checklist Activities.** Activities in this list can be generated by applying a trip report template. Ad-hoc activities can also be created individually.

■   **Follow-up Items.** These are the activities that need to be followed up later. The Current Trip and Follow Up-Items view allows the CRA to record, and later to review, the follow-up items associated with the current site visit. The All Follow-Up Items view (accessed using the filter) lists follow-up items from both previous visits and also from the current visit.

For Site Monitoring and Site Close-Out visit types, a Trip Report contains both of the lists detailed above and also contains an extra list:

■ **Case Report Forms Tracking.** The items in this list track the Case Report Forms corresponding to subject visits.

To select a trip report template

1   Navigate to the Site Visits screen.

2   In the Site Visits list, click the hyperlink in the Visit Start field of the visit for which you want to create the trip report.

   The Trip Report view is displayed. Some of the fields will already be populated from when the site visit was created. For more information about creating site visits, see "Creating a Subject and Setting Up Visits and Visit Activities (End User)" on page 303.

3   Complete or edit other fields in the Trip Report form. See also Step 2 on page 344.

   Some fields are described in the following table.

Field	Comments
Owned By	This field defaults to the creator of the trip report. Other names can be added to indicate a shared trip report.
Site Visit Status	The status of the site, for example, Planned, Completed, and so on.
Visit Start	The date and time on which the site visit is started or planned.
Visit Type	The nature of the visit, for example, prestudy, site initiation, or site monitoring.
Visit Name	A descriptive name for the trip report.

4   In the Template field, select the name of the trip report template that you want to apply.

   When you click off the Template field, the activities defined in the template appear in the Checklist Activities list.

5   (Optional) Edit the activities in the Checklist Activities list or create more activities.

   Some fields are described in the following table.

Field	Comments
Display In	Indicates where the activity should be displayed.

6   If there are follow-up items from previous trips, review them:

   a   In the Current Trip Follow-Up Items list, from the drop-down menu, select All Follow-Up Items.

      This displays all follow-up issues for that site (open and closed; past, present, and future).

b Click Filter.

This displays all the open-to-date follow-up items and any follow-up items that were closed between completed dates of the last trip and the current trip.

To print or email a trip report

1 Navigate to the Site Visits screen.

2 In the Site Visits list, click the hyperlink in the Visit Start field of the visit for which you want to print the trip report.

The Trip Report view is displayed.

3 Click the Reports button and select and run the Trip Report report.

This opens the Siebel Report Viewer.

4 Print, email, or save the report.

For more information about the Siebel Report Viewer, see *Siebel Fundamentals.*

Completing a Trip Report After a Site Visit (End User)

After the site visit, the end users record details of their trips, such as:

■ Which of the planned activities were completed

■ What additional activities were carried out

■ Which site personnel they met

■ Any follow-up items arising from the trip

■ Comments to 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 will want to create a static report at the completion of the trip, 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 trip report

1 Navigate to the Trip Report view and select the trip report that you want to complete.

For details on how to do this, see .

2 Complete or edit fields in the Trip Report form. See also Step 3 on page 342.

Some fields are described in the following table.

Field	Comments
Attendees	The contacts (site personnel) whom you met during the visit.
Completed	The date and time on which the trip report is completed. It is important that this date be filled in because the filter in the All Follow-Up Items list uses this date to determine which closed follow-up items to display (Step 6 on page 342). This field becomes required when the Visit Status is changed to Done.
Trip Report Status	The status of the trip report.

3 In the CheckList list, complete the Status and Comments fields for planned activities and add any unplanned activities that you may have carried out.

4 In the Current Trip Follow-Up Items list, add any follow-up activities resulting from the site visit.

5 In the Current Trip Follow-Up Items list, from the drop-down menu, select All Follow-Up Items and click Filter to display all open follow-up items and those closed between the current and previous trip.

6 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. It is important that this date be filled in. The filter in the All Follow-Up Items list uses this date to determine which closed follow-up items to display (Step 6 on page 342).
Status	This field automatically changes to Done when a completed date is entered for the item.

7 When all the above tasks have been completed and the trip report is ready to be submitted for review, you should change the value of the Trip Report Status to Submitted. This submits the report to the study manager for approval.

To create a case report form tracking activity
NOTE: The Case Report Forms Tracking view is only available for site visits of type Monitoring, Unscheduled, or Close-out.

1 Navigate to the Trip Report view.

2 In the Case Report Forms Tracking view, create a new record.

3 Click the select button in the Visit field, select a subject and visit in the Pick Subject and Visits dialog box, and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Retrieved	This field is checked when the CRA retrieves the case report forms from the site.
Source Document Verified	This field is checked when the case report form has been verified from the source document.

Approving Trip Reports

At various times during a trial, study managers need to review and approve trip reports completed by CRAs. To do this, the study managers use the Site Visits view and query for trip reports with a status of Submitted.

To approve trip reports

1 Navigate to the Site Visits screen.

2 In the sites list, click the drop-down list and select My Team's Site Visits.

All site visits for your team are displayed.

3 Query the list for site visits whose status is set to Submitted.

4 For each report, drill down on the hyperlink in the Visit Start field.

The Trip Report view is displayed.

5 Review the report and change the Trip Report Status to Approved. The Site Visit record and the Trip Report become read only.

If you set the Trip Report Status to Rejected, the CRA will have the opportunity to revise the report and then resubmit it for approval.

To distribute and archive a trip report

1 Follow Step 1 on page 343 to Step 3 on page 343 to create a report in the Siebel Report Viewer.

2 From within the Siebel Report Viewer, email the report, for example, to colleagues and to a manager for approval.

3 From within the Siebel Report Viewer, save the report as an ROI file and then close the Siebel Report Viewer.

For more information about the Siebel Report Viewer, see *Siebel Fundamentals.*

4 Navigate to the Site Management screen > Protocol Site List view.

5 Drill down on the Site #.

6 Click the Attachments view tab.

Add the ROI file as an attachment to the site record.

22 Managing Clinical Projects

This chapter covers the following topics:

About Managing Clinical Projects

This chapter is meant to be used as a supplement to the documentation in *Siebel Project and Resource Management Administration Guide* (in the chapter about projects management) and *Siebel Applications Administration Guide* (in the chapter about professional services).

Siebel Clinical Projects is designed to help project managers manage clinical trial projects. 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 scenario is an example process performed by the administrator and the project manager (PM) for the clinical trial. Your company may follow a different process according to its business requirements.

The PM works for a large clinical research organization (CRO) 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 clinical trial project.

Setup and Staffing

First, the PM enters some basic information about the project into Siebel Clinical and determines which employees should have visibility to the project data by entering them in the project access list.

To optimize the resource assignment, the PM first enters the resource requirements in the team workbook and then uses Siebel Assignment Manager to help with the staffing. The PM 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 may need some subcontractors to complete certain aspects of the project. Because the subcontractors are paid on an hourly rate, the PM associates the appropriate billing rate list to the project. The PM also needs to 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.

Tasks, Activities, and Risks

Milestones can be set as tasks or activities. The PM can create them within Siebel Clinical Projects. Each Siebel activity has a budget and the actual costs of these activities are updated as the project progresses. Periodically, the PM 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 may 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 needs to carry out in support of projects depends upon which features of the Projects will be used by the organization. You may not need to perform all the procedures listed here. These tasks must occur before the project manager creates the project:

- "Creating a Project Activity Template" on page 349. These templates are used by many project managers carrying out similar clinical trials.

- "About Setting Up Employee Profiles" on page 349. 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 350. The position types and rate lists are required to allow subcontractors (and employees) to bill the project for their time.

- "Creating a Project (End User)" on page 351.

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 may be carried out according to your company's business needs:

■ "Creating a Project (End User)" on page 351.

■ "Associating People and Accounts with Projects (End User)" on page 351. Give employees access to the project; add contacts and accounts to the project's team workbook.

■ "Creating Activities and Tasks for a Project (End User)" on page 353.

■ "Monitoring Project Costs (End User)" on page 354.

■ "Managing Risk (End User)" on page 354. Document project risks and resolution activities.

Creating a Project Activity Template

Activities can be created within (Siebel) Projects screen. If the study managers are primarily entering activities through the Projects screen, then creating project activity templates will be advantageous.

Typically, the administrator prepares a number of project templates, perhaps each designed for a different stage in the life of a study.

The project is an activity template of type "Project." Other activity templates used in Siebel Clinical are subject visit templates ("Defining a Subject Visit Template" on page 295), clinical site templates ("Creating a Clinical Protocol Site Template" on page 316), trip report templates ("Creating a Trip Report Template" on page 341), and contact assessment templates ("Creating Contact and Account Assessment Templates" on page 316).

To create a project activity template

■ Create an activity template of type Project.

The Protocol Type field is optional: a project 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*.

About Setting Up Employee Profiles

The end user may 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 on 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.

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, position types and rate lists should be set.

Position types, such as consultant, are set up as products and flagged 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*.

To create position types as products

1 Navigate to the Administration - Product screen > 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	Check this field.

To create a rate list

1 Navigate to the Administration - Pricing screen > 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 hyperlink.

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 a Project (End User)

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, the application does not prevent the association of a protocol to multiple projects. In this case, costs associated with payments to sites are rolled up to each project.

To create a project

1 Navigate to the Projects screen > List view.

2 In the Projects 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.
Protocol #	All protocols in the database can be selected from this drop-down menu. 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, enter it in this field. Use the more button if this field is not visible. (See "Setting Up Position Types and Rate Lists for Billing" on page 350.)

Associating People and Accounts with Projects (End User)

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's team workbook. (For more information about adding subcontractors, see *Siebel Project and Resource Management Administration Guide*.)

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, 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 projects management, see *Siebel Project and Resource Management Administration Guide*.

To add a contact to a project using the Organization Analysis view

1 Navigate to the Projects screen > List view.

2 Drill down on the Name of a project.

3 Click the Organization Analysis view tab.

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.

To add a partner account to a project

1 Navigate to the Projects screen > List view.

2 Drill down on the Name of a project.

3 Click the Partners view tab.

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 account site, a unique identifier for the account. It is not related to the sites where clinical trials are carried out.

Creating Activities and Tasks for a Project (End User)

Activities can be created for the project in a variety of ways:

■ Enter activities in the Activities view.

■ Generate activities in the Activity Plan view by applying a project activity template. (See "To create an activity for a project using a project activity template" on page 353.)

■ Enter activities manually in the Activity Plan view. These activities must be associated with an activity plan based on a template.

■ Create a task in the Task view and associate activities with the task. (See "To create a task and associate activities to it" on page 353.)

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 project activity templates. They can only be created manually from within the Project Task Activity view. A standalone activity cannot be added to a task, nor can a task activity be disassociated from the task.

For more information, see about creating activities and tasks for projects management in *Siebel Project and Resource Management Administration Guide*.

To create an activity for a project using a project activity template

1 Navigate to the Projects screen > List view.

2 Drill down on the Name of the project.

3 Click the Activity Plans view tab.

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 subview.

NOTE: Activities can also be created manually in the Activities view.

To create a task and associate activities to it

1 Navigate to the Projects screen > List view.

2 Drill down on the Name of the project.

3   Click the Tasks view tab.

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

5   In the Tasks list, drill down on the Name hyperlink.

6   In the Activities list, create a new record, and complete the necessary fields.

Monitoring Project Costs (End User)

The Cost view provides the end user with a valuable summary of all costs associated with a particular project and protocol.

The cost items are displayed in three 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 form.

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.

To view costs associated with a project

1   Navigate to the Projects screen > List view.

2   Drill down on the Name of the project.

3   Click the Costs view tab.

4   Click a hyperlink in the Clinical Payments or Project Tasks list to see the activities associated with a cost item.

Managing Risk (End User)

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 projects management, see *Siebel Project and Resource Management Administration Guide*.

To create risk and resolution activities for a project

1   Navigate to the Projects screen > List view.

2 Drill down on the Name of the project.

3 Click the Risks view tab.

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

5 In the Risks list, drill down on the Name hyperlink.

6 In the Resolution Activities list, create a new record, and complete the necessary fields.

About Views in the Projects Screen

There are many views in the Projects screen for the standard Siebel Clinical application. Many implementations may choose to use only a subset of these views. Refer to Table 29 for a brief description of each of the views that are available in the Projects screen.

Table 29. Views in the Projects Screen

View	Comments
Access	Use this view to provide project visibility. 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 may have been created manually or by project activity templates. Activities belonging to tasks do not appear in this view.
Activity Plans	Use this view to generate activities from project activity templates. 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*.

Table 29.   Views in the Projects Screen

View	Comments
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.
Partners	Use this view to maintain a list of partner accounts associated with the project.
	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.
	Because the Partners, Subcontractors, and Clinical Contacts views contain account information, depending on your business process, you may use one or more of these views to keep track of accounts associated with 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. (See also "Partners" on page 356 in this table.)
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, see about time sheets and expense reporting in *Siebel Project and Resource Management Administration Guide*.

23 Capturing Adverse Events and Complaints

This chapter covers the following topics:

About Adverse Events and Complaints Management

Adverse events and complaints management (AECM) is an important process in the regulated medical device and pharmaceutical industries. The FDA in the USA and similar agencies in other countries have specific requirements for capturing, investigating, reporting, and resolving adverse events and complaints on medical devices and drugs.

Poor handling of adverse events and complaints can lead to non-compliance penalties such as warning letters, restrictions, fines, and recalls.

Siebel Adverse Events and Complaints Management

Siebel Adverse Events and Complaints Management (Siebel AECM) is designed to manage the life cycle of an adverse event or a medical product complaint. Users collaborate and capture all of the necessary data to track the complaint through investigation to corrective action and generate the required regulatory reports. Table 30 illustrates such a life cycle. Each step in the process represents a chapter in this book.

Table 30.   Complaints Process Flow

Process	Roles	Typical Activities
1 Capture adverse event or complaint	Call Center Agent	■ Capture and verify customer contact information ■ Identify whether service request is potential adverse event or complaint ■ Capture adverse event and patient consequences; identify devices ■ Diagnose and solve problem ■ Assess the problem ■ Dispatch Field Engineer ■ Create RMA and replacement orders
2 Investigate adverse event or complaint	Quality or Regulatory Agency	■ Review information for correctness ■ Identify FDA codes, other similar agencies codes, and internal codes to label the problem ■ Assess whether reportable ■ Perform trend analysis ■ Contacts customer for information ■ Coordinate investigation
3 Manage product analysis and CAPA	Product Analysis and CAPA Team	■ Make sure receipt of product ■ Decontaminate devices ■ Ship devices to manufacturing or third party for analysis ■ Review complaints ■ Analyze the devices and records results ■ Approve analysis ■ Submit requests for CAPA

Table 30.   Complaints Process Flow

Process	Roles	Typical Activities
4 Report to regulatory agency	Quality or Regulatory Agency	■ Verify and approve analysis ■ Assess whether problem is reportable ■ Complete information for regulatory reports ■ Generate and submit reports ■ Submit supplemental and annual reports
5 Manage customer communication	Call Center Agent or Quality or Regulatory Agency	■ Notify customer about investigation ■ Identify all customers with potentially defective devices ■ Execute product recalls ■ Create communication materials for sales and regional offices
6 Close adverse event or complaint	Quality or Regulatory Agency	■ Verify that all necessary activities are completed ■ Initiate complaint closure approval ■ Close complaint

Where to Find More Information

The following chapters describe other aspects of the complaints and adverse events management process:

- Chapter 24, "Investigating Adverse Events and Complaints"

- Chapter 25, "Recording Product Analysis for AECM"

- Chapter 26, "Managing CAPAs"

- Chapter 27, "Regulatory Reporting"

- Chapter 29, "Communicating with Customers for AECM"

- Chapter 28, "Closing Adverse Events and Complaints"

Integration with Other Siebel Applications

Siebel AECM is integrated with Siebel Call Center, Siebel Sales, Siebel Field Service, and Siebel Clinical. This allows the flexibility to share varying levels of visibility to adverse event or complaint details, investigation status, and corrective action across different users and functions within the organization. The Siebel Audit Trail functionality keeps a record of changes made to records throughout the course of the investigation.

About Capturing Adverse Events and Complaints

This chapter describes capturing information about a medical product complaint or adverse event as a service request and then escalating that complaint as a product issue for further investigation.

One of the goals in capturing such information is to identify complaints accurately, making sure that all valid complaints are identified while at the same time minimizing the number of false-positive complaints that are escalated for investigation.

Siebel AECM Terms

Table 31 lists some important terms and abbreviations used in Siebel AECM.

Table 31.   Siebel AECM Terms

Term	Description
Adverse Event	An adverse event is a customer event associated with a product malfunction or adverse reaction to a pharmaceutical. It can be initially captured as a service request and then escalated to a product issue (which becomes the complaint file associated with the event). In some places in this text, *complaints* includes both adverse events and complaints.
AECM	Adverse Events and Complaints Management
Call Center Agent	Another name for this job title is customer service agent. This agent is trained to identify a product complaint and distinguish it from a normal service or information request.
CAPA	Corrective and preventive action. This specifies the changes in product or process needed to resolve the root cause of the adverse event or complaint. For example, a CAPA could be a request from the analysis team for the correction of the manufacturing, design, or process flaw that caused the initial adverse event or complaint.
Complaint	A complaint is a customer event associated with a product malfunction. It can be initially captured as a service request and then escalated to a product issue (which becomes the complaint file associated with the event). In some places in this text, *complaints* includes both adverse events and complaints.
Initial regulatory report	The first report to a regulatory agency regarding a product complaint or an adverse event.
MDR	Medical device reports are required to be submitted to a regulatory agency when an adverse event or complaint is determined to be reportable.
MDV	Medical Device Vigilance

Table 31.   Siebel AECM Terms

Term	Description
Medical Product	Examples of medical products are capital equipment, disposables, reagents, implanted devices, and pharmaceuticals.
MedWatch 3500A	U.S. Food and Drug Administration (FDA) report for mandatory reporting of adverse reactions and medical product problems by drug and biologic manufacturers and packers and by medical device manufacturers, distributors, importers, and user-facilities.
MedWatch 3500A Supplemental	A 3500A report sent as a follow-up to an initial 3500A report.
NCA	National Competent Authorities. Regulatory reports are often sent to these agencies. These country-specific agencies also report adverse events to each other.
Product Issue	A product issue is the adverse event or complaint file. The product issue is often first captured as a service request record. Then the information is transferred to a product issue record, which becomes the adverse event or complaint file.
Product Issue Assessments	A product issue assessment evaluates a product issue on defined criteria. For example, a product issue assessment can be used to determine whether the product issue should be reported to a regulatory agency.
Quality Manager	Other names for this job title are complaint investigator, regulatory affairs representative, safety and regulator manager, regulatory liaison, and quality group liaison.
Regulatory report	There are four types of regulatory reports supported by Siebel AECM (preconfigured): ■ MedWatch 3500A ■ MedWatch 3500A Supplemental ■ MDV Initial ■ MDV Follow-up **Regulatory report record.** The record in the Regulatory reports screen. **Regulatory report.** The report created using data contained in the regulatory report record. Other regulatory reports like CIOMS can be configured using other reporting tools.
Siebel AECM	The Siebel Adverse Events and Complaints Management module.
Signature capture	See User authentication.

Table 31. Siebel AECM Terms

Term	Description
SmartScripts	A SmartScript is a collection of predefined questions, answers, and branches that can be used to guide the quality manager through potentially complex decision making processes to arrive at a solution to a problem or query. For more information about SmartScripts, see *Siebel SmartScript Administration Guide*.
Inbox	The Inbox allows managers and other employees to view and approve items (of multiple types) from one screen. In Siebel AECM, the Inbox is used to approve product analyses. For more information, see *Siebel Applications Administration Guide*.
User authentication	The user authorization check captures and verifies the user's name and password. This user authentication is controlled by the LS Medical User Verification workflow. **NOTE:** User authentication is sometimes called signature capture, but should not be confused with electronic signature capture on mobile devices or tablet PCs used elsewhere in the Siebel Life Sciences application.

Scenario for Capturing and Escalating Adverse Events and Complaints

This scenario is an example workflow performed by the Siebel administrator and a call center agent. Your company may follow a different workflow according to its business requirements.

This workflow is designed to illustrate the functionality of Siebel AECM.

Introduction

A medical manufacturing company makes capital equipment for use in hospitals. The company has recently released a new blood analyzer system. The company manufactures both the instrument and the consumables.

The Siebel Administrator

In preparation for the new blood analyzer being released on the market, the Siebel administrator performs a number of preparatory administration tasks so that the product and all necessary codes and lot numbers are set up in the Siebel application. In case the company has to file a 3500A report, the administrator refers to the MedWatch coding manual and sets up appropriate codes for event problems and evaluation.

The Siebel administrator also sets up the activity templates used by the call center agents to create activity plans for handling customer complaints. The Siebel administrator needs to have all these ready before the call center agents begin to receive calls about the product.

When troubleshooting and problem resolution information becomes available for the new blood analyzer, the Siebel administrator creates solution records that contain this troubleshooting information.

The Call Center Agent

A call center agent takes a customer call about a failing blood analyzer system.

In addressing the customer's complaint, the call center agent does the following:

■ Enters a service request, recording details about the product and the failure.

■ Works with the customer to troubleshoot the problem, searching the solution database for possible solutions. In this case, he finds a solution document about running a diagnostic test. The test does not resolve the problem, but it does indicate the repair that is needed.

■ Creates an activity plan—a list of predefined activities—to dispatch a service engineer to the customer site.

■ Dispatches a service engineer to make a repair to the analyzer.

■ Sets up an RMA (return materials authorization) to return the cartridge and reagents that were in use when the analyzer failed.

■ Reviews the report of the work done by the field engineer.

The call center agent has been trained to identify calls as potential complaints. He recognizes that this customer's problem needs to be escalated as a product issue. Before escalating, he reviews the information entered in the service request, making sure that the service request is classified correctly, for example, with accurate types and codes. When the call center agent creates the product issue from the service request record, the appropriate data is transferred from the service request to the product issue record.

Process of Capturing and Escalating Adverse Events and Complaints

This example process represents the tasks that are carried out in the Scenario for Capturing and Escalating Adverse Events and Complaints on page 362.

Administrator Procedures

The Siebel administrator sets up the service request functionality so that call center agents can capture adverse events and complaints. To do this, the Siebel administrator performs the following tasks:

■ Confirming Standard Setup for Service Requests on page 364

■ Setting Up Codes on page 365

■ Setting Up Lot Numbers for Medical Products on page 369

End-User Procedures

To capture and escalate adverse events and complaints, end users perform the following tasks:

1 Capturing Adverse Events and Complaints as Service Requests (End User) on page 369

2 Escalating Adverse Events and Complaints as Product Issues (End User) on page 371

3 Adding Complaint-Specific Information to Product Issues (End User) on page 372

Confirming Standard Setup for Service Requests

Before service requests can be logged against products, the Siebel administrator sets up the following:

■ **Products.** Records need to be set up for products against which there may be adverse events and complaints.

■ **Product Lines and Categories.** Product lines and categories can both be associated with codes. If you configure your application to filter codes according to product line or category, make sure to set these up. For more about codes, see "Setting Up Codes" on page 365.

■ **Assets.** Asset records should be set up for devices with serial numbers. Assets do not need to be set up for items such as consumables.

■ **Activity Templates of type Service Request.** Call center agents use activity templates to create service request activity plans—sets of predefined and scheduled activities associated with service requests.

■ **Solutions.** Many service requests are similar to previously addressed issues. Solution documents contain information about previously resolved requests.

■ **LOVs for Type, Area, and Sub Area.** These fields are particularly important for classifying service requests. You can customize these LOVs.

You might have already completed these setup tasks for other reasons in Siebel Life Sciences. These setup tasks are standard in many Siebel applications and are not unique to Siebel Life Sciences.

TIP: To aid call center agents with information gathering and problem diagnosis associated with adverse events and complaints, you may wish to set up SmartScripts. For more information about SmartScripts, see *Siebel SmartScript Administration Guide.*

This task is a step in "Process of Capturing and Escalating Adverse Events and Complaints" on page 363.

Setting up Products, Product Lines, Categories, Assets, Activity Templates, Solutions, and LOVs

For information, consult Table 32.

Table 32.   Setting up Products, Product Lines, Categories, Assets, Activity Templates, Solutions, and LOVs

To Set Up...	Use This Screen...	And for More Information, See...
Products	Product Administration	"Defining External Products" on page 81 and *Siebel Product Administration Guide*
Product Lines	Product Administration > Product Lines	*Siebel Product Administration Guide*
Categories	Catalog Administration	"Adding Products to Catalogs" on page 95
Assets	Assets	*Siebel Field Service Guide*, *Siebel Communications Guide*
Activity Plans of type Service Request	Data Administration > Activity Templates	*Siebel Field Service Guide*
Solutions	Solution Administration	*Siebel Field Service Guide*
LOVs	Data Administration > List of Values	*Siebel Applications Administration Guide*

Setting Up Codes

Codes allow you to codify many aspects of the AECM process. For example, codes are used to categorize the service request that triggers the adverse event or complaint, and codes are used to categorize the corrective actions initiated at the end of a complaint's life cycle.

Multiple codes and sometimes codes of multiple types can be specified in one code field.

Think carefully when designing and setting up your code system. Codes are used as search criteria for service requests and product issues.

According to your business needs, you may decide to use:

■ Industry codes such as FDA patient, device, method, results, and conclusion codes required for the MedWatch 3500A form

■ Company-specific codes

■ A combination of industry and company-specific codes

Table 33 lists where code fields appear in the Siebel AECM module.

Table 33.   Code Fields in the Siebel AECM Module

Screen	View	Field Name	Notes
Service Requests	More Info	Codes	None
Product Issues	More Info	Codes	Copied from the service request when a product issue is created. Codes from the service request record are copied to this field when a product issue is created from a service request.
	Corrective Actions	Codes	Typically, codes of type Corrective Action are entered in this field, although any type of code can be entered.
	Investigation	Method Codes	Only codes of type Method can be entered.
		Result Codes	Only codes of type Result can be entered.
		Conclusion Codes	Only codes of type Conclusion can be entered.
		Non-Evaluation Codes	Only codes of type Non-Evaluation can be entered.
	Importer	Patient Codes	Only codes of type Patient can be entered.
	MDV	Device Codes	Only codes of type Device can be entered.
Repairs	More Info	Codes	Typically, codes of type Product Analysis are entered in this field, although any type of code can be entered.
Corrective Actions	More Info	Codes	Typically, codes of type Corrective Action are entered in this field, although any type of code can be entered.

Table 33.   Code Fields in the Siebel AECM Module

Screen	View	Field Name	Notes
Regulatory Reports	More Info	Method Codes	Only codes of type Method can be entered. Copied from the product issue when a regulatory report is populated.
		Result Codes	Only codes of type Result can be entered. Copied from the product issue when a regulatory report is populated.
		Conclusion Codes	Only codes of type Conclusion can be entered. Copied from the product issue when a regulatory report is populated.
		Non-Evaluation Codes	Only codes of type Non-Evaluation can be entered. Copied from the product issue when a regulatory report is populated.
Regulatory Reports	Importer MDV	Patient Codes	Only codes of type Patient can be entered. Copied from the product issue when a regulatory report is populated.
		Device Codes	Only codes of type Device can be entered. Copied from the product issue when a regulatory report is populated.
Activities	Items	Code	Single value field.

An Example

When you set up codes, you can enter values for Product, Product Line, Category, Type, Area, and Sub Area that are associated with the code. Call center agents can use these values to search for and identify the correct code for a service request.

Table 34 is an example of the field values used to describe one code.

Table 34.   Example Fields for a Code Classifying a Pump Error on a Blood Analyzer

Field	Example Value
Name	Error 333
Description	Blood analyzer pump overflow.
Code Type	Device
Product	Blood Analyzer Model 350, Blood Analyzer Model 373 [1]

Table 34.   Example Fields for a Code Classifying a Pump Error on a Blood Analyzer

Field	Example Value
Product Line	Blood analyzer, Dialysis system [1]
Category	Nephrology
Type	Potential Complaint
Area	Software
Sub Area	Pump timing

1.   Field can have multiple values.

How to Set Up Codes

Create the codes needed to classify your company's adverse events and complaints.

Codes are needed for the procedures in this chapter and for procedures in the following AECM chapters.

This task is a step in .

To set up codes

1   Navigate to Administration - Service screen > Code Administration view.

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

Some fields are described in the following table.

Field	Comments
Name	Enter the name for the code. Typically this is a number or a letter number combination.
Code Type	Examples are: Method, Result, Conclusion, Device, Patient.
Product	Multiple products can be associated with a code.
Product Line	Multiple product lines can be associated with a code.
Category	A grouping of products. Only one category can be associated to a code. To set up categories, see *Siebel Order Management Guide*.
Type	Use to categorize the type of service request, for example, as a potential complaint. This is the same LOV used in service request and product issue records.
Area	The Type field constrains this drop-down list.
Sub Area	The Area field constrains this drop-down list.

Setting Up Lot Numbers for Medical Products

Create lot numbers for all batches of products that are tracked by lot number.

Lot numbers for Siebel Medical and Siebel Pharma are the same except that:

For...	Lot numbers are set up in ...
Siebel Medical	Administration - Service screen > Lot Administration view
Siebel Pharma	Administration - Samples screen > Lot Setup view

This task is a step in .

To set up lot numbers

1 Navigate to Administration - Service screen > Lot Administration view.

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

   Some fields are described in the following table.

Field	Comments
Expiration Date	This information can be used for recalls of expired products.
Effective Start Date	The date of manufacture, the date on which the product was received, or another date defined by your company.
Lot #	Enter an unique value that corresponds to the lot number printed on the label of the product.
Product	The name of the product with which this lot number is affiliated. For more information, see "Defining Internal Products" on page 82 paying specific attention to Table 11 on page 83 and Table 12 on page 84.
Product Level	Applies only to drug samples.

Capturing Adverse Events and Complaints as Service Requests (End User)

The creation of the service request by the call center agent is often the first step in AECM.

The following procedure assumes that you are familiar with the service request screen and associated functionality. (For information about the service request screen, see *Siebel Field Service Guide*.)

This task is a step in .

To create a service request

1 Navigate to the Service Requests screen > Service Request List view.

2 In the Service Request list, create a new record, and complete the necessary fields, such as account, contact, product, summary, and description.

Some fields are described in the following table.

Field	Comments
Codes	Codes to describe or categorize the service request.
Lot #	Select an existing lot number or enter a new lot number.
	You can enter a *new* lot number in one of two ways:
	■ Formally enter a new lot number using the New button on the Lot Setup dialog box.
	■ Use the Lot # field as a simple text field. If you enter a Lot # this way, the value is only stored in this product issue record and is not checked against a table of valid lot numbers. This does not create a new lot # record in the Lot Administration view.
Product Issue	This is automatically flagged if the service request is escalated to a product issue.
Type	Use this field to categorize the type of service request, for example, as a potential complaint.
Area	The Type field constrains this drop-down list.
Sub Area	The Area field constrains this drop-down list.

3 Search for a solution to the service request:

a Drill down on a record.

b Click the Solutions view tab.

c Create a new record to the Solutions list.

d In the Add Solutions dialog box, query for a solution and add it.

e In the Solutions list, drill down on the Name field to see details about the solution.

For more information about solutions, see *Siebel Field Service Guide*.

4 Set up activities for the service request using an activity plan. For example, the appointments the field service engineer can be set up from the Activities view.

For more information about field service activities, see *Siebel Field Service Guide*.

5 Dispatch a field engineer.

For more information about dispatch and scheduling, see *Siebel Field Service Guide*.

6 If products or materials need to be returned for analysis, set up an RMA order.

For more information about shipping and receiving, see *Siebel Field Service Guide*.

Escalating Adverse Events and Complaints as Product Issues (End User)

A valid adverse event or complaint that is first recorded as a service request should be transferred to a product issue record. As a product issue, it can be investigated by the quality manager. This allows the Call Center to retain ownership of the service request and the Quality team to manage the investigation and processing of the complaint.

NOTE: Only one product issue can be created from a given service request using the Create Product Issue button. Additional product issues for a service request can be created using the Create Related PI button in the Product Issues screen.

This procedure describes creating a product issue from the Service Requests screen. Product issue records can also be created in the Product Issues screen and the Site Management screen.

TIP: To aid call center agents with information gathering and problem diagnosis associated with adverse events and complaints, you may wish to set up SmartScripts. For more information about SmartScripts, see *Siebel SmartScript Administration Guide*.

This task is a step in .

To create a product issue from a service request

1 Navigate to the Service Requests screen > Service Request List view.

2 Select the service request for which you want to create a product issue.

3 Click Create Product Issue.

This starts the Create a Product Issue from a Service Request workflow that:

■ Makes these fields in the Service Request read-only:

Account	Last Name	First Name	Product

■ Creates a product issue record from a Service Request.

■ Copies these fields from the service request to the new product issue:

Account	Type	Product
Summary	Area	Codes
Last Name	Sub Area	Asset #
First Name	Priority	Lot #
Description	Severity	

■ Takes you to the Product Issues screen.

For more information about the workflow, see "About Configuring Adverse Events and Complaints Capture" on page 373.

4 Complete the necessary fields in the product issue record.

Typically, call center agents enter data such as the event date, the outcome, and whether the product was returned. If more than one product is involved with the adverse event or complaint, it is entered in the product issue record. (Only one product can be associated with a service request record.)

Adding Complaint-Specific Information to Product Issues (End User)

The call center agent enters complaint-specific information to the product issue record, for example, patient details. Information about only one patient can be associated with a product issue.

This task is a step in "Process of Capturing and Escalating Adverse Events and Complaints" on page 363.

To add information about the patient to the Product Issue record

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

NOTE: If you created the product issue using the Create Product Issue button in the Service Requests screen, the workflow takes you to this view.

3 Click the Patient view tab.

4 Complete the fields in the Patient form.

Some fields are described in the following table.

Field	Comments	Mapping to 3500A Form
Patient Identifier	None	A1
Gender	None	A3
Age	None	A2
Date of Birth	None	A2
Weight	None	A4
U/M	Unit of measurement for weight	A4

About Configuring Adverse Events and Complaints Capture

There are two aspects of the Create Product Issue button that you can configure:

■   The Create a Product Issue from a Service Request Workflow

■   The fields that are copied from the Service Request to the Product Issue record

Create a Product Issue from a Service Request Workflow

This workflow (LS Medical Create PI from SR) is initiated from the Create Product Issue button on the Service Requests screen.

The workflow appears in Figure 13.
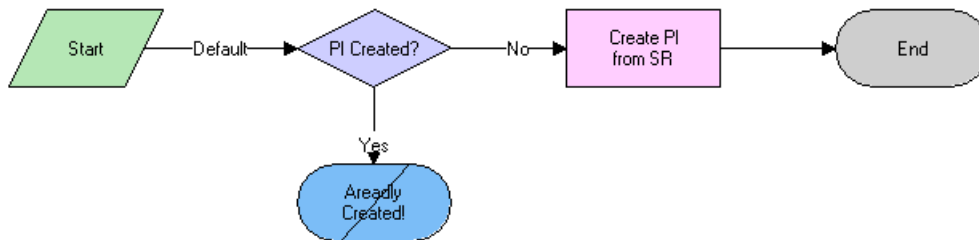
Figure 13. LS Medical Create PI from SR Workflow

The workflow does the following steps:

1   Checks if a product issue has already been created from this service request. If it has, the workflow ends. (Only one product issue can be created from a service request using the Create Product Issue button.)

2   Creates a new product issue.

3   Copies data from the service request to the product issue.

4   Goes to the Product Issue screen > More Info view.

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

Changing Which Fields Are Copied to the Product Issue

When the Create Product Issue button is used to create a product issue record from a service request record, data from various fields are copied from the service request record to the new product issue record.

To change which fields are copied when a product issue is created

■   Use the Data Transfer Utilities to edit the LS Medical Create PI from SR data map object.

For information about the Data Transfer Utilities, see *Siebel Finance Guide*.

24 Investigating Adverse Events and Complaints

This chapter covers the following topics:

About Investigating Adverse Events and Complaints

This chapter describes review and investigation of a product complaint or adverse event using the Siebel Adverse Events and Complaints Management (Siebel AECM) module. This typically involves entering more information about the product issue, determining if the issue should be reported, and creating an activity plan for researching and addressing the issue.

Where to Find More Information
The following chapters describe other aspects of the complaints and adverse events management process:

Scenario for Complaint Investigation

This scenario is an example process performed by the Siebel administrator and the quality manager. Your company may follow a different process according to its business requirements.

This process is designed to illustrate the functionality of the Siebel AECM.

The Siebel Administrator

The administrator sets up the assessment and activity templates that the quality manager uses in the course of investigating product issues.

Before creating templates, the administrator consults with the quality manager who thoroughly understands the company's business processes. The quality manager suggests the text for the templates that administrator sets up and reviews the templates before roll out.

The Quality Manager

The quality manager reviews the complaints assigned to her. Her job is to determine if an investigation of the complaint is required and if the complaint needs to be reported to a regulatory agency.

The quality manager notices that a new product issue has been added to her queue. This complaint was initially reported as a service request and was escalated by a call center agent. It concerns a failure in a blood analyzer.

Upon taking ownership, the quality manager reviews the service request associated with the product issue, including the work done by the service engineer.

Next, the quality manager contacts the customer and obtains more details about the issue. She discovers that there are two product issues associated with this incident: the cartridge may have been faulty as reported in the service request, but also the third-party reagents used may have exacerbated the problem. The quality manager creates a second product issue to investigate the reagents.

To help guide the investigation and keep it on schedule, the quality manager applies an activity template that generates an activity plan — a list of activities that need to be carried out, some by her and some by other employees.

Her next step is to determine if the product issues are reportable. She answers the series of questions in the Assessments view and looks at the score. Scores of above 75% indicate that the product issues should be reported.

After completing the review, the quality manager changes the status of the product issue records to Review Complete. This locks down some data in the complaint file and makes other data read-only.

Process of Adverse Events and Complaints Investigation

This example process represents the tasks that are carried out in the Scenario for Complaint Investigation on page 376.

Administrator Procedures

■ Creating Product Issue Assessment Templates on page 377

■ Creating Product Issue Activity Templates on page 377

End-User Procedures

■ Reviewing and Editing the Product Issues (End User) on page 378

■ Creating Multiple Product Issues Related to One Service Request (End User) on page 383

■ Creating Product Issue Activity Plans (End User) on page 384

■ Assessing if a Product Issue Is Reportable (End User) on page 385

■ Completing Adverse Events and Complaints Reviews (End User) on page 385

Creating Product Issue Assessment Templates

The purpose of the assessment is to quantify an evaluation of the product issue. The assessment template is made up of a series of questions about the product issue with an associated list of possible answers. Each question and each answer is assigned a weighting from which a single score is calculated.

This value can be used to indicate the risk associated with the issue or whether the issue should be reported to the regulatory agency.

This task is a step in "Process of Adverse Events and Complaints Investigation" on page 377.

To create an assessment template

■ Refer to *Siebel Applications Administration Guide* for information about how to create assessment templates. Make sure to set the template type to Product Issue.

Creating Product Issue Activity Templates

Product issue activity templates are used to create a standard set of activities that the quality manager and other employees do to investigate product issues.

This task is a step in "Process of Adverse Events and Complaints Investigation" on page 377.

To create a product issue activity template

1   Navigate to the Administration - Data screen > Activity Templates view.

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

   a   Set the Type field to Product Issue.

   b   Leave these fields blank: Sales Stage, Sales Method, Protocol Title; they do not apply to product issue activities.

3   Associate individual activities with the template, as described in *Siebel Applications Administration Guide.*

NOTE: Lead times for product issue activities are defined as the amount of time between the start date for an activity plan and the date that the selected activity should start.

Reviewing and Editing the Product Issues (End User)

Early in the investigation, the quality manager reviews, updates, and adds information to the product issue record. This record becomes the adverse event or complaint file for the investigation.

There are many fields in the product issue record. Some are filled in by the call center agent, some automatically, and others by the quality manager. Of particular importance are those fields that are used to populate the regulatory reports. For more information, see Chapter 27, "Regulatory Reporting."

This task is a step in "Process of Adverse Events and Complaints Investigation" on page 377.

To review and edit a product issue

1   Navigate to the Product Issues screen > Product Issue List view.

2   Select a product issue.

3   Edit fields in the Product Issues list and form as required.

   Some fields are described in the following table.

   (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
Account	The name of the account associated with the product issue.	E1
Address	Account address - street address.	E1

Field	Comments	Mapping to 3500A Form
Alert Age	The number of days since the product issue was identified as reportable. If an initial report has been filed, the alert age is the number of days that the product issue was marked reportable before the report was filed.	None
Alert Date	The date when a representative of a company becomes aware that the event needs to be reported. For example, when: ■ A call center agent captures the adverse event or complaint. ■ An assessment indicates that the event is reportable.	None
Area	The general categorization area for the product issue. This field is constrained by Type.	None
City	Account address - city.	E1
Contacts (Contact Last Name in list)	The last name of the customer contact associated with the product issue. These contacts can also be entered using the Contacts view of the Product Issues screen > Contacts view.	E1
CSN	Customer service number. A unique number to identify the account.	E1
Evaluation	This field appears in the list applet. It also appears in the form in the Investigation view.	None
First Name	The first name of the investigator carrying out a particular clinical trial at a site.	None
First Name (Contact First Name in list)	The first name of the customer contact associated with the product issue.	E1
Investigator	The last name of the investigator carrying out a particular clinical trial at a site. If the product issue is associated with a clinical trial, this field is auto-populated with the last name of the investigator at the protocol site, specified in the Protocol number field.	None
Mfg Report #	This field appears in the list applet. It also appears in the form in the Importer view.	None

Field	Comments	Mapping to 3500A Form
Occupation	Occupation of the contact. This is copied from the value of the Type field in the Contacts screen.	E3
Open Age	The number of days since the product issue was opened, or, if the product issue is closed, this is the number of days that the product issue was open.	None
Phone #	Contact's work phone number.	E1
PI #	Unique number to identify the product issue. It is auto-generated when the product issue is created.	None
Postal Code	Account address - postal code.	E1
Protocol #	Protocol number identifies the clinical trial at a site. If regulatory report is an IND safety report, enter the protocol number.	G6
Provider	Indicates if the contact is a health professional.	E2
Received (Received Date in the list)	The date when a company representative became aware of the event.	None
Reported FDA	Indicates if initial reporter sent a report to the FDA.	E4
SR #	The service request from which the product issue was created.	None
State	Account address - state.	E1
Status	The current status of the product issue. The status of the product issue can be changed by the owner of the product issue, using the Review Complete, Close, and Reopen buttons. Changes to this field are tracked in the Approvals view.	None
Sub Area	This further refines the area categorization. (The Area field constrains this drop-down list.)	None
Sub Status	The Status field constrains this drop-down list.	None

4 In the Event Detail form edit fields as required.

Some fields are described in the following table. (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
Event Type	Describes the type of event.	B1
Event Date	The approximate date of the adverse event.	B3
Description (Event Description in the list)	Detailed description of the event	B5
# Occurrences	Number of times the event occurred before it was reported	None
External Products	List of other medical products (for example, drugs, medical devices) used by patient at the time of the event and dates of use	C10 or D11
Tests/Data	All appropriate relevant test and laboratory findings and dates	B6
Life Threatening	Life Threatening	B2
Disability	Disability	B2
Hospitalization	Hospitalization	B2
Congenital Anomaly	Congenital Anomaly	B2
Relevant History	Relevant history, including preexisting medical conditions	B7
Death	Death	B2
Required Intervention	Required Intervention	B2
Date of Death	Date of Death	B2
Other	Describe the reported outcome if it was not covered in the above selections	B2

5 In the Products list, create records and edit fields as required.

Some fields are described in the following table. (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
Product	The name of the product associated with the event	C1
Lot #	Lot number of the product	C6, D4
Asset #	Asset number for the product	D4
Serial #	Serial number for the asset	D4
Mfg Name	Full name of the manufacturer of the product	D3
Mfg Date	The date the product was manufactured	H4
Expiration Date	Expiration date of the lot or product	C7, D4
Labeled Single Use	Indicates if the device is labeled for single use	H5
Device Operator	Type of person operating or using the suspect medical product on the patient at the time of the event	D5
Device Available	Indicates if the device is available for evaluation by the manufacturer	D10
Return Date	Date that the device was shipped to the manufacturer	D10
Device Type	Generic or common name of the suspect medical device	D2
Reprocessed	Indicate if this is a single-use device that was reprocessed and reused on a patient	D8
Reprocessor	Name and address of the reprocessor of the reused single-use device	D9
NDC#	National drug code #	C9
Part #	Part number	D4
Implant Date	The implant date or best estimate for medical devices that are implanted in the patient	D6
Explant Date	The date or best estimate for medical devices removed from a patient	D7
Street Address	Manufacturer's street address	D3
City	Manufacturer's address: City	D3
Postal Code	Manufacturer's address: Postal Code	D3

Field	Comments	Mapping to 3500A Form
State	Manufacturer's address: State	D3
Model #	Model number	D4
Catalog #	Catalog number	D4
Dose Per Unit	Dosage per unit of drug	C2
Frequency	Frequency of drug administration	C2
Route Used	Route used to administer the drug	C2
Indication	The indication for which the product was prescribed or used in this particular patient	C4
Therapy From Date	The date drug administration was started (or best estimate)	C3
Therapy To Date	The date drug administration was stopped (or best estimate)	C3
Event Abated	Event abated after use stopped or dose reduced	C5
Reintroduce Reoccur	Event reappeared after reintroduction	C8

6 Review any service requests associated with the product issue:

   a Drill down on the product issue record.

   b Click the Service Request view tab.

   c Drill down on the SR #.

Creating Multiple Product Issues Related to One Service Request (End User)

Only one product issue can be created directly from a service request (using the Create Product Issue button on the Service Requests screen). However, in the Product Issues screen, the quality manager can create additional product issues related to the service request and the original product issue.

Here are some examples where multiple product issue records are needed:

■ A medical kit contains a drug and a device. The drug and the device may have caused the event. Separate adverse event and product complaint investigations have to be completed.

■ There are several products involved with the adverse event or complaint and the quality manager wants a unique product issue for each product.

To create a new product issue

1   Navigate to Product Issues screen > Product Issue List view.

2   Drill down on a product issue.

3   Click Create Related PI.

This starts a workflow (LS Medical Product Issue Create Related PI), which creates a new product issue record, copying fields from the current product issue.

For more information about the workflow, see *"About Configuring Create Related PI and Review Complete Buttons" on page 386*.

4   Edit fields in the Event Detail form as required.

5   Enter information about the products associated with the issue in the Products list.

Creating Product Issue Activity Plans (End User)

A product issue activity plan is a list of activities associated with the product issue. The quality manager applies an activity template, suited to the type of product issue being investigated. The activity template sets up predefined activities that the quality manager and others follow to complete the product issue investigation.

This task is a step in *"Process of Adverse Events and Complaints Investigation" on page 377*.

To create activities for product issue investigation using a template

1   Navigate to Product Issues screen > Product Issue List view.

2   Drill down on a product issue.

3   Click the Activity Plans view tab.

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.
Template	Only templates whose type is Product Issue can be selected in this field.

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

Assessing if a Product Issue Is Reportable (End User)

Assessments allow end users to calculate a single numerical value based on their answers to questions about the product issue. An quality manager can then use the assessment score to decide how to proceed with the investigation.

These are some example assessment questions used to determine if a product needs to be reported:

■ Was there any patient injury? {No, Mild, Moderate, Severe}

■ Was there a labeling problem? {No, Yes}

■ Did the product function according to specification? {No, Yes}

TIP: An alternate way to assess product issues is by using a SmartScript which guides the quality manager through a series of questions using a decision tree. For more information about SmartScripts, see *Siebel SmartScript Administration Guide*.

This task is a step in "Process of Adverse Events and Complaints Investigation" on page 377.

To assess a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Assessments view tab.

4 In the Assessments list, create a new record.

5 In the Template Name field, select the assessment template that has been prepared for you.

The application fills in other fields in the record when the record is saved.

6 In the Assessment Attributes list, enter a value for each attribute.

The assessment score and percentage are calculated and shown in the Assessments list.

Completing Adverse Events and Complaints Reviews (End User)

The exact meaning of the adverse event or complaint review status depends upon your business process. For example, it could indicate that there is sufficient data to begin a second phase of the investigation (trend analysis and recreation of the problem in the lab).

As part of the review process, the quality manager changes the status the record to Review Complete. An important effect of changing the status of a product issue to Review Complete is that a number of key fields are locked down and others are made read-only.

This task is a step in "Process of Adverse Events and Complaints Investigation" on page 377.

To complete a review of a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Select a product issue.

3 Click Review Complete.

This starts a workflow (LS Medical Product Issue Review Complete) that:

■ Changes the status of the product issue to Review Complete

■ Authenticates the user

■ Locks down these fields:

Primary Contact first and last names	Contact work phone #
Reported By	Account Name
Account Address	Product
Device Type	Part #

■ Makes these fields read-only:

Account	Account Address
Date of Event	Summary
All patient information (on Patient view)	Description

For more information about the workflow, see "About Configuring Create Related PI and Review Complete Buttons" on page 386. For more information about field lockdown, see Chapter 28, "Closing Adverse Events and Complaints."

About Configuring Create Related PI and Review Complete Buttons

There are two buttons associated with adverse events and complaints investigation. You can configure the workflows and fields copied for these buttons.

■ LS Medical Product Issue Create Related PI Workflow

■ Changing Which Fields Are Copied to the New Product Issue

■ LS Medical Product Issue Review Complete Workflow

■ LS Medical User Verification Workflow

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

LS Medical Product Issue Create Related PI Workflow

This workflow is initiated from the Create Related PI button on the Product Issues screen.

The workflow appears in Figure 14.
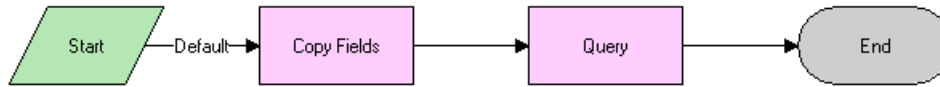
Figure 14. LS Medical Product Issue Create Related PI Workflow

The workflow does the following steps:

1   Creates a new product issue.

2   Copies data from the original product issue to the new product issue.

3   Makes the new product issue the active record.

Changing Which Fields Are Copied to the New Product Issue

When the Create Related PI button is used to create a product issue, data from various fields are copied from the original product issue record to the new product issue record.

To change which fields are copied when a product issue is created

■   Use the Data Transfer Utilities to edit the LS Medical PI Create Related PI data map object.

For information about the Data Transfer Utilities, see the *Siebel Finance Guide*.

LS Medical Product Issue Review Complete Workflow

This workflow is initiated from the Review Complete button on the Product Issues screen.

The workflow appears in Figure 15.
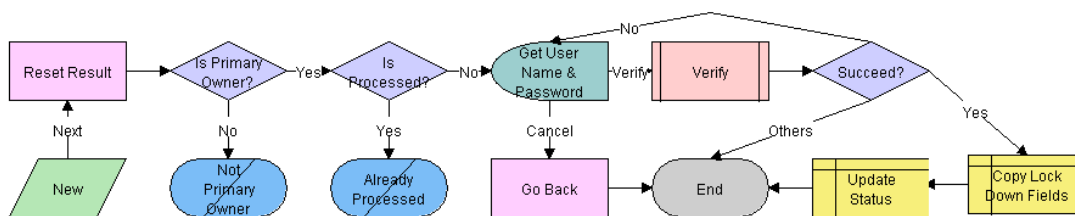
Figure 15. LS Medical Product Issue Review Complete Workflow

The workflow does the following steps:

1   Checks if the user is the primary owner of the product issue. If not, the workflow ends.

2 Checks if the product issue has already been processed. If it has, the workflow ends.

3 Calls the LS Medical User Verification workflow.

4 If the user authentication is successful, copies the lockdown fields, makes some fields read-only, and changes the status to Review Complete.

LS Medical User Verification Workflow

This workflow authenticates the user's name and password. This workflow is called from other workflows.

TIP: You can configure the User Verification workflow to capture the user name and password of two users.

The workflow appears in Figure 16.
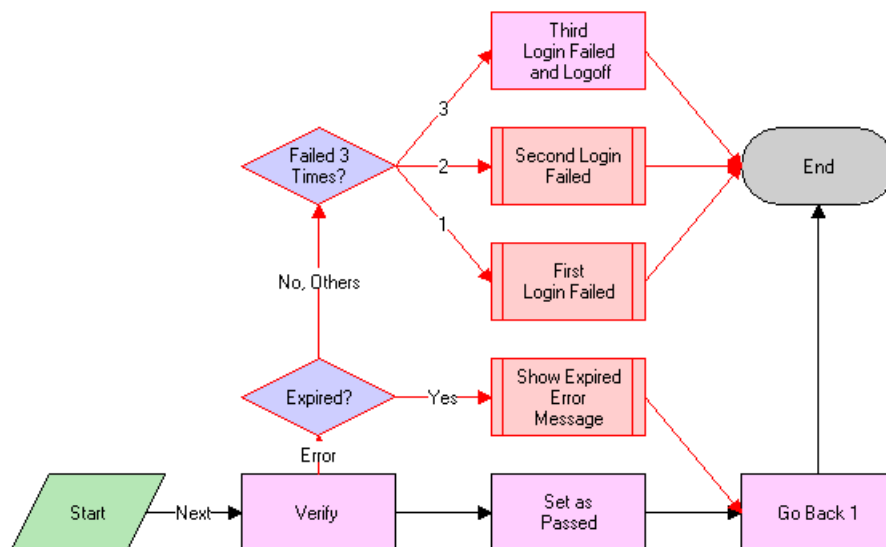
Figure 16. LS Medical User Verification Workflow

The workflow does the following steps:

1 Calls the Authentication business service to verify the user name and password. The Authentication business service calls two methods to perform this action as follows:

■ **ValidateSessionUser.** This method validates that the logged-in user is the current session user.

■ **Authenticate.** This method checks that the supplied username and password are valid in the system.

2 If the authentication passes, returns to the original view and sets the result code to 100—passed.

3 If the user name and password are expired, shows an error dialog box and sets the result code to 200—expired.

4 If the authentication fails, increases the result code by 1 and on the third failure logs the user out of the application.

About the LS Medical Product Issue Service Business Service

The LS Medical Product Issue Service is based on the class CSSServiceLSProductIssue. It is a placeholder for the business services used by Siebel AECM.

Customizing the LS Medical Product Issue Service

The LS Medical Product Issue Service business service is written in C++ and cannot be modified. However, the methods in this business service are modular and can be used in workflows that you create.

The LS Medical Product Issue Service Business Service Methods

The LS Medical Product Issue Service has three methods. These are described in Table 35.

Table 35.   LS Medical Product Issue Service Business Service Methods

Method	Description	Used in Workflow
GenerateReportNum	Generates report numbers for MedWatch and MDV reports as follows. *If the Report Is…* *Then the Method…* An initial report Generates a new report number. A supplemental report Takes the report number from the initial report.	LS Medical Product Issue RR Submit
Logoff	Logs out the user.	LS Medical User Verification
Query	Queries with the input search spec and sort spec.	LS Medical Create Related Product Issue

25 Recording Product Analysis for AECM

This chapter covers the following topics:

About Recording Product Analysis for AECM

This chapter describes how to use the Siebel application during the product analysis phase of an adverse events and complaints investigation.

When a faulty product is returned to the manufacturer for study, a product analysis record is opened. This record documents details of the analysis. When the analysis is complete, root cause and corrective action information are added and the record is submitted for approval.

Where to Find More Information
The following chapters describe other aspects of the complaints and adverse events management process:

Scenario for Product Analysis Arising from a Complaint

This scenario is an example process performed by the Siebel administrator, the manager of the product analysis team, a team member, and the quality manager. Your company may follow a different process according to its business requirements.

This process is designed to illustrate the functionality of the Siebel AECM.

Introduction

A customer had a problem with a new blood analyzer system. The analyzer's cartridge was determined to be faulty, and the customer returned it to the manufacturer for analysis. The quality manager has already opened a product complaint file (product issue record) for this problem.

The Siebel Administrator

The administrator sets up the activity templates that the product analysis team uses in the course of analyzing product issues. Before creating these templates, the administrator consults with the quality manager and reviews the company's S.O.P (standard operating procedure) for product analysis.

The administrator checks that all the necessary codes for product analysis have been set up as appropriate for the company's business process and products.

Quality Manager

The initial review of the product complaint has been completed and the faulty cartridge has been sent by the customer. The quality manager creates a product analysis record in the complaint file. She assigns a member of the product analysis team to be the primary owner of the product analysis record.

Member of the Product Analysis Team

The decontamination unit initially receives and processes the faulty cartridge. After decontamination, the cartridge is sent to a member of the product analysis team. He records receipt of the faulty cartridge, reviews the product analysis record associated with this complaint, and begins analysis of cartridge.

During the course of the analysis, the team member creates activities to keep track of the analysis steps. He records the results of the analysis. At the conclusion of the analysis, he records the root cause of the problem and proposes corrective action.

When analysis of the cartridge is complete, the team member submits the product analysis information for approval.

Quality Manager and Product Analysis Manager

Both the manager of the product analysis team and the owner of the product complaint file are required to approve the product analysis. When they review their Inboxes, they learn that the product analysis is complete and ready for approval. Individually, they review and approve the product analysis.

Process of Product Analysis Following a Product Issue

This example process represents the tasks that are carried out in the Scenario for Product Analysis Arising from a Complaint on page 392.

Administrator Procedures

■ Creating Product Analysis Activity Templates on page 393

■ Setting Up Codes for Product Analysis on page 394

End-User Procedures

■ Creating Product Analysis Records from a Product Issue (End User) on page 394

■ Filling in Product Analysis Records (End User)

■ Completing Product Analysis and Creating CAPAs (End User) on page 395

■ Approving or Rejecting Product Analysis Records (End User) on page 397

Creating Product Analysis Activity Templates

Product analysis activity templates are used to create standard sets of activities that the product analysis team use to guide them as they carry out decontamination procedures, validation tests, and so on.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To create a product analysis activity template

1 Navigate to the Administration - Data screen > Activity Templates view.

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

   a Set the Type field to Repair.

   b Leave these fields blank: Sales Stage, Sales Method, and Protocol Title; they do not apply to product analysis activities.

3 Associate individual activities with the template, as described in *Siebel Applications Administration Guide*.

Setting Up Codes for Product Analysis

The administrator defines the codes that are used to categorize product analysis.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To set up codes for Product Analysis

■ See "Setting Up Codes" on page 365.

NOTE: Typically, you create codes of type Product Analysis for use with Product Analysis records. However, all types of codes can be associated with Product Analysis records.

Creating Product Analysis Records from a Product Issue (End User)

The first task in analyzing a defective product is to create a product analysis record. The product analysis record captures information from the associated product issue and serves as a repository for all information associated with the product analysis.

Typically, the product analysis record is created by the quality manager who has access to the Product Issues screen. The quality manager can then assign the product analysis to a member of the analysis team who has access to the Repairs screen but not necessarily to the Product Issues screen.

The product analysis record is a repair record of type Product Issue Analysis. For information about the Repairs screen, see *Siebel Field Service Guide*.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To create and assign the product analysis record

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Product Analysis view tab.

4 Create a new product analysis record.

Account, product, asset number, lot number, and service request number are copied from the product issue to the new product analysis record.

5 Click the Repair # to drill down to the product analysis record in the Repairs screen.

6 Complete the Owners field.

If Assignment Manager is set up, you can assign an owner by clicking the menu button and selecting Assign.

Filling in Product Analysis Records (End User)

The product analysis team member records information such as the results of decontamination and validation tests.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To complete a product analysis

1 Navigate to Repairs screen > Repair List view.

2 Select a product analysis.

3 Complete the fields.

Some fields are described in the following table. Other fields are described in *Siebel Field Service Guide*.

Field	Comments
Codes	Codes to describe or categorize the product analysis. Typically, select codes of type Product Analysis.
Product	The primary product associated with the product issue.
Received	Defaults to the date and time that the record was created.
Repair #	A unique identifying number for the repair. Automatically populated.
Type	Defaults to Product Issue Analysis.

4 Create activities in the Activity Plans view.

5 Attach documents in the Attachments view.

6 Add notes in the Notes view.

Completing Product Analysis and Creating CAPAs (End User)

At the conclusion of the product analysis, the product team member adds information about the root cause of the problem and initiates corrective and preventive actions (CAPA).

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To add root cause and corrective actions to a product analysis record

1 Navigate to Repairs screen > Repair List view.

2 Drill down on a product analysis record.

3 Complete the Root Cause field.

4 Add corrective actions to the record:

   a Click the Corrective Actions view tab.

   b Click Add or New.

If the corrective action...	Click...	And...
Already exists	Add	Select a corrective action from the Add Corrective Actions window
Is new	New	Complete the fields in the new CAPA record

For more information about CAPAs, see Chapter 26, "Managing CAPAs."

Submitting Product Analysis Records (End User)

Once the root cause has been recorded and corrective actions initiated, the product analysis is ready to be submitted for approval.

Here are some restrictions on submitting a product analysis record:

■ Only the primary owner of the product analysis record can submit it.

■ The owner of the product analysis must have a manager.

■ The product analysis must have a product issue associated with it.

■ The associated product analysis must have an owner.

NOTE: These restrictions can be modified to meet your business needs. For information about configuring the submit workflow see "About Configuring Product Analysis Approvals" on page 398.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 393.

To submit a product analysis

1 Navigate to Repairs screen > Repair List view.

2 Select a product analysis.

3 Click Submit.

This starts a workflow (LS Medical PA Submit) that sends requests for approval to the Inboxes of the designated approvers. For more information about the workflow, see "About Configuring Product Analysis Approvals" on page 398.

NOTE: If you submit a product analysis record in error, click the Withdraw button to unsubmit it. This starts the LS Medical PA Withdraw workflow. For more information about the workflow, see "About Configuring Product Analysis Approvals" on page 398.

4 Verify that the product analysis was submitted to the correct approvers:

    a Drill down on the product analysis.

    b Click the Approval History view tab.

       The list should contain three records for:

       ❏ The primary owner (This should already be approved)

       ❏ The primary owner's manager

       ❏ The product issue's primary owner

Approving or Rejecting Product Analysis Records (End User)

Depending on your business process, an approved product analysis may be required before corrective actions can be taken.

In the preconfigured application, the required approvers for product analysis records are:

■ The manager of the product analysis primary owner

■ The primary owner of the product issue record that generated product analysis

This task is a step in .

To approve a product analysis record

1 Navigate to Inbox screen > Inbox Items List view.

2 Review and approve the item.

    The status of the product analysis becomes Closed and the sub status becomes Approved.

To reject a product analysis record

1 Navigate to Inbox screen > Inbox Items List view.

2 Review and reject the item.

    The status of the product analysis becomes Rejected. (The product analysis team member can submit the record again.)

    If Manager 1 rejects the item before Manager 2 takes action on it, Manager 2 never sees the item (it is deleted from Manager 2's Inbox when it is rejected by Manager 1).

For more information about the Inbox, see *Siebel Applications Administration Guide*.

About Configuring Product Analysis Approvals

There are two buttons associated with adverse events and complaints investigation. You can configure the workflows for these buttons.

■ Submit button (LS Medical PA Submit Workflow)

■ Withdraw button (LS Medical PA Withdraw Workflow)

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

LS Medical PA Submit Workflow

This workflow is initiated from the Submit button on the Repairs screen.

The workflow appears in Figure 17.
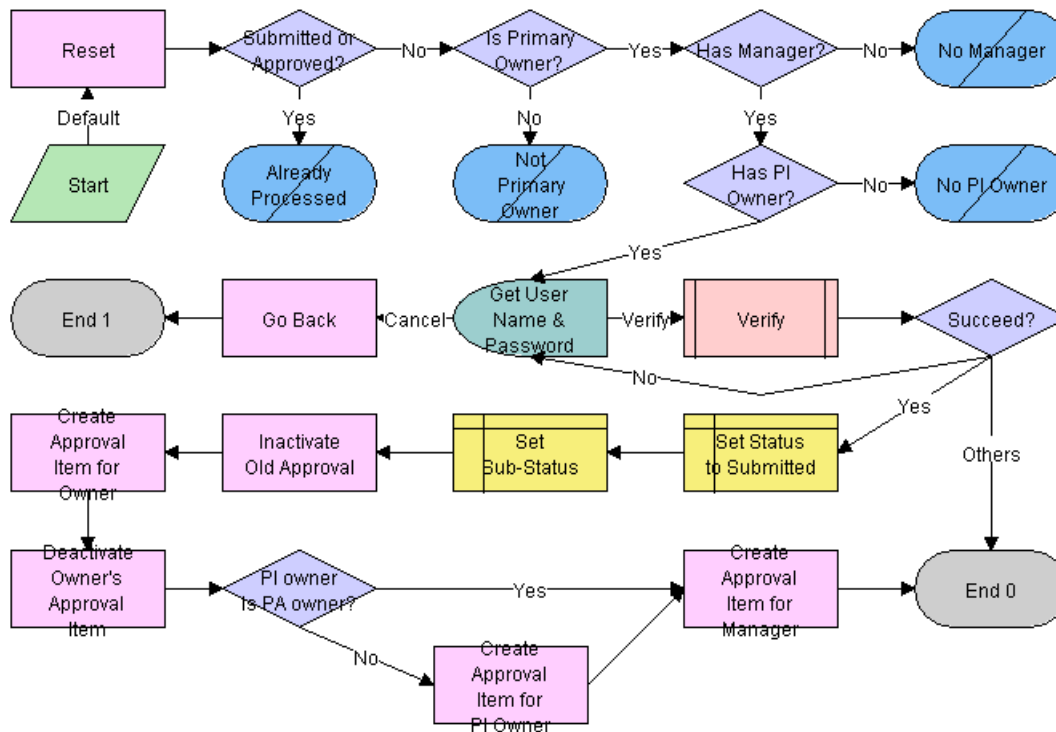
Figure 17. LS Medical PA Submit Workflow

This workflow does the following steps:

1 Checks if the current record has already been submitted. If it has, the workflow ends.

2 Checks if the current record has an owner, if the owner has a manager, and if the product issue record that generated this record has a primary owner. If these criteria are not met, the workflow ends.

3 Calls the LS Medical User Verification workflow. If the authentication does not pass, the workflow ends.

4 Sets the status to Submitted and the sub-status to Waiting.

5 Deactivates any approval record associated with the current product analysis record.

6 Creates an inactive approval record for the current owner (for record purposes).

7 Creates approval items for the owner's manager and for the owner of the product issue.

LS Medical PA Withdraw Workflow

This workflow is initiated from the Withdraw button on the Repairs screen.

The workflow appears in Figure 18.
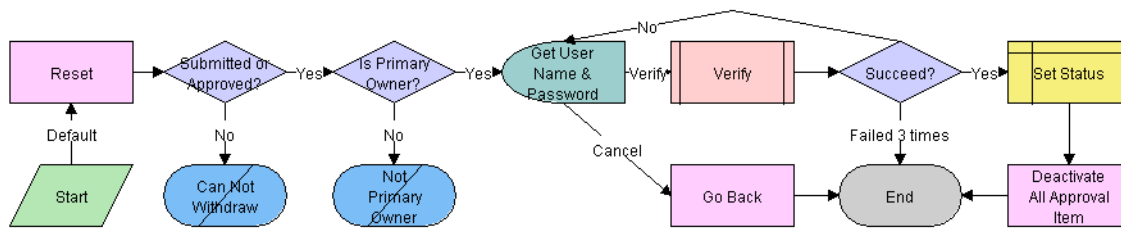
Figure 18. LS Medical PA Withdraw Workflow

This workflow does the following steps:

1 Checks if the current record has already been submitted. If it has not, the workflow ends.

2 Checks if the user is the primary owner. If not, the workflow ends.

3 Calls the LS Medical User Verification workflow. If the authentication does not pass, the workflow ends.

4 Sets the status to Reopen.

5 Deactivates any approval record associated with the current product analysis record.

26 Managing CAPAs

This chapter covers the following topics:

About Managing CAPAs

This chapter describes recording and managing corrective actions and preventive actions for Siebel Adverse Events and Complaints Management (Siebel AECM). Table 36 defines and distinguishes these two terms. But generally, corrective and preventive actions are called CAPAs; this is how they will be referred to generically in this chapter.

Table 36. Terms Defined with Examples

Term	Definition from ISO 8402	Example
Corrective Action	Action taken to eliminate the causes of an existing non-conformity, defect, or other undesirable situation in order to prevent recurrence.	When devices were returned because of damage caused by electrostatic discharge (ESD) during assembly, the corrective actions were (i) implementation of ESD controls and (ii) ESD control training for operators.
Preventative Action	Action taken to eliminate the cause of a potential non-conformity, defect, or other undesirable situation in order to prevent occurrence.	When control charts indicated the diameter of a molded part was drifting towards the upper limit, the preventive action was to replace the mold and validate that the new parts met the specifications.

The CAPA record in Siebel AECM is designed to contain all information about a corrective or preventive action: from its creation through planning and implementation through authentication, closure and beyond.

Where to Find More Information

The following chapters describe other aspects of the complaints and adverse events management process:

- Chapter 23, "Capturing Adverse Events and Complaints"

- Chapter 24, "Investigating Adverse Events and Complaints"

- Chapter 25, "Recording Product Analysis for AECM"

- Chapter 27, "Regulatory Reporting"

- Chapter 29, "Communicating with Customers for AECM"

- Chapter 28, "Closing Adverse Events and Complaints"

Scenario for Managing CAPAs

This scenario is an example process performed by the Siebel administrator, and the CAPA team. Your company may follow a different process according to its business requirements.

This process is designed to illustrate the functionality of Siebel AECM.

The Siebel Administrator

The administrator sets up the activity templates that the CAPA team members use in the course of planning, implementing, and verifying CAPAs.

Before creating these templates, the administrator consults with the CAPA team. It is very important that the activities defined by the template accurately and completely reflect the company's policies and procedures for the handling of CAPAs.

The administrator also checks the necessary codes for CAPA have been set up as appropriate for the company's business needs.

The CAPA Team Members

The product analysis team has alerted the CAPA team that some of the cartridges used in the new blood analyzer are out of tolerance and that this is causing them to jam in the analyzer. The CAPA team is responsible for correcting this problem.

The CAPA manager creates a corrective action record. He fills in all the information known about the problem and its root cause, including the associated product analysis and product issue records. The CAPA team use this record as the project file, referring and adding to it throughout the life cycle of the CAPA.

All information associated with the CAPA is stored and accessible from this record. The information takes a variety of forms, from short comments where employees share information about recent actions and findings, to longer notes (both public and private), and large documents such a reports and specs that are saved as file attachments.

The CAPA manager uses the activity template to generate a standard set of activities that outline the team's standard operating procedure for implementing CAPAs. He assigns the activities to members of his team. The manager uses the list of activities to monitor the progress of the CAPA; noting the start and end dates and which activities have been completed and which are still to be done.

CAPA team members are assigned activities, with start and due dates. They carry out their assigned activities, recording the tools and parts used, how long each activity takes to complete, and the results and measurements obtained.

Major milestone dates, both target and actual, are recorded on the main form of the CAPA record. Also the approval history of the CAPA record is tracked as changes in the CAPA's status are made, from Open, through Approved, to Verification.

Process of Managing CAPAs

This example process represents the tasks that are carried out in the Scenario for Managing CAPAs on page 402.

Administrator Procedures

■ Creating Corrective Action Activity Templates on page 403

■ Setting Up Codes for CAPAs on page 404

End-User Procedures

■ Creating a CAPA Record (End User) on page 404

■ Managing CAPAs (End User) on page 406

■ Tracking Approvals and Other Changes to CAPAs (End User) on page 406

Creating Corrective Action Activity Templates

Corrective action activity templates are used to create a standard sets of activities that the CAPA team follow as they plan, implement, and verify a CAPA.

This task is a step in "Process of Managing CAPAs" on page 403.

To create a corrective action activity template

1 Navigate to the Administration - Data screen > Activity Templates view.

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

   a Set the Type field to Corrective Action.

   b Set start and end dates for the activities by specifying Lead Times and Durations.

   c Leave these fields blank: Sales Stage and Sales Method; they do not apply to product issue activities.

3 Associate individual activities with the template, as described in *Siebel Applications Administration Guide*.

Setting Up Codes for CAPAs

The administrator defines the codes that are used to categorize CAPAs and their root causes.

This task is a step in .

To set up codes for CAPAs

■ See .

   NOTE: Typically, you create codes of type Corrective Action for use with CAPA records. However, all types of codes can be associated with CAPA records.

Creating a CAPA Record (End User)

Corrective actions can be created and viewed in these screens:

■ **Corrective Actions.** When a CAPA record is created in this screen, no default type is associated with the CAPA.

■ **Product Issues.** When a CAPA record is created in this screen, the default type is Product Issue.

■ **Repairs.** When a CAPA record is created in this screen, the default type is Product Analysis.

When a CAPA is created from the Product Issues or the Repairs screen, a CAPA number is assigned automatically. You can configure the application to copy information from the Product Issue or the Product Analysis record to the CAPA record. Review the configuration of the Create Product Issue button (see) for an example of a similar configuration.

This task is a step in .

To create a CAPA record in the Corrective Actions screen

1 Navigate to the Corrective Actions screen > Corrective Action List view.

2 Create a new record and complete the necessary fields.

Only some fields described in the following table are filled in when the CAPA is first created; other fields are filled in later in the CAPA investigation.

Field	Comments
Accounts	The accounts requiring the fix.
Actual Fixed	The date when the fix was actually implemented.
Area	Classification for the corrective action. The Type field constrains this drop-down list.
Asset #	For example, the asset number of the first machine to which the fix is applied.
CA #	Unique number to identify the CAPA. It is auto-generated when the CAPA record is created.
Codes	Typically, select codes of type Corrective Action. Example uses: ■ Use codes to indicate the root cause of the CAPA. ■ Use codes to classify the CAPA.
Comments	Use this field to record and share short notes during the life cycle of the CAPA.
Corrective Action	Detailed description of the corrective action and its root cause.
Fix Age	Number of days since the Actual Fixed date.
Lot #	For example, the first lot number to which the fix is applied.
Mfg Name	Typically this is the (internal) manufacturing site.
Serial #	Serial number of the asset. This field is automatically populated if there is a serial number associated with the asset.
Status	Changes to this field are tracked in the Approvals view.
Sub Area	The Area field constrains this drop-down list.
Sub Status	The Status field constrains this drop-down list.
Target	The version of the product targeted to have the fix.
Type	The type of corrective action: Product Analysis, Product Issue, Manufacturing, Preventive Action, Other.

3 Drill down on the record and click the Related Products view tab and enter records for the products related to the CAPA.

4 Click the Product Issues view tab and enter records for any product issues related to the CAPA.

5 Click the Product Analysis view tab and enter records for any product analyses related to the CAPA.

Managing CAPAs (End User)

Use the views on the Corrective Actions screen to store, maintain, and share many types of information about a CAPA.

Typically several employees are assigned ownership of a CAPA record and are assigned activities related to the CAPA. All owners update the CAPA record during the course of the CAPA's life cycle.

To add information to CAPA records

1 Navigate to the Corrective Actions screen > Corrective Action List view.

2 Drill down on a CAPA record.

3 Update the record by editing status, comment, and date fields.

4 Create activity plans for the CAPA:

   a Click the Activity Plan view tab.

   b 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.
Template	Only templates whose type is Corrective Action can be selected in this field.

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

5 Create private and public notes for the CAPA record using the Notes view.

6 Associate files to the CAPA record using the Attachments view.

For general information about activities, notes, and attachments, see *Siebel Fundamentals*.

Tracking Approvals and Other Changes to CAPAs (End User)

Changes in the status of the CAPA record are tracked in the Approvals view. Changes to other fields in the CAPA record can be seen in the Audit Trail view. For information about enabling Audit Trail, see *Siebel Applications Administration Guide*.

NOTE: For information about configuring the Corrective Action screen to use buttons and workflows for changing the status of a CAPA record, see "About Configuring CAPA Approvals" on page 407.

To track approval history and other changes to CAPA records

1 Navigate to the Corrective Actions screen > Corrective Action List view.

2 Drill down on a CAPA record.

3 Click the Approvals view tab.

Changes in the Status of the CAPA record is tracked in this view.

4 Click the Audit Trail view tab.

Changes made to fields in the CAPA record are tracked in this view.

About Configuring CAPA Approvals

There are no buttons or workflows associated with the Corrective Actions screen.

However, you can configure your application with Submit and Withdraw buttons and workflows similar to those used for approving product analysis records on the Repairs screen.

See:

■ "About Configuring Product Analysis Approvals" on page 398 for specific information on the product analysis approval workflows

■ *Configuring Siebel Business Applications* for information about how to configure buttons

■ *Siebel Business Process Framework: Workflow Guide* for information about how to create workflows

27 Regulatory Reporting

This chapter covers the following topics:

About Regulatory Reporting

This chapter describes how to use the Siebel application to create and manage regulatory reports for product complaints and adverse events. The reports are generated with unique and sequential numbers and formatted ready for submission to the FDA or other regulatory agencies.

Where to Find More Information
The following chapters describe other aspects of the complaints and adverse events management process:

■ Chapter 28, "Closing Adverse Events and Complaints"

About Regulatory Reports

From the time an adverse event or complaint is confirmed as reportable, companies generally have less than 30 days to report to a regulatory agency. An adverse event or complaint can be verified as reportable at various stages of the AECM process, from the initial customer call through to the review of the findings by the analysis team. Companies usually follow certain assessments that determine if an adverse event or complaint is reportable or not.

Separate reports have to be filed for each product that malfunctioned or caused the adverse event. Reports filed are based on the product issue, which typically contains much of the needed information. After the initial report, companies generally file additional supplemental, summary, and annual reports to update information on the investigation and resolution process.

The preconfigured Siebel AECM module supports MedWatch and MDV reports:

■ **MedWatch Reports.** Using Siebel AECM, you can automatically generate MedWatch 3500A reports. Sections A to H of the report are populated from the relevant fields in the regulatory report record. The completed report can be printed and mailed to the FDA or saved as a PDF file and submitted electronically to the FDA.

■ **MDV Reports.** Medical device companies operating in multiple countries report adverse events or complaints to the various NCAs using the MDV form. Unlike MedWatch reports, there is no standard template for the MDV form. However, the Global Harmonization Task Force (GHTF) has guidelines.

The report created by Siebel AECM follows these guidelines. For more information, see:

http://www.ghtf.org.

About Report Types

Table 37 details the four regulatory reports that can be created in Siebel AECM.

Table 37.   Report Types in Siebel AECM

Report Type	Use	Data for the Report Is Taken from These Views in the Regulatory Reports Screen
3500A	For initial mandatory reports to MedWatch (FDA).	■ More Info ■ Patient ■ Importer (if the Facility Type field in the Importer view is not blank) ■ Manufacturer and Investigation (if the Facility Type field in the Importer view is blank)
3500A Supplemental	For additional information to MedWatch after initial reports have been submitted.	

Table 37.   Report Types in Siebel AECM

Report Type	Use	Data for the Report Is Taken from These Views in the Regulatory Reports Screen
MDV Initial	For initial reports to NCAs who accept MDV forms forms.	■ More Info ■ Patient ■ MDV
MDV Follow-up	For additional information to NCAs after initial reports have been submitted.	

Scenario for Regulatory Reporting

This scenario is an example process performed by the Siebel administrator and the quality manager. Your company may follow a different process according to its business requirements.

This scenario is designed to illustrate the functionality of Siebel AECM.

Introduction

A complaint about a cartridge for a blood analyzer machine has been made to the manufacturer. The complaint has been assessed; it needs to be reported to the FDA. A product issue record has already been set up and contains a lot of information about the complaint.

The Siebel Administrator

The administrator is responsible for setting up the report number schema for the organization. The company started using Siebel AECM in the middle of the year. Because the company had already submitted eight MedWatch 3500A reports to the FDA, the administrator sets the report number sequence to start at 9.

Quality Manager

It is the quality manager's responsibility to prepare the initial MedWatch 3500A form and send it to the FDA. First, she creates a new regulatory report record and populates the record with data from the product issue. Then she reviews the data.

Because her company manufactures the cartridge, she enters data into the Manufacturer and Investigation views. This data will appear in sections G and H of the MedWatch 3500A form.

Satisfied that the necessary data has been entered, she generates the MedWatch 3500A report. This report is a facsimile of the MedWatch 3500A form. But, it is also a standard Siebel report, so the quality manager prints it as she would any other Siebel report.

After reviewing the printed version of the report, she submits it. When she submits the report record, two things happen:

■ A report number is generated.

■ Most fields in the report record become read-only.

It is the submitted version of the MedWatch 3500A form that the quality manager sends to the FDA.

The quality manager complied with regulations by sending her initial report within 30 days of the company becoming aware of the issue. However, the product analysis had not been completed at that time. Later, the product analysis team discovers the root cause of the cartridge failure, and the quality manager submits a supplemental report to the FDA.

Process of Regulatory Reporting

This example process represents the tasks that are carried out in the Scenario for Regulatory Reporting on page 411.

Administrator Procedures

■ Setting Up Report Numbers on page 412

End-User Procedures

1 Creating and Populating New Regulatory Reports (End User) on page 413

2 Entering and Reviewing Data for 3500A Reports (End User) on page 414, or

3 Entering and Reviewing Data for MDV Reports (End User) on page 421

4 Running 3500A and MDV Reports (End User) on page 422

5 Generating Regulatory Report Numbers and Submitting Reports (End User) on page 423

6 Creating Supplemental or Follow-Up Regulatory Reports (End User) on page 425

Additional End-User Procedure

This end-user procedure is not part of the scenario described:

■ Reopening a Regulatory Report (End User) on page 424

Setting Up Report Numbers

The administrator determines the numbering scheme for regulatory reports.

The number is generated automatically when the regulatory report record is submitted.

The report number composed of concatenated fields. The report number field is incremented by 1 each time a report is generated for a new product issue.

Reports numbers of this type...	Are the concatenation of these fields...	Example
MedWatch 3500A	■ Manufacturer Id ■ Report Year ■ Report Number	XERCO-2003-0004
MDV Initial	■ MDV Id ■ MDV Report Number	MEDDEV-000008

This task is a step in .

To set up report numbering scheme

1 Navigate to Administration - Group screen > Organizations view.

2 In the Organizations list, select your organization.

3 To set up numbering for MedWatch 3500A reports complete the following fields

Field	Comments
Manufacturer Id	
Report Year	
Report Number	Set to zero to have the first report numbered 0001.

4 To set up numbering for MDV Initial reports complete the following fields.

Field	Comments
MDV Id	
MDV Report Number	Set to zero to have the first report numbered 000001.

Creating and Populating New Regulatory Reports (End User)

The best way to create a regulatory report record is from the product issue record. When a report is created from the regulatory report, fields (for example, products) can be populated from the product issue record to the regulatory report record.

There are two kinds of initial regulatory report that you can create:

■ MedWatch 3500A

■ MDV Initial

NOTE: If you want to create supplemental or follow-up reports, see "Creating Supplemental or Follow-Up Regulatory Reports (End User)" on page 425.

This task is a step in "Process of Regulatory Reporting" on page 412.

CAUTION: Regulatory report records cannot be deleted.

To create a regulatory report record

1   Navigate to Product Issues screen > Product Issue List view.

2   Drill down on a product issue.

3   Click the Regulatory Reports view tab.

4   In the Regulatory Reports list, create a record.

When the regulatory report is created:

■   These fields are copied from the product issue: PI# and SR #

■   These fields are set with a default value: Status = In Progress, Owner = *Creator of the record*

5   Set the Report Type field to MedWatch 3500A or MDV Initial.

6   Click Populate Report.

This starts the LS Medical Product Issue Populate Report workflow, which copies data from the product issue according to the report type. For more information about the workflow, see "LS Medical Product Issue Populate Report Workflow" on page 436.

Entering and Reviewing Data for 3500A Reports (End User)

When you populate a regulatory report, many fields are copied from the product issue record. When you edit these fields in the regulatory report record, the edits are not copied back to the product issue record.

NOTE: The process described here is to enter data in the Manufacturer, Investigation, and Importer views of the *Regulatory Reports* screen. However, an alternate way is to enter the data in these views in the *Product Issues* screen before the regulatory report is populated. If you use the Product Issues screen, you have copies of the data in both the product issue record and in the regulatory report record.

This task is a step in "Process of Regulatory Reporting" on page 412.

To review and enter data for the 3500A report

1   Navigate to Regulatory Reports screen > Regulatory Report List view.

2   Drill down on a 3500A regulatory report record.

3   Review and edit if necessary the information in the More Info and Patient views.

4   If you are a manufacturer:

   a   Make sure that the Facility Type field in the Importer view is blank. (By default, this field is set to blank.)

   b   Complete the fields in the Manufacturer view.

   These fields populate section G of the 3500A form. Some fields are described in the following table. (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
(A)NDA #	The abbreviated new drug application or the new drug application number. This field is automatically populated if there is an (A)NDA number associated with the protocol site.	G5
STN #	Product Submission Tracking Number (STN). If this number does not exist, then use the U.S. License Number.	
PMA/510(K) #	Pre-market application (PMA) or pre-market notification (510(k)) submission number for the approved or cleared medical device or combination product. If a product has several applicable submission numbers and you cannot determine the specific number to use, then use the first approved PMA or 510(k) number.	
Combo Product	Define whether a suspect product comprises a drug-device, device-biological, drug-biological, or a drug-device-biological product.	
10-day	Select the check box to indicate the report is a 10-day report.	G7
15-day	For reports of serious and unexpected adverse events.	G7
5-day	For events requiring remedial action to prevent unreasonable risk to public health, or where written notice is required.	G7
7-day	Select the check box to indicate the report is a 7-day report.	
30-day	Select the check box to indicate the report is a 30-day report.	
Address	Manufacturer contact office address - Street.	G1

Field	Comments	Mapping to 3500A Form
AE Terms	List of adverse event terms that most accurately characterize the adverse event described in Event Detail section.	G8
City	Manufacturer contact office address - City.	G1
Consumer	Report Source is the consumer or treating health care provider.	G3
Contact Name	Manufacturer contact's last name.	G1
Contact Office	Manufacturer's contact office.	G1
Country	Manufacturer contact office address - Country.	G1
Distributor	Check this if report was received from the distributor (importer) of the suspect product.	G3
First Name	Manufacturer contact's first name.	G1
Follow-up	Check if the report is a follow-up to a previously submitted report.	G7
Follow-Up #	Follow-up sequence number.	G7
Foreign	Report Source is a foreign source (for example, foreign medical facility, affiliate, or government).	G3
IND #	The investigational new drug (IND) application number. This field is automatically populated if there is an IND number associated with the protocol site.	G5
Initial	Check if the report is the first submission of a manufacturer report (30 day report for device).	G7
Literature	Report Source is the scientific literature or an unpublished manuscript.	G3
Mfg Report #	Regulatory report number.	G9
OTC Product	Check if the suspect medication can be purchased over-the-counter (without a prescription).	G5
Other	Report Source is any source not covered by the previous categories.	G3
Periodic	For reports of serious labeled and non-serious (labeled and unlabeled) adverse events.	G7
Phone #	Manufacturer contact's work phone number.	G2
PI Received	The date when a company representative became aware of the event.	G4

Field	Comments	Mapping to 3500A Form
Postal Code	Manufacturer contact office address - Postal Code.	G1
Pre-1938	Check the box if the suspect medication was marketed prior to 1938 and does not have an NDA #.	G5
Products	Product(s) involved in the event.	
Professional	Report Source is a physician, pharmacist, nurse, and so on.	G3
Protocol #	Protocol number identifies the clinical trial at a site. If regulatory report is an IND safety report, enter the protocol number.	G6
Received Report #	Report number for the MedWatch form received from a Importer or a User Facility.	MedWatch Header
Representative	Check this if a company representative reported the event based on information from a health professional.	G3
State	Manufacturer contact office address - State.	G1
Study	Report Source is a postmarketing, clinical trial, surveillance, or other study.	G3
User Facility	Check this if the manufacturer received the report from the MDR contact in a user facility as identified in section F.	G3

5 If you are a device manufacturer, complete the fields in the Investigation view.

These fields populate section H of the 3500A form. Some fields are described in the following table. (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
Evaluation	If an evaluation was conducted, note summary here and choose Evaluation Summary Attached in Evaluated by Mfg Field.	H3
Death	Check only if the death was an outcome of the adverse event.	H1
Correction	Do not check when creating an initial report. Follow-up with changes to previously submitted information.	H2

Field	Comments	Mapping to 3500A Form
Serious Injury	Event is life-threatening, results in permanent impairment, requires intervention to prevent permanent impairment.	H1
Additional Information	Do not check when creating an initial report. Information concerning the event that was not provided in the initial report.	H2
Malfunction	Device malfunctions.	H1
Response to FDA Request	Do not check when creating an initial report. Additional information requested by FDA concerning the device/event.	H2
Other	Event not covered by death, serious injury, or malfunction. This type of category should be rarely used.	H1
Device Evaluation	Do not check when creating an initial report. Evaluation/analysis of device.	H2
Mfg Narrative	Any additional information, evaluation, or clarification of data presented in previous sections.	H10
Recall	Remedial Action - Recall.	H7
Method Codes	Method codes capture two items — the source of the device that was evaluated and the type of evaluation performed. Do not enter more than four codes.	H6
Repair	Remedial Action - Repair.	H7
Result Codes	Describes the results of evaluation and analyses of the reported device problem(s). Do not enter more than four codes.	H6
Replace	Remedial Action - Replace.	H7
Conclusion Codes	Describes the evaluation conclusions. Do not enter more than four codes.	H6
Relabeling	Remedial Action - Relabeling.	H7
Evaluated by Mfg	If you do not check this box, then you should complete the Non-Evaluation Codes field. Identify if the device was evaluated.	H3
Notification	Remedial Action - Notification.	H7

Field	Comments	Mapping to 3500A Form
Non-Evaluation Codes	If an evaluation of a returned medical device was NOT conducted, provide the appropriate code.	H3
Corrected Data	Additional, corrected, or missing information, identifying each data item by the applicable section and block number.	H11
Inspection	Remedial Action - Inspection.	H7
Usage of Device	Indicates whether the use of the suspect medical device was the initial use, reuse, or unknown.	H8
Patient Monitoring	Remedial Action - Patient monitoring.	H7
Mfg Date	Month and year of manufacture of the suspect medical device. This field may be based on asset number (asset manufacture date) or lot number (effective start date).	H4
Modification	Remedial Action - Modification.	H7
Labeled Single Use	Indicates whether the device was labeled for single use.	H5
Other	Remedial Action - Other - Specify the type of action in this field.	H7
Correction #	If action reported to FDA under 21 USC 360i(f), list correction or removal reporting number.	H9

6 If you are a user facility or importer, complete the fields in the Importer view.

These fields populate section F of the form. Some fields are described in the following table. (The letter and number combination in the last column indicates how this field maps to the 3500A form.)

Field	Comments	Mapping to 3500A Form
Facility Type	Indicate whether the report is from a user facility, importer, or others.	F1
Importer	Name of the distributor or importer.	F3
Contact Name	Last name of the distributor's or importer's representative to contact regarding the event.	F4
Device Age	The approximate age of the device.	F9

Field	Comments	Mapping to 3500A Form
Report #	Regulatory report # for this report, which is being submitted by an importer. This number is auto-populated when the report is generated.	F2
Address	Distributor's or Importer's address - Street Address line #1. This field is auto-populated based on the distributor's or importer's name.	F3
First Name	First name of the distributor's or importer's representative to contact regarding the event.	F4
Age UoM	Unit of measurement for device age.	F9
Report Type	Indicates if the report to the regulatory agency will be an initial or follow-up report.	F7
City	Distributor's or importer's address - City.	F3
Phone #	Contact's work phone number.	F5
Patient Codes	Patient codes describe what happened to the patient as a result of the event. Do not enter more than three codes.	F10
Follow-up #	Sequence number of the follow-up report.	F7
Postal Code	Distributor's or importer's address - Postal Code.	F3
Reported FDA	Indicates if the distributor or importer has already sent a report to the regulatory agency.	F11
Device Codes	Device codes describe device failures or problems encountered during the event. Do not enter more than four codes.	F10
Reported Mfg	Indicates if the distributor or importer has sent a report to the manufacturer.	F13
State	Distributor's or importer's address - State.	F3
FDA Report Date	Date the report was sent to the regulator agency.	F11
Event Location	Location of the actual occurrence of the event.	F12
Mfg Report Date	Date the report was sent to the manufacturer.	F13
Country	Distributor's or importer's address - Country.	F3
PI Received	The date when a company representative became aware of the event.	F6

Entering and Reviewing Data for MDV Reports (End User)

When you populate the regulatory report, many fields are copied from the product issue record. When you edit these fields in the regulatory report record, the edits are not copied back to the product issue record.

NOTE: The process described here is to enter data in the MDV view in the Regulatory Reports screen. However, an alternate way is to enter the data in the MDV view in the Product Issues screen *before* the regulatory report is populated. If you use this alternative, you have copies of the data in both the product issue record and in the regulatory report record.

This task is a step in "Process of Regulatory Reporting" on page 412.

To review and enter data for an MDV Initial report

1 Navigate to Regulatory Reports screen > Regulatory Report List view.

2 Drill down on an MDV regulatory report record.

3 Review and edit if necessary the information in the More Info and Patient views.

4 Click the MDV view tab.

5 Complete the fields in the MDV view.

Some fields are described in the following table.

Field	Comments
MDV Report #	MDV Report number. This number is auto-populated when the report is generated.
Authorities	The name of the regulatory agencies to send the report to.
Affiliate Acct	The affiliate account representing the company.
PI Received	The date when the company became aware of the event.
Determination	The type of the reportable event for MDV reporting.
Patient Codes	Patient codes describe what happened to the patient as a result of the event.
Device Codes	Device codes describe device failures or problems encountered during the event.
Usage of Device	Indicates whether the use of the suspect medical device was the initial use, reuse, or unknown.
Follow-up Date	Date field to indicate the approximate follow-up or final report date.
Approval Org	The approval body for the device.
Approval #	The approval number for the device.

Field	Comments
Evaluation	If the evaluation was conducted, note summary here and choose Evaluation Summary Attached in Evaluated by Mfg field.
Mfg Narrative	Any additional information, evaluation, or clarification of data presented in previous sections.

Running 3500A and MDV Reports (End User)

Siebel AECM uses the Siebel Reports Server to create formatted reports suitable for submitting to the FDA or other regulatory agency.

Typically, the user views the report:

■ Before generating it, to make sure that the data is correct

■ After generating it, to print a final report for sending to the FDA or other regulatory agencies

NOTE: The fields used to fill in the report are those in the regulatory report record (not the product issue record).

This task is a step in .

To run a report

1 Navigate to the Regulatory Reports screen > Regulatory Report List view.

2 Drill down on a report.

For this type of report...	Navigate to one of these views...	Select this report from the Reports button menu
MedWatch 3500A	■ More Info ■ Patient ■ Importer ■ Manufacturer ■ Investigation	3500A
MVD	■ More Info ■ Patient ■ MDV	MDV

3 Run, print, and save the report as necessary. For information about reports, see *Siebel Fundamentals*.

Which Sections of the MedWatch 3500A Form Get Filled In?

Not all sections of the MedWatch 3500A get filled in for every report. Which sections are filled in depends upon the Event Type and Facility Type fields.

These sections always get filled in:

■ A. Patient Information

■ B. Adverse Event or Product Problem

■ E. Initial Reporter

Table 38 lists the conditions for which the other sections get filled in.

Table 38.   Sections of the Report Filled In According to Event Type and Facility Type Field Values

If...	And...	These sections are filled in...	And these sections are left blank...
Event Type [1] = Adverse Event Drug, Product Problem Drug, or AE and PP Drug	—	C G	D F H
Event Type [1] = Adverse Event Device, Product Problem Device, or AE and PP Device	Facility Type [2] = NULL (blank)	D G H	C F
	Facility Type [2] = User Facility, Distributor, or Importer (That is, not blank)	D F G	C H

1. Regulatory Reports screen > More Info view

2. Regulatory Reports screen > Importer view

Generating Regulatory Report Numbers and Submitting Reports (End User)

When you generate a 3500A or MDV initial report:

■ The report number is generated and filled in

■ The Status field changes to Submitted

■ The fields in the regulatory report record become read-only (except for the Sub Status field)

Only the primary owner of the regulatory report can generate the report number and submit the report.

This task is a step in "Process of Regulatory Reporting" on page 412.

To generate and submit a regulatory report

1 Make sure the application is running on a server database.

   You cannot generate a report number on the Siebel Mobile Web Client.

2 Navigate to Regulatory Reports screen > My Regulatory Reports view.

3 Drill down on a regulatory report with status of In Progress.

4 Click Generate.

   This starts the LS Medical Product Issue RR Submit workflow, which authenticates the user, adds a number for the regulatory report, changes the status to Submitted, and makes all fields except Sub Status read-only.

   For more information about the workflow, see "LS Medical Product Issue RR Submit Workflow" on page 436.

Reopening a Regulatory Report (End User)

If you want to make a change in a generated (submitted) regulatory report record, you need to reopen it. Only the primary owner of the regulatory report can reopen it.

When you reopen a report:

■ The Status field changes to Reopen

■ The fields in the regulatory report record can be edited

This task is a step in "Process of Regulatory Reporting" on page 412.

To reopen a regulatory report

1 Navigate to Regulatory Reports screen > Regulatory Report List view.

2 Drill down on a regulatory report with status of Submitted.

3 Click Reopen.

   This starts the LS Medical Product Issue RR Reopen workflow, which authenticates the user and changes the status of the report to Reopen.

   For more information about the workflow, see "LS Medical Product Issue RR Reopen Workflow" on page 438.

Creating Supplemental or Follow-Up Regulatory Reports (End User)

Often, it is necessary to follow-up an initial report with a follow-up report that provides supplementary information to the regulatory agency.

When you run a supplemental or follow-up report, the report should contain the initial report number and any corrected or new data.

CAUTION: Regulatory report records cannot be deleted.

This task is a step in .

To create a follow-up or supplemental regulatory report

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Regulatory Reports view tab.

4 In the Regulatory Reports list, create a record.

When the regulatory report is created:

■ These fields are copied from the product issue: PI # and SR #

■ These fields are set with a default value: Status = In Progress, Owner = *Creator of the record*

5 Set the Report Type field to 3500A Supplemental or MDV Follow-up.

6 Click Populate Report.

The Populate Report button only copies the initial report number to the supplemental report. (No other fields are copied.) You can configure the application to copy additional fields such as Mfg Narrative and Corrected Data to the supplemental report. Review the LS Medical Product Issue Populate Report Workflow for an example of a similar configuration.

7 If you are a device manufacturer preparing a 3500A Supplemental report, make sure to check a Follow-Up Type in the Investigation view.

8 After creating a follow-up or supplemental regulatory report, you can view it, submit it, reopen it in the same way as a initial report:

■ "Running 3500A and MDV Reports (End User)" on page 422

■ "Generating Regulatory Report Numbers and Submitting Reports (End User)" on page 423

■ "Reopening a Regulatory Report (End User)" on page 424

Field Mapping for the MedWatch Report (Reference)

Table 39 shows how the fields in the Regulatory Reports screen map to the fields in the MedWatch 3500A report.

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
A. Patient Information		
A1	Patient Identifier	Patient
A2	Age	Patient
A2	Date of Birth	Patient
A3	Gender	Patient
A4	U/M	Patient
A4	Weight	Patient
B. Adverse Event or Product Problem		
B1	Event Type	More Info (Event Detail)
B2	Congenital Anomaly	More Info (Event Detail)
B2	Date of Death	More Info (Event Detail)
B2	Death	More Info (Event Detail)
B2	Disability	More Info (Event Detail)
B2	Hospitalization	More Info (Event Detail)
B2	Life Threatening	More Info (Event Detail)
B2	Other	More Info (Event Detail)
B2	Required Intervention	More Info (Event Detail)
B3	Event Date	More Info (Event Detail)
B4	Report Date	More Info, Regulatory Reports screen only
B5	Description [1]	More Info (Event Detail)
B6	Tests/Data [1]	More Info (Event Detail)
B7	Relevant History [1]	More Info (Event Detail)
C. Suspect Medication(s)		

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
C1	Product	More Info (Products)
C2	Dose Per Unit	More Info (Products)
C2	Frequency	More Info (Products)
C2	Route Used	More Info (Products)
C3	Therapy From Date	More Info (Products)
C3	Therapy To Date	More Info (Products)
C4	Indication	More Info (Products)
C5	Event Abated	More Info (Products)
C6	Lot #	More Info (Products)
C7	Expiration Date	More Info (Products)
C8	Reintroduce Reoccur	More Info (Products)
C9	NDC#	More Info (Products)
C10	External Products	More Info (Event Detail)
D. Suspect Medical Device		
D1	Product	More Info (Products)
D2	Common Device Name	More Info (Products)
D3	City	More Info (Products)
D3	Mfg Name	More Info (Products)
D3	Postal Code	More Info (Products)
D3	State	More Info (Products)
D3	Street Address	More Info (Products)
D4	Asset #	More Info (Products)
D4	Catalog #	More Info (Products)
D4	Expiration Date	More Info (Products)
D4	Lot #	More Info (Products)
D4	Model #	More Info (Products)
D4	Part #	More Info (Products)
D4	Serial #	More Info (Products)
D5	Device Operator	More Info (Products)

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
D6	Implant Date	More Info (Products)
D7	Explant Date	More Info (Products)
D8	Reprocessed	More Info (Products)
D9	Reprocessor	More Info (Products)
D10	Device Available	More Info (Products)
D10	Return Date	More Info (Products)
D11	External Products	More Info (Event Detail)
E. Initial Reporter		
E1	Account	More Info
E1	Address	More Info
E1	City	More Info
E1	Contacts (Contact Last Name in list)	More Info
E1	CSN #	More Info
E1	First Name (Contact First Name in list)	More Info
E1	Phone #	More Info
E1	Postal Code	More Info
E1	Site	More Info
E1	State	More Info
E2	Provider	More Info
E3	Occupation	More Info
E4	Reported FDA	More Info
F. For Use by User Facility/Importer (Devices Only)		
F1	Facility Type	Importer
F2	Report #	Importer
F3	Address	Importer
F3	City	Importer
F3	Country	Importer

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
F3	Importer	Importer
F3	Postal Code	Importer
F3	State	Importer
F4	Contact Name	Importer
F4	First Name	Importer
F5	Phone #	Importer
F6	PI Received	Importer
F7	Follow-up #	Importer
F7	Report Type	Importer
F8	Report Date	More Info
F9	Age UoM	Importer
F9	Device Age	Importer
F10	Device Codes	Importer
F10	Patient Codes	Importer
F11	FDA Report Date	Importer
F11	Reported FDA	Importer
F12	Event Location	Importer
F13	Mfg Report Date	Importer
F13	Reported Mfg	Importer
G. All Manufacturers		
G1	Address	Manufacturer
G1	City	Manufacturer
G1	Contact Name	Manufacturer
G1	Contact Office	Manufacturer
G1	Country	Manufacturer
G1	First Name	Manufacturer
G1	Postal Code	Manufacturer
G1	State	Manufacturer
G2	Phone #	Manufacturer

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
G3	Consumer	Manufacturer
G3	Foreign	Manufacturer
G3	Distributor	Manufacturer
G3	Literature	Manufacturer
G3	Other	Manufacturer
G3	Professional	Manufacturer
G3	Representative	Manufacturer
G3	Study	Manufacturer
G3	User Facility	Manufacturer
G4	PI Received	Manufacturer
G5	(A)NDA #	Manufacturer
G5	STN #	Manufacturer
G5	PMA/510(K) #	Manufacturer
G5	Combo Product	Manufacturer
G5	IND #	Manufacturer
G5	OTC Product	Manufacturer
G5	Pre-1938	Manufacturer
G6	Protocol #	More Info (Product Issues) and Manufacturer
G7	10-day	Manufacturer
G7	15-day	Manufacturer
G7	5-day	Manufacturer
G7	7-day	Manufacturer
G7	30-day	Manufacturer
G7	Follow-up	Manufacturer
G7	Follow-Up #	Manufacturer
G7	Initial	Manufacturer
G7	Periodic	Manufacturer
G8	AE Terms	Manufacturer
G9	Mfg Report #	Manufacturer

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
H. Device Manufacturers Only		
H1	Death	Investigation
H1	Malfunction	Investigation
H1	Other	Investigation
H1	Serious Injury	Investigation
H2	Additional Information	Investigation
H2	Correction	Investigation
H2	Device Evaluation	Investigation
H2	Response to FDA Request	Investigation
H3	Evaluated by Mfg	Investigation
H3	Evaluation	Investigation MDV
H3	Non-Evaluation Codes	Investigation
H4	Mfg Date	Investigation More Info (Products)
H5	Labeled Single Use	More Info (Products) Investigation
H6	Conclusion Codes	Investigation
H6	Method Codes	Investigation
H6	Result Codes	Investigation
H7	Inspection	Investigation
H7	Modification	Investigation
H7	Notification	Investigation
H7	Other	Investigation
H7	Patient Monitoring	Investigation
H7	Recall	Investigation
H7	Relabeling	Investigation
H7	Repair	Investigation
H7	Replace	Investigation

Table 39.   Mapping of Fields from the Siebel AECM UI to the MedWatch 3500A Form

Location on MedWatch Form 3500A	Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen
H8	Usage of Device	Investigation
H9	Correction #	Investigation
H10	Mfg Narrative [1]	Investigation MDV
H11	Corrected Data [1]	Investigation

1. If the text is long, it is appears on continuation pages, starting from the third page.

Field Mapping for the MDV Report (Reference)

Table 40 shows how the fields in the Regulatory Reports screen map to the fields in the MDV report.

Table 40.   Mapping of Fields from Siebel AECM UI to the MDV Report

UI Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen	Text on MDV Report
Report Header		
Report #[1] MDV Report # [2]	More Info MDV	MDV Report #
Affiliate Ref #	MDV	Affiliate Ref #
Type	More Info	Report Type
MDV Determination		
Determination	MDV	MDV Determination
Destination		
Authorities	MDV	Competent Authority Name

Table 40.   Mapping of Fields from Siebel AECM UI to the MDV Report

UI Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen	Text on MDV Report
Address Address 2 City State Postal Code Country	MDV	Address
General		
Report Date	More Info, Regulatory Reports screen only	Report Date
Received	More Info	Manufacturer Awareness Date
Affiliate Acct	MDV	Reporting Firm Name
Auth Rep First Name	MDV	Authorized Representative
Address City State Postal Code Country	MDV	Address
Phone #	MDV	Telephone
Fax #	MDV	Facsimile
Event Information		
Patient Identifier	Patient	Patient Identifier
Gender	Patient	Gender
Age	Patient	Age
Weight	Patient	Weight
Date of Birth	Patient	Date of Birth
Account	More Info	Health Care Facility Name
Site	More Info	Site
Contacts, First Name	More Info	Contact Name

Table 40.   Mapping of Fields from Siebel AECM UI to the MDV Report

UI Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen	Text on MDV Report
Address	More Info	Address
Phone #	More Info	Contact Phone Number
Event Date	More Info (Event Detail)	Event Date
Description	More Info (Event Detail)	Event Description
# Occurrences	More Info (Event Detail)	Number of Occurrences
Labeled Single Use	More Info (Products) Investigation	Device Labeled for Single Use
Patient Codes	MDV Importer	Patient Outcomes
Device Codes	MDV Importer	Device Outcomes
Usage of Device	MDV Investigation	Usage of Device
Authorities	MDV	Competent Authorities Already Notified
Device Information		
Mfg Name	MDV	Manufacturer Name
Contact First Name	MDV	Manufacturer Contact Name
Address City State Postal Code Country	MDV	Address
Phone #	MDV	Telephone
Fax #	MDV	Facsimile
Product [3]	More Info (Products)	Device Name
Device Type	More Info (Products)	Type of Device
Lot #	More Info (Products)	Device Lot #

Table 40. Mapping of Fields from Siebel AECM UI to the MDV Report

UI Field Name	View (Applet) on the Regulatory Reports and the Product Issues screen	Text on MDV Report
Part #	More Info (Products)	Device Part #
Asset #	More Info (Products)	Device Asset #
Serial #	More Info (Products)	Device Serial #
Model #	More Info (Products)	Model #
Catalog #	More Info (Products)	Catalog #
Approval Org	MDV	Device Approval Body
Approval #	MDV	Approval #
Qty Involved	More Info (Products)	Quantity of Devices Involved
Device Available	More Info (Products)	Device Disposition
External Products	More Info (Event Detail)	Associated Products
Results of Investigation		
Evaluation	MDV Investigation	Device Evaluation Result
Remedials	MDV	Remedial Action
MFG Narrative	MDV Investigation	Manufacturer's Narrative

1. On the More Info view.

2. On the MDV view.

3. The primary product only.

About Configuring Buttons in Regulatory Reports

There are three buttons associated with regulatory reports. You can configure the workflows for these buttons.

■ Populate Report button ("LS Medical Product Issue Populate Report Workflow" on page 436)

■ Generate ("LS Medical Product Issue RR Submit Workflow" on page 436)

■ Reopen ("LS Medical Product Issue RR Reopen Workflow" on page 438)

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

LS Medical Product Issue Populate Report Workflow

This workflow is initiated from the Populate button on the Regulatory Reports view of the Product Issues screen.

The workflow appears in Figure 19.
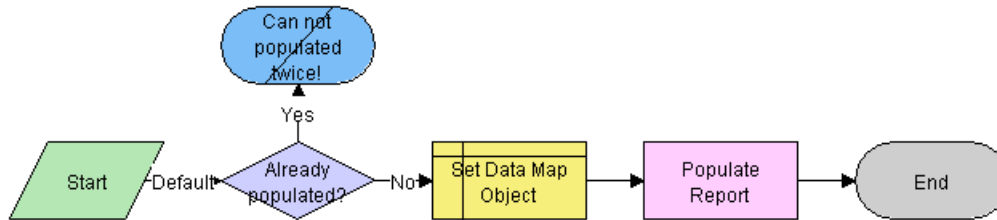
Figure 19. LS Medical Product Issue Populate Report Workflow

The workflow does the following steps:

1 Checks if current record has already been populated. If it has, the workflow ends.

2 Sets the data map object according to the report type.

The data map objects are:

■ LS Medical PI Populate Report - 3500A

■ LS Medical PI Populate Report - 3500 Supplemental

■ LS Medical PI Populate Report - MDV Initial

■ LS Medical PI Populate Report - MDV Follow-up

3 Populates the report from the product issue according to the data map object.

LS Medical Product Issue RR Submit Workflow

This workflow is initiated from the Generate button on the Regulatory Reports screen.

The workflow appears in Figure 20.
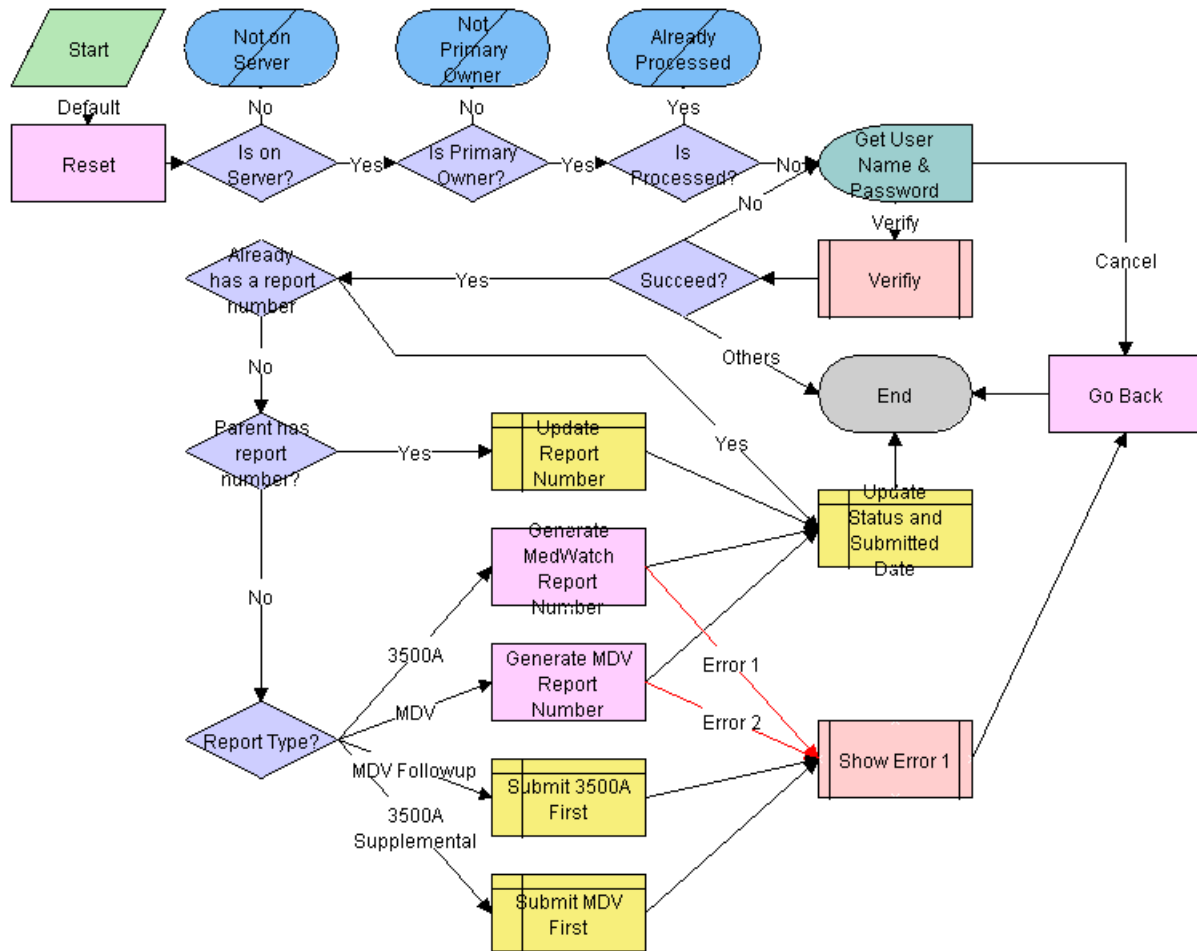
Figure 20. LS Medical Product Issue RR Submit

The workflow does the following steps:

1   Checks if the application is running on a server database. If not, the workflow ends.

2   Checks if the user is the primary owner. If not, the workflow ends.

3   Checks if the record has already been processed. If it has, the workflow ends.

4   Calls the LS Medical User Verification workflow. If the authentication does not pass, the workflow ends.

5 Checks if the parent product issue already has a report number.

If the product issue. . .	and the Report Type Is. . .	Then. . .
Has a report record with a report number	None	Use the same number for the report being submitted.
Does not have a report record with a report number	3500A or MDV	Generate a new report number.
	3500A Supplemental or MDV Follow-up	The workflow ends.

6 Sets the status of the report to Submitted.

LS Medical Product Issue RR Reopen Workflow

This workflow is initiated from the Reopen button on the Regulatory Reports screen.

The workflow appears in Figure 21.
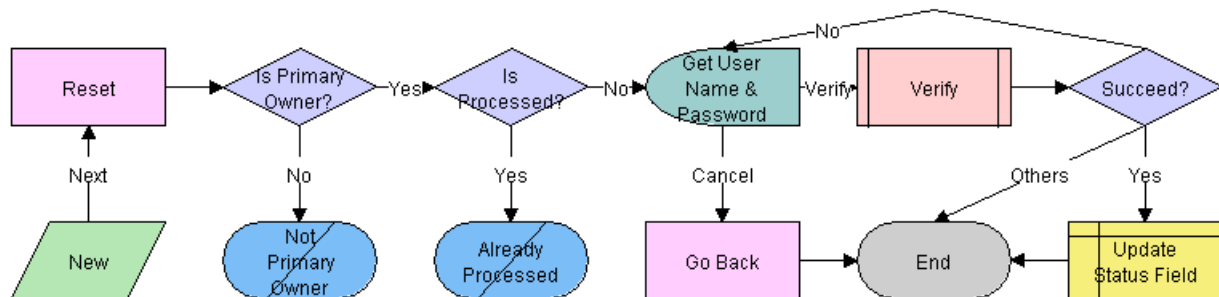
Figure 21. LS Medical Product Issue RR Reopen

The workflow does the following steps:

1 Checks if the user is the primary owner. If not, the workflow ends.

2 Checks if the record has already been processed. If it has, the workflow ends.

3 Calls the LS Medical User Verification workflow. If the authentication does not pass, the workflow ends.

4 Sets the status of the report to Reopen.

28 Closing Adverse Events and Complaints

This chapter covers the following topics:

About Closing Adverse Events and Complaints

This chapter describes the closing of a product issue.

A product issue has come to a conclusion and no new activity or information is anticipated: quality manager closes the product issue record.

When the status of a product issue is changed to Closed, many of the fields in the product issue record become read-only or are locked down to maintain data integrity.

Where to Find More Information

The following chapters describe other aspects of the complaints and adverse events management process:

Scenario for Closing Adverse Events and Complaints

This scenario is an example process performed by the quality manager. Your company may follow a different process according to its business requirements.

This scenario is designed to illustrate the functionality of Siebel AECM.

The Quality Manager

In the course of this scenario, the quality manager closes the product issue, reopens it, reviews its history and finally closes it for good.

Closing

A product issue is ready for closure when:

■ The activities associated with the product issue have been completed and closed.

■ Product analysis has been carried out.

■ The product issue was assessed as reportable and the report sent to the regulatory agency.

■ The customer has been informed about the status of the product issue.

■ A CAPA record has been created.

The quality manager, who is the owner of the product issue, changes the status of the product issue to closed.

Reopening

Some months later, new information resulting from the CAPA work is reported. A new quality manager needs to reopen and revise the product issue based on this new information.

Reviewing History

The new quality manager acquaints himself with the product issue.

He reviews the approval history for the issue, noting who approved the initial product issue review, and who approved the closure.

He also reviews the lockdown fields. This tells him that the name of the account has changed since the product issue was closed.

After updating the fields, the quality manager uses audit trail to review all changes that were made to product issue since reopening. Then he closes the product issue.

Process of Closure for AECM

This example process represents the tasks that are carried out in the *"Scenario for Closing Adverse Events and Complaints" on page 440*. Your company may follow a different process according to its business requirements.

End-User Procedures

■ Closing Product Issues (End User) on page 441

■ Reopening Product Issues (End User) on page 442

■ Reviewing Approvals for Product Issues (End User) on page 442

■ Reviewing Lockdown Fields (End User) on page 443

■ Reviewing Changes Made to Fields (End User) on page 444

Closing Product Issues (End User)

When the status of the product issue is changed to closed, the LS Medical Product Issue Close workflow:

■ Does a user authentication

■ Locks down these fields:

Asset #	Serial #
Lot #	Manufacture Date
Manufacture Name	Street Address
City	State
Postal Code	Country

■ Makes all fields read-only

For more information about the workflow, see *"About Configuring Close and Reopen Buttons for Product Issues" on page 444*.

This task is a step in *"Process of Closure for AECM" on page 441*.

To close a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Select a product issue.

3 Click Close.

4 Complete user authentication.

Reopening Product Issues (End User)

Reopening a product issue reverses the effects of the Review Complaint and Close buttons.

When the status of the product issue is changed to Reopen, the LS Medical Product Issue Reopen workflow:

■ Authenticates the user's login and password

■ Makes read-only fields editable

For more information about the workflow, see "About Configuring Close and Reopen Buttons for Product Issues" on page 444.

TIP: When a product issue is reopened and then closed again, all locked down fields are overwritten with new information: To keep the track of the changes, turn on Audit Trail for the lockdown fields.

This task is a step in "Process of Closure for AECM" on page 441.

To reopen a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Select a product issue.

3 Click Reopen.

Reviewing Approvals for Product Issues (End User)

Any change to the Status field for the product issue record is recorded in the Approvals view. Use the Approvals view to see who has changed that status of the product issue and when the change was made.

To use approval tracking, you must have Audit Trail turned on. For information about Audit Trail, see *Siebel Applications Administration Guide*.

To view approvals for a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Approvals view tab.

In the read-only list, you can view all approvals to the product issue.

Reviewing Lockdown Fields (End User)

About Lockdown Fields

For most purposes, you want your product issue data to contain the up-to-date information. For example, if an account has changed its name, you want have its current name appear in all product issues records so that a query for the current name returns the complete set of product issues associated with the account, both before and after the name change.

However, for record keeping, you may also want to maintain some relational data exactly as it was when the product issue was closed. For example, after the product issue was closed, Dana Frederick changes her name to Dana Feldman. Her new name was updated through the Contacts screen, and this change is reflected in the current product issue record. However, the Lockdown view for the product issue shows Dana's name when product issue was closed. (See Figure 22.)

Figure 22. Lockdown Example

The application should be configured so that the fields appropriate for your business processes are locked down. In the preconfigured application, some fields are locked down at review complete and others are locked down when the product issue is closed.

How to Review Locked Down Fields for a Product Issue

This task is a step in "Process of Closure for AECM" on page 441.

To view lockdown fields for a product issue

1   Navigate to Product Issues screen > Product Issue List view.

2   Drill down on a product issue.

3   Click the Lockdown view tab.

Lockdown fields show the field values as they were when the product issue was closed.

NOTE: For multivalue fields, only the primary value is locked down.

Reviewing Changes Made to Fields (End User)

Using the Audit Trail view, quality managers and other users can see changes made to various fields in the product issue record.

Many fields are set to be audited in the preconfigured application. You can configure the application to audit more or fewer fields. For more information about enabling the audit trail function, see *Siebel Applications Administration Guide*.

To view changes made to product issue fields

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Audit Trail view tab.

4 Review records in the Audit Trail list.

About Configuring Close and Reopen Buttons for Product Issues

There are two buttons associated with closing a product issue. You can configure the workflows for these buttons.

■ Close button (Close Complaint Workflow)

■ Reopen button (Reopen Complaint Workflow)

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Framework: Workflow Guide*.

Close Complaint Workflow

This workflow (LS Medical Product Issue Close) is initiated from the Close button on the Product Issues screen.

The workflow appears in Figure 23.
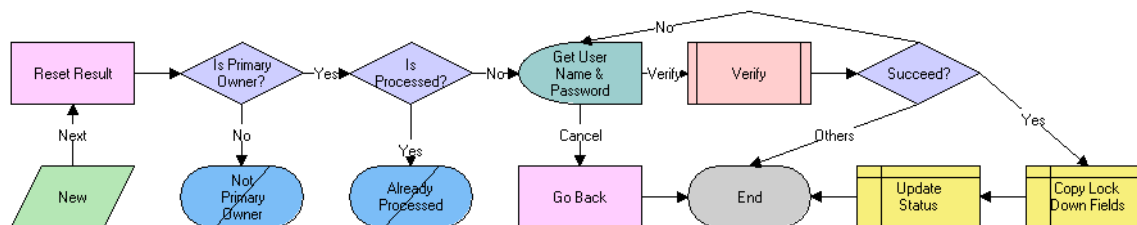
Figure 23. LS Medical Product Issue Close Workflow

The workflow does the following steps:

1 Checks if the user is the primary owner of the product issue.

2 If the user is not the primary owner, shows an error dialog box and ends.

3 Checks if the product issue has already been processed.

4 If the product issue has already been processed, shows an error dialog box appears and ends.

5 Calls the User Verification workflow.

6 If the user authentication is successful, copies the lockdown fields and changes the status to Closed.

Reopen Complaint Workflow

This workflow (LS Medical Product Issue Reopen) is initiated from the Reopen button on the Product Issues screen.

The workflow appears in Figure 24.
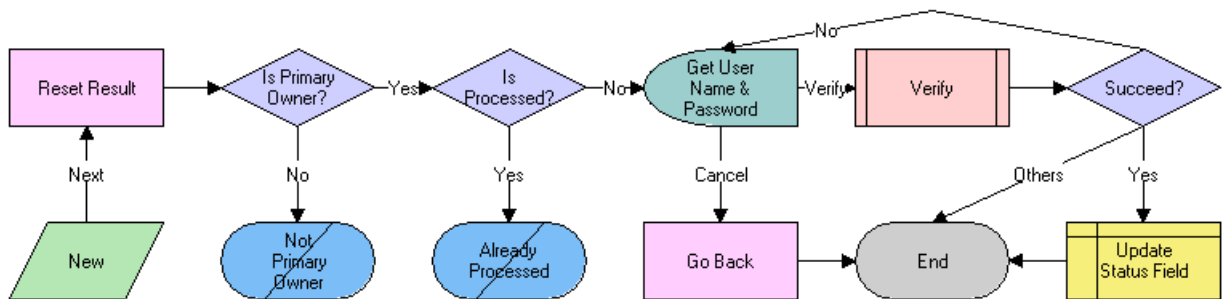
Figure 24. LS Medical Product Issue Reopen Workflow

The workflow does the following steps:

1 Checks if the user is the primary owner of the product issue.

2 If the user is not the primary owner, shows an error dialog box and ends.

3 Checks if the product issue has already been processed.

4 If the product issue has already been processed, shows an error dialog box appears and ends.

5 Calls the User Verification workflow.

6 If the user authentication is successful, changes the status to Reopen and makes the read-only field editable.

29 Communicating with Customers for AECM

This chapter covers the following topics:

About Communicating with Customers for AECM

This chapter describes ways to communicate with the customers and coworkers about an adverse event or complaint. If you have installed the Siebel Document Server, you can create documents such as letters, reports, and presentations from within the Siebel Medical application.

Where to Find More Information

The following chapters describe other aspects of the complaints and adverse events management process:

- Chapter 23, "Capturing Adverse Events and Complaints"
- Chapter 24, "Investigating Adverse Events and Complaints"
- Chapter 25, "Recording Product Analysis for AECM"
- Chapter 26, "Managing CAPAs"
- Chapter 27, "Regulatory Reporting"
- Chapter 28, "Closing Adverse Events and Complaints"

Scenario for Customer Communication

This scenario is an example process performed by the Siebel administrator and the quality manager. Your company may follow a different process according to its business requirements.

This scenario is designed to illustrate the functionality of the Siebel AECM.

The Siebel Administrator

The administrator sets up the Document Server and the Proposals, Presentations, and
Correspondence templates that the quality manager uses to create customized reports, letters, and
presentations. The administrator works closely with the quality manager who provides the text for
the templates.

The Quality Manager

The quality manager is the owner of the complaint investigation about a faulty cartridge in a blood
analyzer system. The investigation is coming to a close: the product analysis has been completed
and a corrective action has been logged.

The quality manager has been assigned two activities:

■ To communicate the status of the product issue with the customer who made the initial complaint

■ To give a short presentation about the product issue at the CAPA team's weekly meeting

To Brief the Customer

The quality manager prepares two sets of documents. First, she generates a report. The report takes
a standard template for product issue reports and automatically incorporates data from the product
issue into the report. She reviews the report in MS Word, making edits and changes as necessary.

There are five contacts associated with the account that made the initial complaint. As a courtesy,
the quality manager wants to send each of them a copy of the report. She uses the Correspondence
feature to generate five personalized cover letters to be mailed with the report.

To Present Data to Colleagues

The quality manager is routinely asked to present information about various product issues at the
weekly CAPA meeting. The administrator has prepared a Power Point template which she uses to
generate a standard product issue presentation, incorporating specific data from the selected
product issue.

Conclusion

After mailing the report packages to the customer contacts and delivering her presentation at the
CAPA meeting, the quality manager changes the status of her two activities to Closed.

Process of Customer Communication in AECM

This example process represents the tasks that are carried out in the "Scenario for Customer
Communication" on page 447. Your company may follow a different process according to its business
requirements.

Administrator Procedures

■ Setting Up Proposals, Correspondence, and Presentations on page 449

End-User Procedures

■ Communicating about Product Issues Using Proposals (End User) on page 449

■ Communicating about Product Issues Using Correspondence (End User) on page 450

■ Communicating about Product Issues Using Presentations (End User) on page 450

Setting Up Proposals, Correspondence, and Presentations

Siebel Proposals, Correspondence, and Presentations allow your employees to create documents based on templates that you create in Microsoft Office.

This task is a step in .

To set up proposals, correspondence, and presentations

■ See *Siebel Correspondence, Proposals, and Presentations Guide* for how to:

    a Install the Document Server.

    b Install the correct version of Microsoft Office.

    c Create field mappings.

    d For proposals and correspondence, create template files in Microsoft Word.

    e For presentations, create template files in Microsoft PowerPoint.

    f Add the templates to the Siebel application.

For This Template	Set the Category Field to
Proposal	Product Issue Proposal
Presentation	Product Issue Presentation

Communicating about Product Issues Using Proposals (End User)

During the course of an investigation, the quality manager may need to create reports containing information about the product issue.

Such reports, as Microsoft Word files, can be generated automatically, incorporating fields from the selected product issue. Predefined product issue proposal templates are set up by the administrator. End users can edit the generated report file in MS Word.

This task is a step in "Process of Customer Communication in AECM" on page 448.

To create a Microsoft Word report for a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Proposals view tab.

For information about creating proposals, see *Siebel Correspondence, Proposals, and Presentations Guide*.

Communicating about Product Issues Using Correspondence (End User)

During the course of an investigation, the quality manager may want to send letters to the contacts associated with the product issue.

The Correspondence feature is used to generate MS Word files (typically letters) where the file is personalized for each contact. That is, information about the contact (name, address, and so on) is incorporated into the letter.

Information about the product issue cannot be incorporated using Correspondence. Use the Proposals feature to incorporate information about the product issue. Predefined correspondence templates are set up by the administrator. End users can edit the generated files in MS Word.

This task is a step in "Process of Customer Communication in AECM" on page 448.

To create a Microsoft Word correspondence

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Contacts view tab.

4 Select the contacts who you want to send correspondence to.

5 From the application-level menu, choose File > Send Letter.

The Correspondence screen appears.

For information about creating correspondence, see *Siebel Correspondence, Proposals, and Presentations Guide*.

Communicating about Product Issues Using Presentations (End User)

During the course of an investigation, the quality manager might need to present information about the product issue.

Microsoft PowerPoint presentations can be generated automatically, incorporating fields from the selected product issue. Predefined product issue presentation templates are set up by the administrator. End users can edit the generated presentation file in MS PowerPoint.

This task is a step in .

To create a Microsoft PowerPoint presentation for a product issue

1 Navigate to Product Issues screen > Product Issue List view.

2 Drill down on a product issue.

3 Click the Presentations view tab.

For information about creating proposals, see *Siebel Correspondence, Proposals, and Presentations Guide*.

30 Using Personalized Content Delivery

This chapter describes how to use Personalized Content Delivery (PCD). It includes the following topics:

About Personalized Content Delivery

Personalized Content Delivery enables companies to deliver presentations that are tailored to meet customer needs using multimedia content. It allows sales teams to deliver the right message to the right customer at the right time. PCD enables sales representatives to optimize each selling opportunity, resulting in improved customer acquisition, satisfaction, and retention.

Sales representatives can use PCD to convey product messages to their customers during a face-to-face sales call. PCD is integrated into the call-reporting process for Siebel Pharma allowing sales representatives to:

- Present key messages and related information
- Capture responses
- Conduct assessments of the messages delivered
- Capture signature for samples

PCD automatically tracks all the interactions and the content presented. The PCD Viewer and PCD Planner leverage Adobe Flash Player technology to render the user interface (UI). The client machine must have Abode Flash installed to allow users to use PCD functionality in a Siebel Business Application.

Defining System Preferences for PCD

Your system administrator must define the following system preferences before you can begin to use PCD.

- Server Uncompression Location

    Specifies the Siebel Server file path location from where uncompressed message files are cached.

■ Decompressed Files Path

Specifies the relative path to cache uncompressed message files when using Siebel Mobile Web Client.

■ CheckForNeedToSync

For remote users, only messages with the user property, NeedToSync, set to Y are decompressed. Otherwise, all messages are decompressed.

■ Skin

Specifies the theme as custom graphical appearances for PCD.

For more information about setting system preferences, see "Setting System Preferences for PCD" on page 494. Table 52 lists the system preference values that you need to set before you start using PCD.

Managing Content for PCD

Siebel Literature allows you to give your users access to sales and marketing literature, such as product brochures, white papers, data sheets, multimedia presentations, interactive presentations, and other types of literature items. For information about literature, see *Siebel Applications Administration Guide*.

PCD uses the content loaded in to the Siebel database. This content is defined as a literature item and the literature type is set to Message. The process for managing PCD content is as follows:

■ Create new content using content creation tools

■ Obtain Legal and Marketing approval for the content

■ Load the content into the Siebel Business Application

■ Verify the content

■ Provide access to content users who create messaging plans

This topic contains the following information:

■ "PCD Support for Content File Formats" on page 455

■ "Loading Content for PCD Usage" on page 455

■ "Associating Attributes with PCD Content" on page 457

■ "Adding Component Files to PCD Content" on page 458

■ "Verifying PCD Content" on page 459

■ "Providing Access to PCD Content" on page 460

■ "Providing Access to PCD Content" on page 460

PCD Support for Content File Formats

Users can create content using a number of third-party content creation tools. The following file types are among the most common:

- Adobe Flash (SWF)

- Portable Network Graphics (PNG)

- Graphics Interchange Format (GIF)

- Photographic Experts Group (JPEG and JPG)

NOTE: You can enable support for additional file formats such as Bitmap (BMP), Abode Acrobat (PDF), Word (DOC), PowerPoint (PPT and/or PPS), and Excel (XLS) by editing the IsSupportedFormat calculated field. However, these file formats are not recommended for creating content.

In order to view a document in PCD, your computer must have the document's native application installed. For example, if you are trying to view a Microsoft Word 2000 document (.doc), Microsoft Word 2000 must reside on your computer.

For more information about the calculated fields for the PCD business components, see "PCD Business Component Calculated Fields" on page 497.

Loading Content for PCD Usage

You must create content before you can load it in your Siebel database. You can create the content using a content creation tool. After you have created a content file, create a literature record in the Siebel database to make the file available to users of Siebel Business Applications. In the Literature record, set the Literature Type field to Message to differentiate the content available to users in PCD from other document files loaded and managed in the Literature view.

To create a literature record

1 Navigate to the Administration - Document > Literature view.

2 In the Literature list, create a new record, and attach the literature file.

   The new literature file is added to the available literature items. Some information is displayed in the Literature list view and the More Info view.

3 Enter the required information in the Literature list and the More Info views for the new record.

   Some fields are described in the following table.

Field	Description
Name	Enter the name of the literature record. It is recommended to remove any dot extension added in the Name field by default when you load the file.
File Name	Click Browse and in the Choose File dialog box, select the document file. You can also enter the file name manually.

Field	Description
Literature Type	Select the type of the literature as Message. You must set this field to Message type, because the Literature Type field is used to filter the literature items that are available in PCD.
Release Date	Select a date after which this content can be used in PCD. This is required for records of Literature Type equal to Message.
Expiration Date	Select a date after which this content should not be used in PCD. This is required for records of Literature Type equal to Message.
Distribution Method	Select Publish to automatically distribute the content to remote users based on permissions.
Questionnaire	(Optional). Click Browse and in the Questionnaire dialog box, select the Template Name that you want, and click OK. Sales assessment templates for Messages are created in Data Administration screen > Sales Assessment Templates view, where assessment template type must be set to Message.
Thumbnail Image	(Optional). Click Browse and in the Images dialog box, select the image that you want and click OK. The associated thumbnail image file is used in PCD Planner.
Verification Status	Set to default value of Not Verified. After the Administrator verifies that the content can be loaded and displayed in PCD Viewer, the verification status is set to Success or Failed. For more information about verification, see "Verifying PCD Content" on page 459.

4 Click Show More to capture additional information about the new content.

Some fields are described in the following table.

Field	Description
Synopsis	(Optional). Enter a brief synopsis of the content.
Description	(Optional). Enter a description of the content.
Subtype	(Optional). Use the drop-down list to select a subtype of the literature file.
Rating	(Optional). Select the rating for the content, if any.
Speaker Notes	(Optional). Enter any Speaker notes for the content.
Audience	(Optional). Enter the intended audience for the content.
External Author	(Optional). Enter the name of the author of the content.
Detail Product	(Optional). Click Browse and in the Pick Product dialog box, select the product name for which this message is created and click OK.
Legal Approval	(Optional). Select if content was approved by Legal.
Legal Approver	(Optional). Select the Legal approver of the content.
Legal Approval Date	(Optional). Select the date the content was approved by Legal.
Marketing Approval	(Optional). Select if content was approved by Marketing.
Marketing Approver	(Optional). Select the Marketing approver of the content.
Marketing Approval Date	(Optional). Select the date the content was approved by Marketing.

NOTE: Do not associate any Accounts, Competitors, Industries and Products to the content as this action might result in unnecessary distribution of content based on associated visibility.

In addition, do not change Local (Checked), Request (Unchecked), Update File (Checked) and Internal (Checked) fields. If you uncheck Internal, Literature is available as an enclosure in the Correspondence screen, and it is displayed in the Competitive Literature list of the Competitors screen.

Associating Attributes with PCD Content

You can associate attributes such as name, product, segment, and so on, with the PCD content to enable users to filter content based on the specified values.

To associate attributes with the PCD content

1 Navigate to the Administration - Document > Literature view.

2 In the Literature list, select a record.

3 Click the Applies To tab, and indicate which product, indications, decision issues, and therapeutic class that the message applies to.

Some fields are described in the following table.

Field	Description
Product	Select the product that you want to apply to the message.
Indication	Use the drop-down list to select the indication for which the message was designed.
Issues	Use the drop-down list to select the issue that the message was designed to address.
Therapeutic Class	Use the drop-down list to select the therapeutic class for which the message was designed.

Adding Component Files to PCD Content

You might want to add additional component files to the PCD content. For example, the message might be composed of one or more files, such as logos, help text, and translation files. Other component files might contain dynamic content to promote content reuse.

Adding component files to PCD content

1 Navigate to the Administration - Document > Literature view.

2 In the Literature list, select a record.

3 Click the Component Files tab to indicate the component files that you want to add to the selected message, and click New. The Component Files dialog box is displayed.

Some fields are described in the following table.

Field	Description
Description	Enter a description of the component file.
Literature Type	Use the drop-down list to select a literature type for this component file.
Subtype	Use the drop-down list to select a subtype. For example, Message, Video, Document, Clinical Reprint, Case Study and so on.
Relationship Type	Use the drop-down list to select the relationship type of the file in relation to the message, for example, Help, Component File, Translation File, Logos, and so on.

NOTE: You can add only one help file to each PCD content record. In PCD Viewer, click the Help button to display the help component file associated with the message being presented.

Verifying PCD Content

You must verify that the PCD content loads in to the Siebel database correctly, and that the content works as intended before making the content available to users of Siebel Business Applications. Ensure that any help files or assessments associated with the message displays properly.

You can click Verify to load and verify the PCD content. When you close the Verify window, you are prompted to select a verification status of Success or Failed.

To verify PCD content

1 Navigate to the Administration - Document > Literature view.

2 In Literature view, click Verify.

The PCD content and component files are loaded, and a Verify window (PCD Planner) is launched in preview mode.

3 Check the content and ensure that all links are working.

4 Click Save and the Message Verification dialog displays.

5 Select the verification status, either Success or Failed.

You can select Success, if the content is successfully loaded to PCD. If you select Failed, the content is not loaded, and the content might have to be revised. For example, you might have to recreate content using a compatible format.

The result is written to the verification status field of the message record.

Providing Access to PCD Content

PCD content can be made accessible to brand managers and sales operation managers by adding appropriate categories to the Literature record. You can create private categories for users you want to have access to the content by associating the categories to the PCD content.

For more information about access groups, see *Siebel Security Guide*.

To add category information for PCD content

1   Navigate to Administration - Document > Literature > Category view.

2   Click Add and from the Sub Categories dialog, select the record that you want, and click OK.

3   Drill down on the Catalog Name and select Private in order to restrict visibility and to route the PCD content to the selected users.

Working with Messaging Plans

Messaging plans combine a number of messages in a specific sequence. For example, a presentation that comprises of a number of slides are displayed in a specific sequence. Messaging plans are created by brand managers, product managers, and sales operation managers. You can associate messaging plans with objectives for a sales representative. You can also associate messaging plans with marketing communications (Contact Call Offers) directed at a contact.

A high level process of messaging plans is as follows:

■   Create, update and revise messaging plans

■   Preview messaging plan

■   Release messaging plan

■   Provide sales representatives access to messaging plans

■   Associate messaging plans to Objectives and Marketing Communications Offers

This topic contains the following information:

Creating and Editing Messaging Plans

After you have verified the approved PCD content and made it accessible to select users by adding appropriate private categories to the Literature record, you must create a messaging plan that can be distributed to the various sales representatives. The sales representative can use these messaging plans during their face to face calls with targeted customers.

To create a messaging plan

1 Navigate to Messaging Plans > Messaging Plan List view.

2 Click New to launch the Create Messaging Plan window.

NOTE: This window is often referred to as PCD Planner when messages are loaded into the Siebel Business Application.

3 From the Create Messaging Plan window:

   a Click the Items tab to view the content items that are available to you.

   b Drag and drop individual items in to the Presentation Items area to start creating your own customized messaging plan.

   You can associate additional items to be made accessible to the user as Related Messages and Detailed Messages when viewing a presentation item in PCD Viewer as follows:

   ❏ Drag an item to the Presentation Items area.

   ❏ Select the item, then drag and drop the item to the Related Messages or Detailed Messages area to automatically create an association with the selected additional items.

   c Click the Plans tab to view previously created messaging plans that you might want to reuse.

   d Drag and drop previously created plans to the Presentation Items, Related Messages and Detailed Messages area, as required.

4 Click More Information to view additional messaging plan information as required.

   For example, you can view a short description or some speaker notes to aid with the presentation of the message. You might also see some information about the audience for whom the message is targeted.

5 Click Filter if you want to search the messaging plan for a specific value.

   If the Items tab is selected, then the Filter tab shows the filter attributes for the messages, (that is, content items). If the Plans tab is selected, the Filter tab shows the filter attributes for the messaging plans.

   a Enter the field attributes that you want to filter and click OK to start the filtering process.

   b Click Reset to clear the messaging plan filter attributes previously set.

6 Click Save As to display the Save Messaging Plan dialog box.

7 Enter your messaging plan name.

8 Select the Product for which the messaging plan is being created.

9 Determine if the messaging plan can be customized by selecting Allow Personalization.

10 Select the Disclosure Mandatory option and define the disclosure message if disclosure is mandatory.

11 Click Save.

The Create Messaging Plan window closes and the Messaging Plan List view is displayed. The messaging plan is written to the Siebel database and is visible from the Messaging Plans screen.

After you have created a messaging plan, you can edit the plan by clicking the Edit button in the Messaging Plan Detail view.

To edit a messaging plan

1 From the Messaging Plan Detail view, select a record, drill down on the Name field, and click Edit.

You can modify any of the presentation items or related or detailed messages in your messaging plan.

2 Click Save.

3 (Optional) Click Preview if you want to review the messaging plan.

Updating Messaging Plans

When you have created your messaging plan, you can configure it to suit your specific requirements. When you navigate to Messaging Plans screen > Messaging Plans view and drill down on a messaging plan, you are presented with the Messaging Plans Detail view. Under the Presentation Items detail view tab are three applets namely Presentation Items, Related Messages and Detail Messages. All three applets are edit only. You cannot create new records or delete records here. These applets are populated when the Messaging Plan is created in PCD Planner (Create Messaging Plan window).

You can sequence the information to suit a particular presentation. You can also associate any related messages and detailed messages with the messaging plan.

Select the Assess Group tab to control access of the messaging plans, the related data, and component files. You can also add help text to your messaging plan to aid in the presentation of your message.

You can update the presentation details for a messaging plan.

To update the presentation details for a messaging plan

1 Navigate to Messaging Plans > Messaging Plans view.

2 In the Messaging Plan list, select a record, and drill down on the Name field.

3 Click the Presentation Items tab, and update the details for the presentation items.

Some fields are described in the following table.

Field	Description
Sequence #	Display only. Shows the sequence number for this presentation item.
Name	Display only. Shows the name for the literature record.
Display Name	When a messaging plan is selected in PCD Viewer, its presentation items are displayed as tabs. The name appearing on these tabs depends on the value in this Display Name field. You can enter a display name of your choice. The default value is equal to the Name field value.
Status	Use the drop-down list to select Show or Hide status for this presentation item.
Disclosure Message	Disclosure Message is the disclosure content that needs to be displayed before this messaging plan is presented. One of the presentation items in a messaging plan can be set as Primary. This primary presentation item in a plan is called the disclosure message and always has a sequence # equal to 0.
	If a messaging plan is selected for presentation in PCD Viewer and the disclosure mandatory flag for the plan is equal to Y, then this disclosure message is automatically presented. If you add a new physician to the messaging plan, the disclosure message is displayed. If the disclosure mandatory flag for the messaging plan is equal to N, then the disclosure message is shown only if the sales representative clicks on the Show Disclosure button in the PCD Viewer.
Questionnaire	Select the Template Name that you want to add to this presentation item.
	Sales assessment templates for Messages are created in Data Administration screen > Sales Assessment Templates view, where assessment template type must be set to Message.
Synopsis	Enter a brief description for the presentation item.
Speaker Notes	Add your notes for this presentation item.
Description	Enter a brief description of the contents for this presentation item.
Type	Display only. Shows the literature sub type field in Literature list applet in Administration - Document > Literature view.
Rating	Use the drop-down list to select a rating for this presentation item.
Audience	Enter the type of user for which the content is targeted.

Releasing a Messaging Plan

You can only revise a messaging plan if its status is equal to either Approved or Released. When you create a new messaging plan, its status is In Progress. The messaging plan must go through the approval process. You must set the status to Submitted and associate a required category with the messaging plan so that approvers have access to the messaging plan.

The approver can then set the status of the messaging plan to either Approved or Rejected. If the status is Approved, then you can release the messaging plan by setting the status to Released and by associating the required category with the messaging plan to make it visible to the required sales representatives.

To release a messaging plan

1 Navigate to Messaging Plans > Messaging Plans view.

2 Select Submitted from the Status drop-down list to submit the messaging plan for approval.

3 Associate the category to make the messaging plan accessible to the approver.

The approver approves the messaging plan by changing the status field to Approved.

Finally, the owner can release the messaging plan by setting the status to Released.

Providing Access to Messaging Plans

You can control access to the messaging plan, presentation items, related messages, and detailed messages.

To assign access groups to a messaging plan

1 Navigate to Messaging Plans > Messaging Plan List view.

2 In the Messaging Plan list, select a record, and drill down on the Name field.

3 Click the Access Group tab, and then click Add to add access group details for the messaging plan.

Some fields are described in the following table.

Field	Description
Category Name	Enter the category name associated with the messaging plan, presentation items, related messages, and detailed messages.
Display Name	Enter the display name for the access group.
Catalog Name	Enter the catalog name used to control access to the messaging plan, presentation items, related messages, and detailed messages.
Description	Enter a description for the access group.

Field	Description
Effective Start Date	Enter the date when the catalog becomes visible to the assigned users.
Effective End Date	Enter the date when the catalog will no longer be visible to the assigned users.

4 Select a record, and click Delete if you want to remove an access group.

5 Click Refresh Cache to view the recent changes to your messaging plans.

Associating Help to Messaging Plans

You can create help text for your messaging plan.

To associate help text for a messaging plan

1 Navigate to Messaging Plans screen > Messaging Plans view.

2 In the Messaging Plan list, select a record, and drill down on the Name field.

3 Click the Help File tab, click New, and add the help text for the messaging plan.

Some fields are described in the following table.

Field	Description
Name	Enter the name of the help file.
Description	Enter a description of the help file.
Sub Type	Use the drop-down list to select a sub type for the help file.
Literature Type	Use the drop-down list to select a literature type for the help file.

4 Select a record, and click Delete if you want to remove the help text for a specific messaging plan.

Revising Messaging Plans

You can only revise a messaging plan with status of Released. Revising a messaging plan creates a new copy of the original messaging plan and increments the version number. After you make modifications, the new version of the messaging plan can be released.

You can also specify a Start Date and an Expiry Date for a messaging plan. Release Date, Start Date and Expiry Date control when users with access to a messaging plan can start to use the messaging plan in PCD Viewer during calls with customers.

NOTE: When you revise a messaging plan, a new version number is created and the revised messaging plan must go through the same approval process before it become active. When the new version is active, the older version does not become inactive.

To revise a messaging plan

1   Navigate to Messaging Plans > Messaging Plan List view.

2   In the Messaging Plan list, select a record that has a status of Released.

3   Click Revise, and enter the revised information for the messaging plan.

Two or more versions of a messaging plan can be active simultaneously. A messaging plan is active if the release date is before or is today's date, and is before the expiration date. When you load messaging plans in PCD Viewer, only the highest, active version of a messaging plan is loaded. For more information about loading messaging plans in PCD Viewer, see "Availability of Messaging Plans in the PCD Viewer" on page 496.

Associating a Messaging Plans with an Objective

You can define multiple objectives for your call plan period. You can associate messaging plans with these objectives. When associating messaging plans, you must provide a segment code for each association. The segment code indicates which messaging plan to recommended for which segments of the targeted contacts.

A single messaging plan can be associated with multiple objectives, and multiple messaging plans can be associated with a single objective. You can also have the same target segment code for multiple messaging plans.

To specify a segment code for a target

1   Navigate to Objectives > My Objectives screen.

2   Select a record, and drill down on the Objective field.

3   Click on Targets tab and click New to select the targeted contacts.

4   For each target, specify a Segment value, for example High, Medium, or Low.

To associate a messaging plan with an objective

1   Navigate to Objectives > My Objectives screen.

2   Select a record, and drill down on the Objective field.

3   Click the My Messaging Plans List tab, and then click New to select the messaging plan to associate with the objective.

4 For each associated messaging plan, specify a Segment field value equal to the value that you specified for the target, for example, High, Medium, Low. This action indicates which messaging plan to use with which segment of the target contacts.

When you create a new call on target contact, you can select the Objective for the call. When you click Detail in Call Detail View, PCD compares the segment code on the target to find the recommended messaging plans that are accessible to you. These messaging plans are displayed on the top in PCD Viewer. For more information about recommended messaging plans, see "Recommended Messaging Plans" on page 500.

Associating a Messaging Plan with Contact Call Offers

Brand teams create new Contact Call offers as part of the campaign planning and execution process. The Contact Call offers are marketing communications that can be delivered by sales representatives as part of their face to face calls. Once a messaging plan is created and released, you can navigate to Offers > Contact Call Offers view to associate a messaging plan with the Contact Call offer.

You can view the marketing communications (offers) targeted to a contact when planning a Contact Call. When you launch the PCD Viewer for a call on a target contact, PCD loads the messaging plan associated to the Contact Call offers accessible to you for the target contact as recommended messaging plans. You can use switch presentation and select the appropriate messaging plan.

To associate messaging plans with contact call offers

1 Navigate to Offers > Contact Call Offers screen.

2 Select a record, and drill down on the Name field.

3 Click the My Messaging Plans List tab, and then click New to create a new record.

4 Click on the Name field picklist to associate a messaging plan with the Contact Call Offer.

Accessing and Delivering Messaging Plans

PCD enables sales representatives to provide high impact presentations using multimedia visualization content created by the marketing teams. The PCD Viewer provides the mechanism to start an interaction session, switch between different product messages, show related collateral, show detailed level messages, or collect feedback.

PCD Viewer auto-loads the optimal set of messaging plans for each customer visit. You can capture electronic signatures for samples during a call or visit. PCD Viewer tracks the messages presented and the time spent on each message. You can indicate a physician's response and add notes based on a call or conversation.

You can start an interactive customer interaction session in several ways by accessing the PCD Viewer from the Contact Call Detail screen, the Account Call detail screen or the Account Contact Call Detail screen.

To start the PCD Viewer from the Call Detail screen

1 Navigate to Activities > Contact Call Detail screen. Alternatively, navigate to Activities > Account Call Detail screen

2 Create a New Call.

3 For Contact Calls, add any samples drops, if required.

NOTE: You will need to pre-record the sample drops if signature needs to be captured from contact. Signatures for Samples can be captured only for contacts valid to receive and sign for samples. For more information about signature capture, see Chapter 9, "Recording Calls in Pharma." For more information about samples, see Chapter 8, "Managing Pharma Samples."

4 Click Detail to display the PCD Viewer.

PCD viewer auto-loads the optimal set of messaging plans for each customer interaction.

5 Review the loaded messages and the various messages plans in preview mode.

6 Click the Click To begin button from the PCD Viewer toolbar when you are ready to meet your contact.

7 Present the various messages and message plans. For more information about presenting your message, see "Using the PCD Viewer" on page 476.

8 Click Open Questionnaire if a questionnaire is associated to a message.

In PCD Viewer, if a presentation item has an associated Questionnaire, the toolbar displays a flashing (or glowing) button. You can click this flashing button to display the Questionnaire and capture a physician's response.

9 Capture the physician's response and click on Close to close the dialog box when complete.

10 Click Close or Sign from the PCD Viewer toolbar when you have completed the details.

If you click Sign, the Signature Capture view is displayed when the call data is validated.

If the validation for Signature Capture fails, an error message is displayed. Update the call data as directed by the error message, and then click Sign to try capturing the signature again. Once you successfully save the signature, you return to the Contact Call view.

NOTE: For Account Call, the PCD Viewer toolbar does not display the Sign button.

If you click Close, you return to the Contact Call view.

PCD automatically updates the:

■ Presentation Details Applet with tracking information about your customer interaction, navigation path, content used and time spent on each asset.

■ Products Detailed Applet based on the Messaging Plans for various products used by you during the customer interaction.

■ Questionnaire applet based on the questions and response you captured during your customer interaction.

11 Update the call data as required and then submit the call.

Decompressing PCD Content

As part of remote synchronization based on catalog visibility, all new messaging plans and PCD content files are automatically downloaded to the remote client. Sales representatives must decompress and cache the PCD content before they can use the new PCD content and messaging plans for an interactive session during a call.

Click the Decompression button from the Siebel Application toolbar. Literature records have a calculated field called, NeedToSync. The value of this field is set to True if the record is modified after decompression.

If the value of the user property, CheckForNeedToSync, is set to Y, then the next time you click the Decompression button, only messages with the user property, NeedToSync, set to Y are decompressed. Otherwise, all messages are decompressed.

For more information about how PCD content decompression works, see *"Setting System Preferences for PCD" on page 494*.

Using Signature Control

With signature control, users can capture signatures for samples disbursement to qualified contacts.

This section contains the following topics:

- *"About Loading Signature Control" on page 469*
- *"Configuring Signature Control Modes" on page 470*
- *"Signature Capable Messages" on page 471*
- *"Capturing a Signature" on page 473*
- *"Modifying Contacts in the Signature Component" on page 474*
- *"Deleting a Sample Row" on page 475*
- *"Cancelling a Transaction" on page 475*
- *"Viewing all Captured Signature Data" on page 475*

About Loading Signature Control

There is a separate component for capturing signatures in Flex. This component is available in PCD as an SWF file called SignatureCtrl.swf.

Signature control can be loaded in PCD using three different modes:

- **Mode 1**. A signature message is defined on the message plan and the current message has an allocated space for the signature control. For information about configuring this mode, see*"Configuring Mode 1 Signature Control" on page 470*.

- **Mode 2**. A signature message is not defined on the message plan and the current message has an allocated space for the signature control. For information about configuring this mode, see *"Configuring Mode 2 Signature Control" on page 470*.

■ **Mode 3**. A signature message is not defined on the message plan and the current message does not have an allocated space for the signature control. This is the default configuration, no additional configuration is needed for this mode.

Configuring Signature Control Modes

This section outlines the required configuration steps for different signature control modes. For additional information about the modes available, see "About Loading Signature Control" on page 469.

Configuring Mode 1 Signature Control

This topic contains information about configuring signature control for mode 1. When the instructions in this section are applied to a messaging plan, the specified signature message will be displayed when the representative clicks Sign.

To configure mode 1 signature control

1 Navigate to Administration-Document > Literature screen.

2 Load the signature message in view, as explained in the "Loading Content for PCD Usage" section.

3 Set the value of field SubType to Signature Capable. For additional information about signature capable messages, see the "Signature Capable Messages" section.

4 Navigate to Messaging Plans > Messaging Plan List screen.

5 Click the name of the messaging plan to which you want to associate the signature message.

6 Click the Signature Asset tab.

7 Click the New button and associate a signature message with the messaging plan.

Configuring Mode 2 Signature Control

This topic contains information about configuring signature control for mode 2. When the instructions in this section are applied to a messaging plan, the specified signature message will be embedded in the message that is being played at that moment.

To configure mode 2 signature control

1 Navigate to Administration-Document > Literature screen.

2 Load the signature message in view, as explained in the "Loading Content for PCD Usage" section.

3 Set the value of field SubType to Signature Capable. For additional information about signature capable messages, see the "Signature Capable Messages" section.

4 Navigate to Messaging Plans > Messaging Plan List screen.

5 Click New to create a new plan or click edit button to edit a plan.

6 While creating or updating a plan, add the signature message to the plan as a presentation item.

Signature Capable Messages

A signature capable message is an SWF file that has a space allocated in it for displaying the PCD signature control: SignatureCtrl.swf. The file communicates with both the signature control and the PCD application.

To properly implement a signature capable message certain requirements are member variables must be set, and certain methods must be applied. Follow the requirements in the following sections before using signature control:

■ "Member Variable Requirement for Signature Capable Messages" on page 471

■ "Method Requirements for Signature Capable Messages" on page 471

Member Variable Requirement for Signature Capable Messages

In order to hold a pointer to the SignatureCtrl.swf embedded within the message set the following variable:

    private var m_signCtrl:SystemManager;

This pointer will be used to invoke methods in SignatureCtrl.swf

Method Requirements for Signature Capable Messages

The following method requirements must be met in order to properly implement signature control:

■ The appLoaded method must be called on the applicationComplete event with the following predefined string:

    Application.application.signAssetLoadComplete(this);

For an example of this method requirement, see "FlexApp appLoaded Example" on page 472

■ The loadSignCtrl method will be called by the Interactive Detailer to notify the Asset with the path of the SignatureCtrl.swf and asset will load.

For an example of this method requirement, see "FlexApp LoadSignCtrl Example" on page 472

■ The InvokeSignCtrlMethod method will be called by the Interactive Detailer to invoke a method in SignatureCtrl.swf by way of the Asset.

For an example of this method requirement, see "FlexApp InvokeSignCtrlMethod Example" on page 473

FlexApp Examples

FlexApp is a sample signature asset created in Flex. This asset has the following minimum method requirements:

■ Loading the SignatureCtrl.swf

■ Enabling communication between the Interactive Detailer and the signature control, by way of the Signature Asset

FlexApp appLoaded Example

FlexApp.mxml has a method called appLoaded. The appLoaded method is called by the applicationComplete event. The call is shown in the following sample:

```
<mx:Application ....................applicationComplete="appLoaded();">

....................

public function appLoaded():void

{

    Application.application.signAssetLoadComplete(this);

}
```

The appLoaded method notifies the parent application -- in this case Interactive Detailer -- that the Signature Asset is loaded and ready to load SignatureCtrl.swf, using the following statement:

```
Application.application.signAssetLoadComplete(this);
```

Where Application.application refers to Interactive Detailer and signAssetLoadComplete refers to a method in Interactive Detailer that receives a pointer to the Signature Asset as an input parameter. This pointer will be used by the Interactive Detailer to send data to the SignatureCtrl.swf embedded in the Asset.

FlexApp LoadSignCtrl Example

FlexApp.mxml has member variable of type SystemManager. This member variable holds a pointer to the SignatureCtrl.swf embedded within the asset. The pointer is shown in the following sample:

```
private var m_signCtrl:SystemManager;

public function loadSignCtrl(strSignCtrl:String):void

{

    loader.autoLoad = true;

    loader.percentHeight = 100;

    loader.percentWidth = 100;

    loader.load(strSignCtrl);

    loader.addEventListener(Event.INIT, loadComplete);

    loaderBox.addChild(loader);

}

private function loadComplete (event:Event) : void

{
```

```
        m_signCtrl = SystemManager(event.target.content);

    }
```

The Interactive Detailer sends the path of SignatureCtrl.swf and notifies the Signature Asset to load the Signature Control by calling a method called loadSignCtrl. This is all implemented by the Asset.

The Signature Asset method, loadSignCtrl, will load SignatureCtrl.swf into an SWF loader. The pointer to SignatureCtrl.swf is stored in the member variable m_signCtrl, as displayed above in loadComplete function.

FlexApp InvokeSignCtrlMethod Example

FlexApp.mxml also implements a method called InvokeSignCtrlMethod. When the Interactive Detailer is required to send data to SignatureCtrl.swf, it does so by calling this method in the Asset. The following XML data is passed to the Asset:

```
public function InvokeSignCtrlMethod(strXMLData:String):void

    {

        if(m_signCtrl != null)

        Object(m_signCtrl.application).InvokeMethod(strXMLData);

    }
```

Capturing a Signature

With signature control, users can capture signatures for samples disbursement.

To capture a signature

1 Navigate to Activities > Contact Call Detail screen. Alternatively, navigate to Activities > Accounts Contacts Call Detail screen.

2 Select a sample from Samples Dropped.

   NOTE: You will need to pre-record the sample drops if the signature needs to be captured from contact. Signatures for Samples can be captured only for contacts valid to receive and sign for samples. Click Detail to display the PCD Viewer.

   The PCD viewer auto-loads the optimal set of messaging plans for each customer interaction.

3 Click Sign from the PCD Viewer toolbar.

   NOTE: The Sign button in the PCD viewer will only be visible if there is at least one sample drop record in the samples dropped applet in call detail view.

4 In the Signature Component, a white space is reserved for a signature. Sign within the white space reserved for the signature.

If the validation for Signature Capture fails, an error message is displayed. Update the call data as directed by the error message, and then click Sign to try capturing the signature again. Once you successfully save the signature, you return to the Contact Call view.

For additional information about signature validation, see "Configuring the Sign Button" on page 176.

5 Click Save to save the signature.

Modifying Contacts in the Signature Component

A representative can change the contact to another contact within the signature component.

For example, a representative is speaking with Dr. A. A Contact Call Record has already been created for Dr. A. The representative adds sample drop records to this call by clicking the Detail button in Call view. Now consider that the signature was captured for Dr. A and saved. The status of the record has been changed to Signed.

If instead of Dr. A, the representative selects a different contact: Dr. B. The signature control will then create a new contact call record in the Siebel database for Dr. B, and the sample records will be copied over to the new call. This new call will be validated, and the signature is captured and saved and the status of the call record will be set to Signed.

The module will only allow the representative to change the contact if the validation process confirms that the contact is eligible. Otherwise, an error message will appear.

To modify contacts in the signature component

1 Navigate to Activities > Contact Call Detail screen. Alternatively, navigate to Activities > Accounts Contacts Call Detail screen.

2 Select a sample from Samples Dropped.

3 Click Detail to display the PCD Viewer.

The PCD viewer auto-loads the optimal set of messaging plans for each customer interaction.

4 Click Sign from the PCD Viewer toolbar.

5 Click the Change Professional button.

6 Select the desired contact.

7 Click Select.

NOTE: If the contact does not have a license for the geographic region, a Sign Validation Failed message will appear indicating the following: *This contact does not have a license number for <region>.*

8 Click Save.

Deleting a Sample Row

A representative can delete a sample in signature component. For example, if the representative is speaking with Dr. A and discovers that the sample is not of use, the sample row can be deleted.

To delete the sample row in the signature component

1 Navigate to Activities > Contact Call Detail screen. Alternatively, navigate to Activities > Contact Call Detail screen

2 Select a sample from Samples Dropped.

3 Click Detail to display the PCD Viewer.

    The PCD viewer auto-loads the optimal set of messaging plans for each customer interaction.

4 Click Sign from the PCD Viewer toolbar.

5 Click the Delete button next to the sample that you want to delete.

6 Click Save.

Cancelling a Transaction

The following topic describes how to cancel a transaction. The Cancel button will cancel but will not delete all of the data associated with the transaction. When the Cancel button is clicked, it marks the transaction as voided, but is sent back to the system as a no signature activity.

To cancel a transaction

1 Navigate to Activities > Contact Call Detail screen. Alternatively, navigate to Activities > Accounts Contacts Call Detail screen.

2 Select a sample from Samples Dropped.

3 Click Detail to display the PCD Viewer.

    The PCD viewer auto-loads the optimal set of messaging plans for each customer interaction.

4 Click Sign from the PCD Viewer toolbar.

5 Capture a signature.

6 Click Cancel.

When you click the Cancel button in signature control, a cancelled transaction record will be written to the Siebel database only if the transaction was valid. A transaction is valid only when it passes all the validation checks and the signature was captured but the action was cancelled.

Viewing all Captured Signature Data

Once a signature is captured, it is stored in the Siebel database for future reference. You can view all of the captured signature data in one location.

To view all captured a signature

1 Click the Site Map.

2 Navigate to Administration - Samples > Sample Audit Administration.

3 Scroll through the list to view all of the signatures. Sort the columns by the criteria that you want.

   NOTE: You can click Query to search for a signature.

Using the PCD Viewer

The PCD Viewer provides a mechanism to deliver interactive, digital-marketing content. It enables you to chat, present key messages, use highly-interactive content created using Adobe Flash, video and other formats.

The icons available from the PCD Viewer toolbar are described in Table 41.

Table 41.   PCD Viewer Toolbar Icons
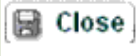
Icon	Description	Shortcut
☆ ☆ ☆ ☆ ☆	You can quickly capture responses by selecting the right option. For example, click on the first star to denote Continue Discussion. Click the second star to denote Need Data, the third star might denote Accepted, the fourth star might denote Not Interested and the final star might denote that the customer has Rejected the message. **NOTE:** The number of stars and the associated values is controlled by a List of Values defined for PCD_RESPONSE_TYPE.	None
Sign	Click to close and sign. Sign can immediately navigate you to Signature Capture for Samples screen.	CTRL + I
Close	Click to save the session. PCD automatically tracks and updates all the interactions and responses along with duration and sectional information. It also automatically updates the products detailed.	None
(pencil icon)	Click to switch to markup mode where you may have access to markup capabilities to support the discussion.	CTRL + M
(eraser icon)	Erase all markups.	CTRL + E
(add contact icon)	Click to add a contact to this session. For example, in group practices, you can easily add multiple physicians to a session.	CTRL + SHIFT +Y

Table 41.   PCD Viewer Toolbar Icons

Icon	Description	Shortcut
	Click to switch between different product messages.	CTRL + 3
	Click to lock the PCD Viewer. A numeric keypad will appear with a prompt asking you to enter a number between 5 and 8 digits. This number will be required to unlock the PCD viewer.	CTRL + 8
	Click to view help associated with the message you are viewing.	CTRL + 1
	Click to open questionnaire. You can also capture physician's attitude, beliefs and needs using the questionnaires associated to different messages.	CTRL + 5
	Click to show disclosure message.	None
	Click to show related messages. You have access to related messages such as clinical reprints, case studies and so on.	CTRL + 7
	Click to drill down to detailed messages.	CTRL + 2
	Move to previous slide.	None
	Move to next slide.	None

A Configuring Siebel Life Sciences

This appendix contains information on configuring the Siebel Life Sciences application using Siebel Tools. It assumes that you are familiar with the processes and conventions of working with Siebel Tools to change one or more user properties. For further information about changing user properties, see *Configuring Siebel Business Applications*.

This appendix contains information about the following topics:

Targeting Configuration

The Siebel Life Sciences targeting engine can be configured through the user properties found in Table 42 and Table 43. Table 42 details the TargetCategory user properties.

Table 42.   TargetCategory User Property

Field	Required	Description
Name	Required	TargetCategory.
Changed	Read-only	An indicator of whether or not the user property is changed.
Value	Required	A value that the targeting engine uses to determine which saved lists are available to the business component. This value is strictly user-defined. Siebel Pharma ships with the default values, Contacts, for contact-related business components and, Accounts, for account-related business components. One TargetCategory can be active for each business component.
Inactive	Optional	An indicator of whether the user property is active.
Comments	Optional	Comments describing the user property.

Table 43.   TargetId User Property

Field	Required	Description
Name	Required	TargetId.
Changed	Read-only	An indicator of whether or not the user property is changed.
Value	Required	A value the targeting engine uses to determine the field in the business component that will be matched against the saved list ID. If the TargetId record is not defined as a user property for the business component, the targeting engine defaults to ROW_ID. One TargetId can be active for each business component.
Inactive	Optional	An indicator of whether the user property is active.
Comments	Optional	Comments describing the user property.

With these user properties, you can apply a target list in other business components and indicate what value in the business component will be stored for later retrieval. For example, to allow targeting functionality on opportunities, add the user property in Table 44 to each Opportunity business component.

Table 44.   Example TargetCategory User Property

Field	Required	Description
Name	Required	TargetCategory.
Changed	Read-only	An indicator of whether the user property is changed (optional).
Value	Required	"Opportunity" (or any value you choose).
Inactive	Optional	An indicator of whether the user property is active.
Comments	Optional	Comments describing the user property.

Once active, this user property will allow users to save a target list of opportunities and apply the list across screens in any opportunity-related business component.

New Visit Type Configuration

Using Siebel Tools, you can configure buttons that allow you to generate specific visit-type activities based on predefined visit templates. The default configuration provides three default buttons: Screen, Rescreen, Enroll. It uses user properties found in Table 49 on page 489.

■ Create a date field in the Clinical Subject business component, and create a date field with the same name in the LS Subject Status Date VBC business component. This date is used as a starting point for all your visit activities. Visits and Activities in the template belonging to the new visit type are calculated based upon the date entered in this date field and the lead time for the visit or activity.

■ Put the user properties in this field. See Table 49 on page 489 for information on what to set for the user properties. You may need to create a new list of values for the Template Type Code and Subject Status Code.

■ Create a new pop-up dialog box based on LS Subject Status Date VBC business component that displays when a button is clicked from the form. Base the pop-up dialog box on the CSSFramePopupVstTmplDt class. The only required value in this pop-up dialog box is the VisitTemplateDate control. This date field maps to the date field in the LS Subject Status Date VBC created above. All fields in this dialog box are treated as required fields. The users must fill in data for each field.

■ Add the button to the list or form.

NOTE: The best way to configure these buttons is to copy one of the default button configurations and apply the same properties to your new button.

Sequential Priority Configuration

As mentioned in Chapter 9, "Recording Calls in Pharma," the Siebel administrator can configure the Priority field in the Call Products Detailed list to allow each record added to the list to be sequentially and uniquely numbered, with the first record receiving 1. In the preconfigured application, more than one record can contain 1 in the Priority field.

To enable sequential numbering in the Priority field

1 In Siebel Tools, select the Business Component object in the Object Explorer.

2 Query for Pharma Account Call.

3 Lock the associated project, for example Pharma Call.

4 Expand the Business Component object and select the Business Component User Prop object.

5 Change the Value field to Y for the Validate Product Priority business component user property.

6 Repeat Step 1 through Step 5, running a query for the Pharma Professional Call business component in Step 2.

7 Compile the SRF file, selecting the Locked projects radio button.

8 Relaunch the application.

Enabling Inventory Reconciliation Without Lot Numbers

As discussed in Chapter 8, "Managing Pharma Samples," Siebel Pharma allows you to create sample products and associate lot numbers with the samples, then ship and disburse samples by lot numbers while maintaining and reconciling inventory without lot numbers.

Retaining Sample Product Visibility

To allow inventory without lot numbers while retaining sample product visibility, the administrator must do the following:

■ Use Siebel Tools to reconfigure fields and replace business components

■ Set the value of the Lots For Disperse Only system preference to TRUE

■ Check the Lot# Tracking flag in the Administration - Product screen

■ Use the newly complied SRF.

To reconfigure fields and replace business components

1 Open Siebel Tools.

2 Choose View > Object Explorer > Flat tab.

3 Select Fields, and in the Fields list, query in the Picklist Column for PickList Pharma Samples Stocked Lots.

4 Lock each project by choosing Tools > Lock Project.

5 In the Picklist column, replace each occurrence of PickList Pharma Samples Stocked Lots with Picklist Pharma All Unexpired Lots.

6 Choose View > Object Explorer > Types tab.

7 Select Applet, and in the Applet list, query for any applet with the value Pharma Stocked Lot Pick Applet.

8 For each occurrence, set the Business Component to Pharma Sample Lot for Picklist.

9 Compile the SRF.

To change the system preferences and enable Lot# tracking:

1 Logon to the Pharma web client as an administrator.

2 Navigate to the Administration - Application screen > System Preferences view.

3 Query for the following System Preference Name records:

   ■ Lots For Disperse Only

   ■ Samples Lots Enabled

4 Set the System Preference Value for each of these records to TRUE.

5 Navigate to the Administration - Product screen > Products view, and check the Lot# Tracking flag for each product that requires inventory reconciliation of samples without lot numbers.

6 Logoff the Pharma web client.

To use the newly compiled SRF

1 Stop the Siebel Server.

2 Copy the newly compiled SRF to the \siebsrvr\objects\enu folder.

3 Restart the Siebel Server.

Business Component User Properties

Siebel business components are based on the CSSBusComp class directly, or on a C++ class derived from CSSBusComp. Business component user properties allow Siebel configurators to control and adjust the behavior of Siebel Life Sciences using Siebel Tools.

General Business Component User Properties

Table 45 lists the user properties that are general and can apply to any business component.

Table 45.   User Properties for All Business Components

User Property Name	User Property Value	Description
TargetCategory	*Value* User-defined value that connects different business components together so that they interact for the targeting feature. Example: Contacts	Tells the business component which target category to use when saving and applying target lists.
TargetId	*Field* Field from the business component you want to save as the ID of the list and use when applying a target list to this business component. Example: Contact Id	Tells the business component which field from the business component to use when saving and applying target lists.

Specific Business Component User Properties

The following business component user properties are specific to a particular C++ class. This means that the properties are valid only for business components that are based on the C++ class implementing the user property or any of the related derived C++ classes.

Group 1 Business Components

Table 46 lists the user properties that are related to the following business components:

■   Action (class CSSBCActivity)

■   Calendar (class CSSBCCalendar)

Table 46.   User Properties Related to Group 1 Business Components

User Property Name	User Property Value	Description
Read-only Activity Types	*,ActivityType1,Activity Type2,...,* Value must start and end with a comma, and no spaces between values. Example: ,Attendee Call,Meeting Invitee,	Tells the business component which activity types are to be read-only at the record level. Activity Type is the field category.
Read-only Fields for *'Activity Type'* Activity Type is the category value. Example: Read-only Fields for *'Account Call'*	*,field1,field2,...,* Value must start and end with a comma, and no spaces between values. Example: ,Contact Last Name,Opportunity,	Tells the business component which fields are to be read-only for a particular activity type. Activity Type is the field category.
Status Field	*Field* Field from the business component.	Tells the business component which field is to be used to indicate the status.

Group 2 Business Components

lists the user properties that are related to the following business components:

■   Pharma Call Products Detailed (class CSSBCProductDetailed)

■ Pharma GA Call Products Detailed (class CSSBCProductDetailed)

Table 47.   User Properties Related to Group 2 Business Components

User Property Name	User Property Value	Description
Max Auto Generated Priority	*Number* A numeric value. Example: 3	Tells the business component the maximum number to go up to when auto-generating priorities for the products detailed.
Template Fields	*Field1,field2,...* No start or end comma or spaces between values. Example: Name,Priority,Product Issue	Tells the business component what fields to copy from the Smart Call template if a Smart Call is chosen.

Group 3 Business Components
Table 48 on page 487 lists the user properties that are related to the following business components:

■ Pharma Account Call

■ Pharma Attendee Call

■ Pharma Template Call

■ Pharma Professional Call

■ Pharma Promotional Items Dropped

■ Pharma Professional Call Sample Dropped

■ Pharma Activity Product Issues

■ Pharma Call Sample Dropped

■ Pharma Meeting

■ Pharma Meeting Attendee

■ Pharma Meeting Activity

■ Pharma Meeting Speaker

NOTE: Not all properties are used in all business components. For example, Template Fields user property supports Pharma Promotional Items Dropped, Pharma Professional Call Sample Dropped, Pharma Activity Product Issues, and Pharma Call Sample Dropped. These BCs are not applicable to other user properties in Table 48.

Table 48.   User Properties Related to Group 3 Business Components

User Property Name	User Property Value	Description
Attendee Call ReadOnly	*,field1,field2,...,* Value must start and end with a comma. Example: ,Start Date,Start Time,	Tells the business component what fields are read-only when the Category is Attendee Call.
Cascading Fields	*,field1,field2,...,* Value must start and end with a comma. Example: ,Start Date,Start Time,	Tells the business component which fields should cascade values to a child call component. Make these fields Force Active in the child call. Works in combination with the SubCall Component user property.
Must Detail Products	*Y* or *N*	Tells the business component whether detailed products are required for a call.
OnlySubmitByPosition	*Y* or *N*	Tells the business component whether the position that entered the record is the only one that can submit it.
Paper Reference Number Required	*Y* or *N*	If Y and the Paper Sign field is selected, then Ref # is a required field for call submission. Applies to the Pharma Professional Call business component.
Sample Disbursed Required	*Y* or *N*	If Y, at least once sample must be disbursed before a call is submitted. Applies to the Pharma Professional Call business component.
SRE Reference Number Required	*Y* or *N*	If Y and the signature is being captured electronically, Ref # is a required field for call submission. Applies to the Pharma Professional Call business component.
Status Field	*Field* Field from the business component.	Tells the business component which field is to be used to indicate the status of the activity.

Table 48.   User Properties Related to Group 3 Business Components

User Property Name	User Property Value	Description
SubCall Component	*Business component name* Any business component name.	Tells the business component the child component to which it should cascade values. Works in combination with the Cascading Fields user property.
Template Components	*Business component name* Any business component name.	Tells the business component what child components should be copied from the Smart Call template if a Smart Call is chosen.
Template Fields	*Field1,field2,...* No start or end comma. Example: Name,Priority,Product Issue	Tells the business component what fields to copy from the Smart Call template if a Smart Call is chosen.
Update After Recreate Receipt	Last Name, Address, Start Date, Comment, Signature Captured Value must start and end with a comma. You can add additional fields, but do not delete any of the default ones (preceding line).	Tells the business component what fields are editable after the Recreate Receipt button is clicked. Applies to the Pharma Professional Call business component.
Update After Submit	,field1,field2,..., Value must start and end with a comma. Example: ,Comment,	Tells the business component what fields are editable after a call is submitted. Generally this user property should be used only to make the Comment field editable.
Update After Synch	,field1,field2,..., Value must start and end with a comma. Example: ,Comment,	Tells the business component what fields are editable after a call is synchronized (with Siebel Pharma Handheld on a PDA). Generally this user property should be used only to make the Comment field editable.
Validate Sample Ref #	*Y* or *N*	Tells the business component whether it should require a sample reference number when submitting a call.

Group 4 Business Components

lists the user properties that are related to the Clinical Subject (class CSSBCBCClinicalSubject) business components.

These properties, used within the Clinical application, allow you to configure new buttons in the application that relate to subject activity. These user properties are at the Field level (Business Component > Field > Field User Properties).

Table 49.   User Properties Related to Group 4 Business Components

User Property Name	User Property Value	Description
Template Type Code	*No default.* Select CLNCL_SUBJ_VST_TMPL_TYPE from the List of Values (Application Administration > List of Values > List of Values)	Defines the visit activity applied when the newly configured button is selected.
Subject Status Code	No default. Select CLNCL_SUBJECT_STATUS from the List of Values (Application Administration > List of Values > List of Values)	Defines the status for the subject that is applied when the newly configured button is selected.
Template Version Field Name	*No default.* Must be made Force Active in the Business Component.	The corresponding Version ID Field Name that is populated with the version ID of the template version that created the activity.
Subject Consent Required	*Y* or *N* Default=*N*	This flag indicates whether or not the subject has the Informed Consent Date filled in for the active template for your protocol site. If you set this to Y, and the date is not filled in correctly, an error occurs.
Append All Activities	*Y* or *N* Default=*N*	When set to Y, activities are appended.

Configuring the Visit Generation Buttons

The standard Siebel Clinical application has three visit generation buttons (Screen, Rescreen, and Enroll) on the Subject form.

Using Siebel Tools, you can:

■ Reconfigure the buttons to better suit your business needs

■ Create new buttons for application of additional templates on the Subject form

The flow chart in Figure 25 illustrates the logic behind these buttons. The logic is the same for all three buttons, although content of the error messages does vary.
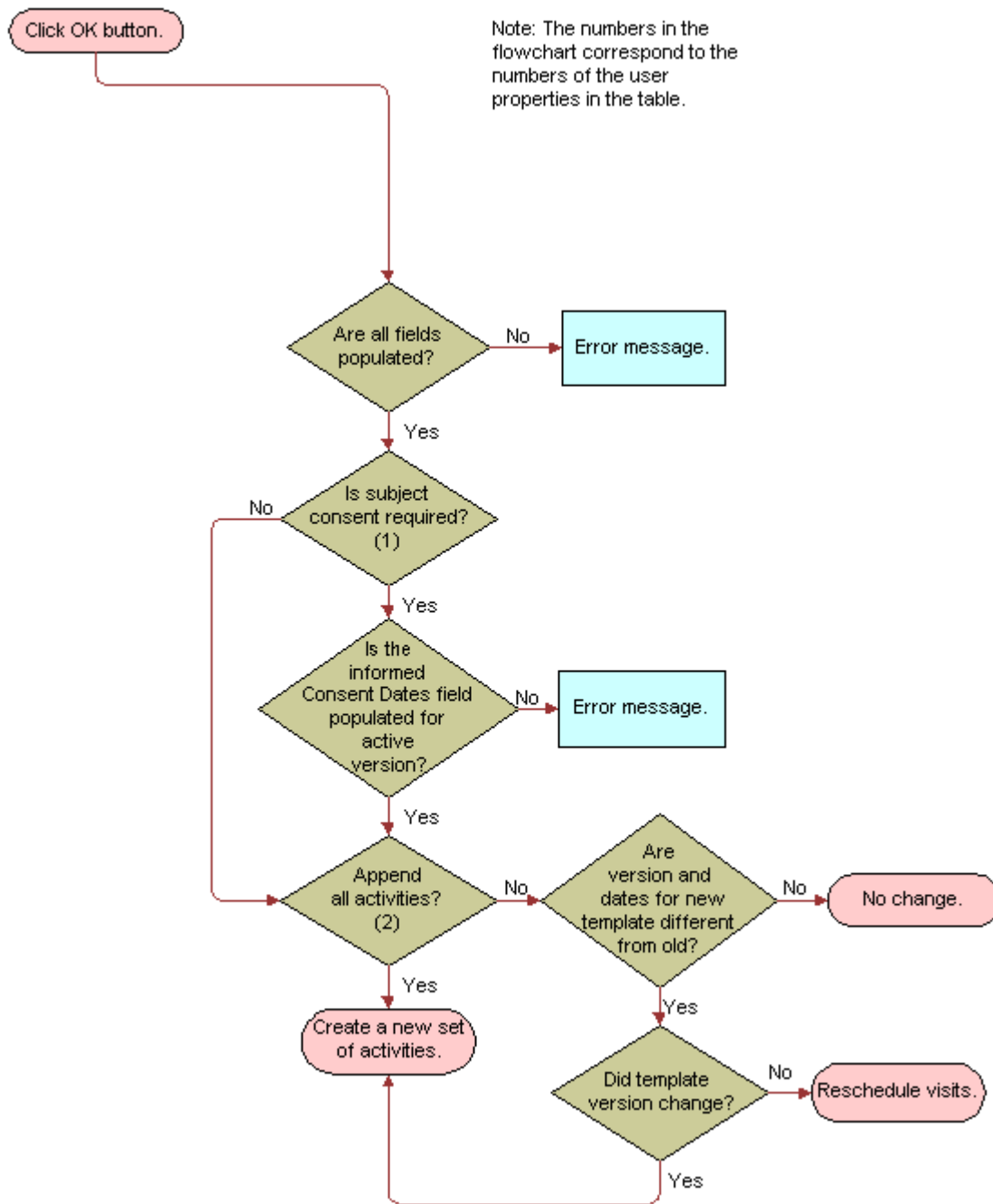
Figure 25. Siebel Clinical application visit generation button logic

Editing the Labels of the LS Pharma HI Activity Calendar View Buttons

In the Siebel Pharma application, the LS Pharma HI Activity Calendar View has three buttons displayed on the LS Pharma Activity HI Calendar Applet. These buttons are:

■ **New Contact Call.** Creates a new contact call.

■ **New Acct Call.** Creates a new account call.

■ **New Meeting.** Creates a new meeting.

These buttons (or controls) are not configured at the applet level, but are generated by the specialized class of the applet, namely CSSSWELSHICalendarFrame.

NOTE: You can modify the caption of the buttons using Siebel Tools by changing the Caption property or specifying an alternative name in the Caption - String Override property.

Special MedEd Classes—User Properties

There are two special C++ classes for MedEd:

■ CSSBCPharmaMEPlan

■ CSSBCPharmaMESubPlan

Both classes support EditMode user property. When the EditMode user property value is set to the value Admin, the data ownership (granting update or delete privilege to the user) is not checked. This means that anyone on the sales team, for example, can update the fields in this business component.

Two existing Buscomp classes, CSSBCPharmaMEActCost and CSSBCPharmaMEEventPos, are classes without these user properties, and therefore require administrator privileges to update or delete.

Submitting Contact Details from Third-Party Applications

When you click the Submit button from the Contact Call Detail view, the C++ class CSSSubmitFrame validates the contact details data and then invokes the CSSBCSubmitBusComp class. This business component class is the great grandparent class of the CSSBCPharmaCall (BC [Pharma Professional Call]) class.

The Pharma Professional Call class wraps the SubmitImp method in a database transaction. The SubmitImp method contains a high-level call submission function that automates the entire submission process. If any part of the submission fails, then all transactions performed up to that point are rolled back. The SubmitImp method is a recursive process that calls itself for each child call (Attendee Calls) and then continues with the parent. The process contains the following four main steps:

■ Create transactions for each sample dropped.

■ Create transactions for each promotional item dropped.

■ Set the status to Submitted.

■ Update the Last Call Date for the current user.

Invoking the Submit Functionality from Third-Party Applications

There are two ways to invoke the Submit functionality from third-party applications:

■ UI Layer

■ Business Object Layer

Working in the UI Layer

From your third-party application:

1 Invoke the CSSSubmitFrame class Submit on the Pharma Professional Call form applet.

2 Make sure that the property set is empty and contains no arguments.

NOTE: This is equivalent to pressing the Submit button in the Contact Call Detail view.

To suppress the Submit confirmation dialog box, make sure that the business component user property, SuppressSubmitConfirmation, has the value Y on the business component Pharma Professional Call.

Working in the Business Component Object Layer

If you have access only to the business component object layer, perform the following:

1 Invoke the CSSBCSubmitBusComp class BCSubmit on the Pharma Professional Call form applet.

2 To skip the check for reconciled inventory periods, specify a property with [Name] = "SkipCheck" in the input property set.

3 Specify a [Value] of Y or TRUE, for example, psIn.SetProperty("SkipCheck","Y").

NOTE: If you want to check for reconciled inventory periods, leave the input property set empty.

Perform the following step to access functionality that is equivalent to when a user clicks the Submit button from the Contact Call Detail view:

4 Invoke the Validate class on the BC [Pharma Professional Call] before invoking the CSSBCSubmitBusComp class "BCSubmit" on the Pharma Professional Call form applet. For this method to work correctly, you have to specify at least one property in the Input property set.

Accounts Contacts Configuration

The user properties outlined in Table 50 must be defined before you can activate a targeting period.

The columns displayed in Accounts Contacts List must be configured in the user properties.

Table 50.　User Properties Related to the Life Sciences Pharma Targeting Business Component

User Property Name	User Property Value	Description
CanMapColumnUpdate	*Y* Default value: Y	Set this to N to make targeting columns in Accounts Contacts List Read Only.
MapColumn *nn*	Default value: name of targeting fields	Targeting fields in the Business Component. There are 72 fields defined with different field types. Targeting Data will be mapped and copied to these fields during activation. Only the fields that you define are used for product data mapping.

The user property outlined in Table 51 must be defined before you can generate and update the column mapping.

Table 51.　User Property Related to the Life Sciences Pharma Target Details Business Component

User Property Name	User Property Value	Description
MapColumn *nn*	Default value: Name of product attribute fields.	Product data fields in the Business Component. Fields that contain data must be defined, so they can be used to generate column mapping, and can be updated by the Accounts Contacts List.

Configuring Personalized Content Delivery

This section includes:

■ "Setting System Preferences for PCD" on page 494

■ "Availability of Messages in PCD Planner" on page 495

Setting System Preferences for PCD

The Server Uncompression Location system preference must have a value pointing to the Siebel file system path `<Siebel installation path>\public\enu`. This is the path where `InteractiveDetailer.swf` is located.

Table 52 lists the system preferences that apply to PCD.

Table 52. System Preferences for PCD

Name	Value	Description
Server Uncompression Location	`<Siebel installation path>\public\enu.`	For the Siebel Server, the value of this system preference is concatenated with the value of the Decompressed Files Path system preference. The messages are decompressed and cached to this location. For Local setup, the system file system path is read from webclientsiteDir and it is configured in epharma.cfg.
Decompressed Files Path	`filesystem\assets`	Specifies the path of the decompressed messages. Do not use slash (\) at either end of the string.

Table 52.   System Preferences for PCD

Name	Value	Description
CheckForNeedToSync	N	When you click the Decompression button in the Siebel toolbar, the decompression time stamp is recorded in the S_USER table. Literature records have a calculated field called, NeedToSync. The value of this field is set to True if the record is modified after decompression.
		If the value of the user property, CheckForNeedToSync, is set to Y, then the next time you click the Decompress button, only messages with the user property, NeedToSync, set to Y are decompressed. Otherwise, all messages are decompressed.
Skin	Default	Specifies the skin or theme mode for the PCD Viewer. If the Skin field is not populated, then the value for Skin system preference is used. If the Skin system preference has no value, then the value of the Skin user property in LS PCD Service is used.

Availability of Messages in PCD Planner

Your system administrator loads and verifies messages in the Document Administration > Literature view. The administrator can then associate categories to the messages to make them visible to users creating messaging plans. Users create new messaging plans using the PCD Planner. Messages that are loaded in PCD Planner appear in the Items tab. Access to the messages depends on the catalog visibility associated to the messages and the CanLoadInPlanner calculated field in the Admin Sales Tool business component. A message with the field, CanLoadInPlanner, set to Y is available to users and is loaded into PCD Planner.

The CanLoadInPlanner calculated field is set to Y if the following conditions apply:

■　The Literature record is of type Message.

■　The message has a status of Active; that is, the release date is before or is today's date and the expiration date is greater than today.

■　The message is a supported file type.

The fields used to controls the loading of messages in PCD Planner are listed in Table 53. For information about the user properties that control access visibility for loading messages in PCD Planner, see .

Availability of Messaging Plans in the PCD Viewer

After the user creates a messaging plan, the messaging plan goes through an approval process. When the messaging plan is approved, the administrator sets the status of the messaging plan as Released and associates a category with it to make it visible to the required users. When you click the Detail button from the Account Call and Contact Call form applets, the messaging plans are automatically loaded in the PCD Viewer.

Access to the messaging plans depend on the catalog visibility associated to the messaging plans and on the CanLoadInDetailer calculated field in the LS Admin Messaging Plans business component. When making contact calls, messaging plans that have the CanLoadInDetailer field set to Y are available to those users who have catalog visibility.

The CanLoadInDetailer calculated field is set to Y when the messaging plan verification status is Successful. The Successful verification status depends on certain conditions.

All presentation items in the messaging plan must:

■ Have a verification status of Successful.

■ Be active, that is, the release date of the presentation items must be before or is today's date and is before the expiration date.

■ Contain supported file types.

All related messages and detail message content associated with each of the presentation items must:

■ Contain products that are in the personal list of the sales representative

■ Not have inactive messages

■ Be the highest, active version

The calculated fields that control the loading of messaging plans in the PCD Viewer and PCD Planner are listed in Table 53. For information about user properties that control access visibility for loading messages in PCD Viewer and PCD Planner, see Table 55 on page 508.

PCD Business Component Calculated Fields

Table 53 lists the calculated fields that apply to PCD business components.

Table 53.   Calculated Fields for PCD Business Components

Business component	Calculated Field	Values	Description
LS Admin Messaging Plans	CanLoadInDetailer	IIF (([Max Version Num] = [Version] AND [Product Owner Id] = LoginId() AND [HasInactiveMessages] = "N" AND [IsVerified] = "Y"),'Y','N')	Messaging plans can be loaded in to the PCD Viewer if the messaging plan: ■ Is the highest, active version. ■ Contains a Product that is in the personal list of the sales representative. ■ Does not have inactive messages. ■ Is verified.
	CanLoadInPlanner	Y	Load all messaging plans into PCD Planner, that is the Create Messaging Plan window.
	IsVerified	IIF (Count(VerificationFailedMessages) >0,"N","Y")	If messaging plan has verification failed presentation items, set verification status to failed. That is, IsVerified is equal to N.

Table 53. Calculated Fields for PCD Business Components

Business component	Calculated Field	Values	Description
LS MP Items	IsVerified	IIf([Verification Status] = LookupValue('VERIFICATION _STATUS','Successful') AND [IsSupportedFormat] = "Y" AND [IsRelatedContentVerified] = "Y" AND [IsDetailContentVerified] = "Y",'Y','N')	If the verification status (obtained from the join to the S_LIT_LSX table) of Message is Successful, and Message is of supported file type, and all the related and detail content associated with this presentation item is verified, then for this presentation item IsVerified is equal to Y.
	IsSupportedFormat	IIF(([LitFileExt] = 'SWF' OR [LitFileExt] = 'swf' OR [LitFileExt] = 'jpg' OR [LitFileExt] = 'JPG' OR [LitFileExt] = 'GIF' OR [LitFileExt] = 'gif' OR [LitFileExt] = 'png' OR [LitFileExt] = 'PNG'), 'Y','N')	Checks if the file type of the presentation item is supported.
	IsDetailContentVerified	IIF (Count(Verified Detail Content) > 0,"N","Y")	Checks if all detail content associated with the presentation item is verified.
	IsRelatedContentVerified	IIF (Count(Verified Related Content) > 0,"N","Y")	Checks if all related content associated with presentation item is verified.
LS Detail Messages	IsVerified	IIf([Verification Status] = LookupValue('VERIFICATION _STATUS','Successful') AND [IsSupportedFormat] = "Y" ,'Y','N')	If the verification status (obtained from the join to the S_LIT_LSX table) of Message is Successful, and Message is of supported file type, then for this related item IsVerified is equal to Y.
	IsSupportedFormat	IIF(([LitFileExt] = 'SWF' OR [LitFileExt] = 'swf' OR [LitFileExt] = 'jpg' OR [LitFileExt] = 'JPG' OR [LitFileExt] = 'GIF' OR [LitFileExt] = 'gif' OR [LitFileExt] = 'png' OR [LitFileExt] = 'PNG'), 'Y','N')	Checks if the file type is supported.

Table 53.   Calculated Fields for PCD Business Components

Business component	Calculated Field	Values	Description
LS Related Messages	IsVerified	IIf([Verification Status] = LookupValue('VERIFICATION _STATUS','Successful') AND [IsSupportedFormat] = "Y" ,'Y','N')	If the verification status (obtained from the join to the S_LIT_LSX table) of Message is Successful, and Message is of a supported file type, then for this related item, IsVerified is equal to Y.
	IsSupportedFormat	IIF(([LitFileExt] = 'SWF' OR [LitFileExt] = 'swf' OR [LitFileExt] = 'jpg' OR [LitFileExt] = 'JPG' OR [LitFileExt] = 'GIF' OR [LitFileExt] = 'gif' OR [LitFileExt] = 'png' OR [LitFileExt] = 'PNG'), 'Y','N')	Checks if the file type is supported.
Admin Sales Tool	CanLoadInPlanner	IIF (([Sales Tool Type] = LookupValue ("SALES_TOOL_TYPE", "Message") AND [IsActive] = "Y" AND [IsSupportedFormat] = "Y"),'Y','N')	Literature item can be loaded in PCD Planner if: ■ The type is equal to Message ■ Is active (release date is before or is today's date and is before the expiration date) ■ Is of supported file type.
	CanLoadInDetailer	IIF (([Sales Tool Type] = LookupValue ("SALES_TOOL_TYPE", "Message") AND [IsSupportedFormat] = "Y"),'Y','N')	Literature Item can be verified if type is equal to Message and is of supported file type.
	IsSupportedFormat	IIF(([LitFileExt] = 'SWF' OR [LitFileExt] = 'swf' OR [LitFileExt] = 'jpg' OR [LitFileExt] = 'JPG' OR [LitFileExt] = 'GIF' OR [LitFileExt] = 'gif' OR [LitFileExt] = 'png' OR [LitFileExt] = 'PNG'), 'Y','N')	Checks if the file type is supported.

Recommended Messaging Plans

When a sales representative launches the PCD Viewer from the Contact Call Detail View, Account Contact Call View, or Account Call Detail View, all messaging plans available to the sales representative are loaded into the PCD Viewer by Life Sciences (LS) PCD Services. For more information about the user properties for the LS PCS Services, see "User Properties of LS PCD Business Service" on page 508.

In LS PCD Service, the OptimizeDetailingPlan method identifies messaging plans that are recommended for the call. These messaging plans are called Recommended Messaging Plans and have an asterisk (*) symbol suffixed to its name in the list of available messaging plans when displayed in the PCD Viewer.

By default, the OptimizedDetailingPlan functionality is configured to identify recommended messaging plans for Contact Call and Account Content Call detailing only. If Objectives or Offers are associated to a Contact Call or Account Contact Call, recommended messaging plans are identified as outlined in this section.

However, if no Offer or Objective is associated to a Contact Call or Account Contact Call, fields for entering target segments, in the Contact Call or Account Contact Call views are available, and recommended messaging plans may be selected based on these field values.

Similarly, if no Objectives are associated to an Account Call, fields for entering target segments in the Account Call view are available, and recommended messaging plans may be selected based on these field values.

To configure fields for entering target segments in Contact Call view or Account Contact Call view

1 Add fields in Pharma Professional Call business component (BC) mapping to one or more extension columns in S_EVT_ACT_X. For example:

Field Name: Call Segment Code 1 Join: S_EVT_ACT_X Column: ATTRIB_01

Field Name: Call Segment Code 2 Join: S_EVT_ACT_X Column: ATTRIB_02

2 Configure the fields in Pharma Professional Call Form Applet.

3 In the Pharma Professional Call BC, update the BC user property Call Seg Code Fields with a list of segment code fields, with each segment code field separated by a comma. For example, Call Segment Code 1, Call Segment Code 2.

To configure fields for entering target segments in Account Call view

1 Add fields in Pharma Account Call business component (BC) mapping to one or more extension columns in S_EVT_ACT_X. For example:

Field Name: Call Segment Code 1 Join: S_EVT_ACT_X Column: ATTRIB_01

Field Name: Call Segment Code 2 Join: S_EVT_ACT_X Column: ATTRIB_02

2 Configure the fields in Pharma Account Call Form Applet.

3 In the Pharma Account Call BC, update the BC user property Call Seg Code Fields with a list of segment code fields, with each segment code field separated by a comma. For example, Call Segment Code 1, Call Segment Code 2.

By default, the OptimizedDetailingPlan functionality is not configured to identify recommended messaging plans for Account Call if an Objective is associated to the Account Call.

To configure fields in Account Call view if Objectives are associated to an Account Call

1 Create one or more extension columns in S_ACCNT_SRC (for example, X_SEG_CODE1, X_SEG_CODE2) and apply these changes in the Siebel Applications database.

2 Add fields in Pharma Campaign Target Account BC and map these fields to the columns created in S_ACCNT_SRC. For example:

Field Name: Segment Code 1 Join: S_ACCNT_SRC Column: X_SEG_CODE1

Field Name: Segment Code 2 Join: S_ACCNT_SRC Column: X_SEG_CODE2

3 Configure the fields in Pharma Campaign Target Account List Applet.

4 In the Pharma Account Call BC, update the BC user property Objective Seg Code Fields with a list of segment code fields, with each segment code field separated by a comma. For example, Segment Code 1, Segment Code 2.

Optimize Detailing Plan Method

Signature of the Optimize Detailing Plan method is as follows:

```
ErrCode OptimizeDetailingPlan (const CCFPropertySet& inputArgs, CCFPropertySet& outputArgs)
```

The input parameters to this method are sent as an input property set (inputArgs).

The output of this method is an xml string, set in the output property set (outputArgs) with property name as RecommendedMsgPlans. For example:

```
outputArgs.SetProperty("RecommendedMsgPlans", <xml string>);
```

The xml string in the output property set should be in the following format:

```
<OptimizedDetailingPlan>
```

```
<ListOfRecommendedMessagingPlans>

    <MessagingPlan>

        <Id>

        </Id>

        <SequenceNumber>

        </SequenceNumber>

        <OfferId>

        </OfferId>

        <ObjectiveId>

        </ObjectiveId>

        <SegmentCode>

        </SegmentCode>

    </MessagingPlan>

    <MessagingPlan>

        <Id>

        </Id>

        <SequenceNumber>

        </SequenceNumber>

        <OfferId>

        </OfferId>

        <ObjectiveId>

        </ObjectiveId>

        <SegmentCode>

        </SegmentCode>

    </MessagingPlan>

</ListOfRecommendedMessagingPlans>

</OptimizedDetailingPlan>
```

You can use your own logic to identify recommended messaging plans by overriding the OptimizeDetailingPlan method using a script.

To override OptimizeDetailingPlan

1 In Siebel tools query for LS PCD Service.

2 Right click LS PCD Service, and click Edit Server scripts.

3 Update the Service_PreInvokeMethod function to override logic for OptimizeDetailingPlan as shown:

```
function Service_PreInvokeMethod (MethodName, Inputs, Outputs)

{

    if(MethodName == "OptimizeDetailingPlan")

    {

        …….

        User logic to identify Recommended messaging plans…

        set output property set…

        ….

        return (CancelOperation);

    }

    else

        return (ContinueOperation);

}
```

Identifying Recommended Messaging Plans

The default OptimizeDetailingPlan method identifies Recommended Messaging Plans as follows:

If an objective is selected for a call, the OptimizedDetailinPlan method provides a list of messaging plans to be loaded to the PCD Viewer based on messaging plans associated with an objective and have a Target Segment Code matching the objective's Contact Target Segment Code fields, that is one or ore fields from S_CAMP_CON table).

The field names from Action BC is configurable. If the Objective Id is null, then the segment code fields (one or more fields from Action BC) are used to match and search for Recommended Messaging Plans based on Target Segment Code field defined for each Messaging Plan.

For example, a sales representative (Sales Rep A) has an Objectives set up called Q1 Objective and has Dr. Adler as a target for this objective. The Target Record of Dr. Adler has two custom extension fields to hold SegCode1 and SegCode2 for two products, A1 and B2, that Sales Rep A deals with. The Sales Operation Manager has also five messaging plans, namely MP1, MP2, MP3, MP4, and MP5, associated with this Objective and each messaging plan has a Target Segment code specified as A1, B1, A2, B2, and A1.

Sales Rep A creates a call on Dr. Adler and selects Q1 Objective as Objective for the call. The OptimizeDetailingPlan finds matching messaging plans associated with Objective Q1 Objective that have Target Segment code as A1 and B2. This scenario results in MP1,MP4 and MP5 selected as recommended messaging plans.

Next, consider the situation where Sales Rep A creates another call on Dr. Adler and does not select Objective for the call. OptimizeDetailingPlan matches custom extension fields defined on the call business component (BC) to hold segment code values against Target Segment Code fields on the messaging plans to identify recommended messaging plans.

For Contact Calls with Marketing Communications, the LS PCD Service method provides a list of messaging plans to be loaded in the PCD Viewer based on messaging plans associated with Contact Call Offers for which the sales representative has access. For example, if Sales Rep A has access to three Contact Call Offers but is in the Access Group of only one of the messaging plans associated with the Contact Call Offer, then only that messaging plan can be loaded in the PCD Viewer.

Using Skins

Once a new skin becomes available for content, you can add the skin to the existing list of available skins as follows:

1 Navigate to folder `<Siebel installation path>\public\<language folder>\ISDData`

2 Open the Make an entry in styles.xml file and include an entry as shown in bold below:

`<?xml version="1.0" encoding="utf-8"?>`

`<styles>`

   `<style>`

   `<label>Default</label>`

   `<swfPath>styles/Oracle.swf</swfPath>`

   `<iconPath>styles/iconProject.swf</iconPath>`

   `</style>`

   `<style>`

   `<label>Oracle</label>`

   `<swfPath>styles/Oracle.swf</swfPath>`

   `<iconPath>styles/iconProject.swf</iconPath>`

   `</style>`

   `<style>`

   `<label>NewSkin</label>`

   `<swfPath>styles/MyNewSkin.swf</swfPath>`

   `<iconPath>styles/iconProject.swf</iconPath>`

   `</style>`

`</styles>`

3 Copy MyNewSkin.swf to folder `<Siebel installation path>\public\<language folder>\styles`.

4 Add the NewSkin value to LOV Type PCD_SKIN in Administration – Data screen > List of Values Explorer view.

Modifying a Tooltip in the PCD Viewer

You can customize the tooltips that are displayed when a user places the cursor over the buttons in the PCD Viewer.

1 Navigate to folder `Siebel installation path>\public\<language folder>\ISDData\<language folder>`.

2 Open the lfs.xml file and enter the tooltip string as per the following example:
`<IDS_NEW_TOOLTIP>New ToolTip </IDS_NEW_TOOLTIP >`

3 Navigate to folder `Siebel installation path>\public\<language folder>`.

4 Open the `toolbar_buttons.xml` file and locate the button tag for which tooltip is to be modified.

5 Update the <toolTip> tag for the selected button with the string tag created in lfs.xml as shown below:

<toolbars>

    <toolbar toolbarId="Detailer - Standard" defaultState="DEFAULT" firstChangeInternal="false" buttonId="1">

    <respectStates>

    <toolbar name="Detailer - Standard"/>

    </respectStates>

    <button buttonId="2">

    <label/>

    <toolTip>IDS_NEW_TOOLTIP</toolTip>

    …….

    </button>

    </toolbar>

</toolbars>

NOTE: It is not recommended to remove buttons from the toolbar_buttons.xml. However, you can hide buttons by adding the DefaultState value to the ReadOnlyStates tag.

User Properties of the PCD Applets

Siebel business components are based on the CSSBusComp class, or on a C++ class derived from the CSSBusComp class. Business component user properties allow Siebel administrators to control and adjust the behavior of Siebel Life Sciences using Siebel Tools.

The following is a list of PCD applets that display the Flex application user properties. Flex is a third-party application used by PCD:

■ LS Admin Edit Messaging Plan

■ LS Admin New Messaging Plan

■ LS Admin Preview Messaging Plan

■ LS Edit Personalized Messaging Plan

■ LS Personalize Messaging Plan

■ LS Preview Messaging Plan

■ LS Verify Message

Table 54 lists the user properties that apply to PCD popup applets that display Flex UI elements.

Table 54. User Properties for PCD popup applets

Name	Value	Description
FlexAppMode	MP-Admin	The Flex application launches PCD in the modes that determine the UI. For example, for preparing for a contact call, PCD is launched in ISDPreview mode. For message plan creation, the MP-Admin mode is launched. **NOTE:** Do not modify this user property.
InitMethod	EditMsgPlan	The method name in LS PCD Service that initializes the Flex application. **NOTE:** Do not modify this user property.
IntegrationObj	AdminMessagingPlanIO	Specifies the I/O (input/output) to be used for writing data to the database. For example, data is sent in XML format. **NOTE:** Do not modify this user property.
CallIOBS	Pharma Account Call IO BS	Name of the business service that executes the I/O for extracting call data.
CallType	Account Call Contact Call	Specifies the type of call.

User Properties of LS PCD Business Service

Table 55 lists the user properties that apply to Life Sciences (LS) PCD Services.

Table 55.   User Properties for LS PCD Services

Name	Value	Description
LoadLOVTypes	PCD_RESPONSE_TYPE MSG_PLAN_ITEM_TYPE VERIFICATION_STATUS MSG_DISPLAY_STATUS	Specifies the LOV type values that are extracted and sent to the Flex application. **NOTE:** Do not modify this user property.
Skin	Default	Specifies the skin mode to use for the PCD Viewer display (fields in Account Call and Contact Call form applets and PCD Planner field in Messaging Plan form applet). If these fields are not populated, then the value for Skin system preference is used. If the Skin system preference has no value, then this user property value is used.
SyncEndConfirmation	Y	If you click Uncompress, an asynchronous process starts and decompresses the messages. At the end of this decompression process, if the value of this user property is equal to Y, then the Siebel Business Application displays a message box to confirm the end of the decompression process. However, this user property value is ignored by the Siebel Server and no confirmation message dialog is displayed.
SyncStartConfirmation	Y	If you click Uncompress, an asynchronous process starts and decompresses the messages. At the start of this decompression process, if the value of this user property is equal to Y then the Siebel Business Application displays a message box to confirm the start of the decompression process. However, this user property value is ignored by the Siebel Server and no confirmation message dialog is displayed.
Verify Disabled Error Msg	Verification cannot be done for this Literature Record	In Administration - Document screen > Literature view, verification is done only on literature records with type equal to Message. For records of type Message, clicking the Verify button displays the error message specified in this user property.
No Messaging Plan Error Msg	No Messages Available for Detail.	In Account Call and Contact Call form applets, if there are no messaging plans available, clicking the Detail button displays the error message specified in this user property.

Table 55.   User Properties for LS PCD Services

Name	Value	Description
ViewModeForLoad ingMPInDetailer	Catalog	Specifies the access type to be used for loading messaging plans in the PCD Viewer.
ViewModeForLoad ingMsgInPlanner	Catalog	Specifies the access type to be used for loading messages in PCD Planner.

API for Using Multi-file Content

The message can access its component files in the main Flash or Flex content by making a call to the getMessageFileName(filename) application programming interface (API).

The parameter filename must be the filename of the component file in the Siebel Business Application. The Siebel Business Application returns the path of the component file. The message can then use the component file path to add additional component files to the PCD content.

For example, to access and load component files, the main message must call the following functions:

Application.application.getMessageFileName(fileName); if using Flex for content creation

root.parent.parent.parentApplication.getMessageFileName(fileName); if using Flash for content creation

The syntax for childData API is as follows:

getMessageFileName(filename:String):void

API for Recording Section Data

PCD Viewer tracks various information such as the duration for which each message (digital content) in a messaging plan was presented. It does this by recording the timestamp when the presentation of a message started and the timestamp when the presentation of the message ended.

The message (digital content) performs additional tracking and make calls to the PCD Viewer to pass tracking information. The PCD Viewer takes the combined information and make calls to Siebel Business Application to write back presentation data.

For example, consider a message that has three critical sections where the start and end time of each section needs to be tracked along with start and end time of the entire message. To track section data. the message must pass the section's tracking information to the PCD Viewer by calling the following function:

Application.application.childData(sectionName, startTime, endTime); if using Flex for content creation

root.parent.parent.parentApplication.childData(strSectionName, startTimeStamp, endTimeStamp); if using Flash for content creation

The syntax for childData API is as follows:

```
childData(name:String, start:Date, end:Date):void
```

When you close the PCD Viewer, data is written to the presentation detail applet. You can view the full section by section record of messages as per the following example:

Message Name	Section Name	Messaging Plan Name	Start Name	End Name
Samp1	None	SampMP	7:30 pm	7:45 pm
Samp1	Sec1	SampMP	7:31 pm	7:35 pm
Samp1	Sec2	SampMP	7:36 pm	7:40 pm
Samp1	Sec3	SampMP	7:41 pm	7:45 pm

B Configuring Data for Oracle Pharma Sales Analytics

This appendix contains information about how to populate data in the Siebel Pharma application to meet the requirements of Oracle Pharma Sales Analytics. The information is for Siebel Pharma and Oracle Pharma Sales Analytics implementation teams, Siebel Pharma application administrators and trainers. It assumes that you are familiar with the functionality and conventions of working with and administering the Siebel Pharma application.

For further information about transactional data extract, transform and load (ETL) rules of Pharma Sales Analytics, see *Oracle Business Intelligence Applications Installation and Configuration Guide.*

This appendix contains information about the following topics:

- "Transactional Data Requirements" on page 511
- "Configuring Product Hierarchies and Product Costs" on page 512
- "Configuring Product Catalog and Category Hierarchies" on page 513
- "Setting Up Sales Objectives" on page 515
- "Entering Call Activity Data" on page 516
- "Configuring Sales Territories for Pharma Sales Analytics" on page 517
- "Creating Target Lists Using Oracle Business Intelligence" on page 523

Transactional Data Requirements

Oracle Pharma Sales Analytics is a set of prebuilt analytical applications to support the analysis and reporting needs of sales and marketing users. The Oracle Pharma Sales Analytics applications are built on top of the Oracle Business Analytics Warehouse, which is a unified data repository for all customer-centric data to support the analytical requirements of Siebel Pharma Applications.

The Oracle Business Analytics Warehouse contains a number of Business Analytics Warehouse tables that are specific to Oracle Pharma Sales Analytics. These tables support the analysis of data stored in the Siebel Pharma application, as well as data from external syndicated data sources. The Oracle Business Analytics Warehouse contains a set of ETL (extract-transform-load) processes that take data from the Siebel Business Applications transactional data (OLTP) and loads this data into the Oracle Business Analytics Warehouse tables.

To implement Oracle Pharma Sales Analytics successfully you must understand the key entities and relationships in the Siebel Pharma application that Oracle Pharma Sales Analytics uses.

The Pharma Sales Analytics ETL processes impose some requirements on how the data must be configured and populated in the Siebel Pharma application in order to minimize the need for configuring data entities, relationships, and hierarchies within the Oracle Pharma Sales Analytics application.

The Oracle Pharma Sales Analytics ETL rules are configured to source data from specific, standard Siebel Pharma transactional database tables and columns. These database tables and columns are mapped to standard Siebel Pharma business components, screens and views. The Pharma Sales Analytics ETL rules require that data is populated in a standard way to make sure that data is successfully loaded into the Oracle Business Analytics Warehouse tables without the need for additional configuration.

The following key entities must be configured and populated correctly in the Siebel Pharma transactional system:

■ Product hierarchies and product costs

■ Product catalog and category hierarchies

■ Sales objectives

Configuring Product Hierarchies and Product Costs

This topic details the tasks performed by application administrators to configure product hierarchies and product costs. Oracle Pharma Sales Analytics provides a prebuilt product hierarchy that allows users to analyze and roll up call activity, medical events, sales and Rx data at the form strength, brand, submarket, and market levels. Oracle Pharma Sales Analytics also allows users to analyze sales and Rx data of competitor brands.

Table 56 shows the required relationships between each of the levels in the Product Level column.

Table 56.   Relationships in the Product Level Column

Pharma Sales Analytics Product Hierarchy	OLTP Product Type	OLTP Product Level	Example	Parent Product	Cardinality
Form/Strength	Sample	3	Aracid 400 MG	Aracid	M:1
Product	Detail	2	Aracid	COPD	M:1
Product	Competitive Products	No Level	SImAir	Asthma or COPD	M:1
Submarket	Submarket	No Level	COPD	Asthma	M:1
Market	Market	1	Asthma	No Parent	None

Oracle Pharma Sales Analytics also allows users to analyze ROI of call detailing and sampling. The underlying cost information used in these ROI calculations is sourced from the product cost fields within the Siebel Pharma application.

To configure product hierarchies and product costs

1 Navigate to the Administration - Product screen > Products view.

2 In the Products list, create a new record, and complete the following fields.

Field	Comments
Name	The name of the form strength, product/brand, submarket, or market.
Type	The type of product as listed in Table 56 on page 512.
Parent Product	The parent product of this product within the product hierarchy. The appropriate parent product must be selected for the current product level as listed in Table 56 on page 512. Market type products do not have a parent product.

3 Drill down on the product.

4 Click the More Info view tab.

5 In the Level field, select the correct numerical value for the level as listed in Table 56.

6 If the Product Type is Sample, then in the Sample Cost field enter the appropriate sample cost. If the Product Type is Detail, then in the Promo Cost field enter the appropriate promotional cost.

7 Repeat Step 2 through Step 6 for the remaining products in the product hierarchy.

For more information about managing products, see Chapter 6, "Managing Products for Life Sciences."

Configuring Product Catalog and Category Hierarchies

This topic details the tasks required to configure product catalogs and category hierarchies performed by application administrators. Oracle Pharma Sales Analytics allows users to use a number of prebuilt alternate product hierarchies to analyze and roll up sales and Rx data. These prebuilt hierarchies are as follows:

■ Manufacturer Product Category

■ Application Form Product Category

■ ATC (Anatomical Therapeutic Class) Product Category

■ User Code (USC) Product Category

■ Chemical Product Category

Table 57 shows the Standard Product Hierarchy along with the prebuilt alternative product
hierarchies.

Table 57.   Standard Product Hierarchy with Prebuilt Product Hierarchies

Standard Product Hierarchy	Manufacturer Product Hierarchy	Application Form Product Category	ATC Product Category	User Code Product Category	Chemical Product Category
Market	Manufacturer	Application Form I	ATC I	USC I	Family
Submarket	Product	Application Form II	ATC II	USC II	Subfamily
Product		Application Form III	ATC III	USC III	
Form/Strength			ATC IV	USC IV	

The Oracle Pharma Sales Analytics ETL uses data stored in the standard Siebel Pharma Product
Catalog and Category application screens to create these alternate hierarchies.

To configure product catalog and product hierarchies

1 Navigate to the Administration - Catalog screen > Catalogs view.

2 In the Catalogs list, create a new record, and complete the following fields.

Field	Comments
Name	The name of the alternate Product hierarchy, for example, R-Respiratory for an ATC hierarchy for Asthma products.
Description	A general description of the catalog.
Effective Start Date	Current date.
Private	The product catalog is only used by the Oracle Pharma Sales Analytics ETL. Select this field to prevent the catalog from being visible to other users within the Siebel Pharma Application.

3 Drill down on the Catalog.

4 In the Category list, create a new record for the top level of the hierarchy, and complete the required fields as described in the following table.

Field	Comments
Name	Name of the hierarchy level (for example, R3-Bronchodilators and Anti-asthma Preparations for the top level in an ATC hierarchy for Asthma products).
Display Name	Display name of the hierarchy level (for example, R3-Bronchodilators and Anti-asthma Preparations for the top level in an ATC hierarchy for Asthma products).
Effective Start Date	Current date.
Usage	From the Pick Category Usage Type dialog box, select one of the following usage types to set the type of alternate Product Hierarchy, and then click OK: ■ ATC ■ Application Form ■ Manufacturer ■ USC ■ Chemical
Private	The Product Catalog is only used by the Oracle Pharma Sales Analytics ETL Check this flag to prevent the Catalog from being visible to other users within the Siebel Pharma Application.

5 For each lower level in the hierarchy, create a new record in the Category list, and repeat Step 4.

6 Set the relationships between the levels by using the Demote level button.

7 For the lowest level in the hierarchy only, click the Products link under the Categories tab.

8 Create a new record in the Product list, and select the appropriate Product record, which is the Form/Strength level Product in the standard Product hierarchy. This action allows Oracle Pharma Sales Analytics to link the alternate product hierarchy to the standard product hierarchy.

Setting Up Sales Objectives

This topic details the tasks that users must do to set up correctly the sales objectives in Oracle Pharma Sales Analytics. Oracle Pharma Sales Analytics allows users to analyze actual call activities, sales, and Rx results and compare them with their sales objective targets. Users must enter the sales objectives data correctly in the Siebel Pharma Application's Objectives screens to enable this analysis.

To set up sales objectives

1 Navigate to the Objectives screen > Retail Objectives List view.

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

Some fields are described in the following table.

Field	Comments
Unit	A unit can only be NRx, TRx, indirect sales, indirect units, sales amounts, sales units, or number (#) of calls.
Product	Select only one product at the appropriate product level. For a unit value of NRx, TRx, or number (#) of Calls, then the product value must be detail. For a unit of indirect sales, indirect units, sales amounts, or sales units, then the product level is form/strength.
Team	Only one team member can be the owner of each objective.

3 Drill down on the Objective.

4 Click the Target Contacts tab.

5 Click the New button, and select the appropriate Contact records.

6 For each Contact record that is added to the Target Contacts list, enter a value in the Target Value field.

7 In the Target Accounts list, click the New button, and select the appropriate Account records.

8 For each Account record that is added to the Target Accounts list, enter a value in the Target Value field.

Entering Call Activity Data

Oracle Pharma Sales Analytics allows users to analyze the Account Calls, Contact Calls, and Attendee Calls data entered in the Siebel Pharma application. The Oracle Pharma Sales Analytics ETL requires a number of key call activity fields to be populated and the data to be entered correctly so that the Oracle Business Analytics Warehouse is loaded.

Table 58 outlines which fields must be populated for Oracle Pharma Sales Analytics

Table 58. Fields that must be Populated for Oracle Pharma Sales Analytics

Records	Fields That Must Be Populated
Account Call - Header Records	■ Status (set to Submitted) ■ Account ■ Address ■ Start Date
Contact Call - Header Records	■ Status (set to Submitted) ■ Last Name, First Name ■ Address ■ Start Date
Attendee Call - Header Records	■ Status (set to Submitted) ■ Last Name, First Name ■ Address ■ Start Date
Call Products Detailed - Child Records	■ Product ■ Priority ■ Indication
Samples Dropped - Child Records	■ Name ■ Quantity
Promotional Items Dropped - Child Records (Contact calls)	■ Name ■ Quantity

Configuring Sales Territories for Pharma Sales Analytics

This topic describes how to perform the following tasks:

■ "Creating Primary Sales Force Hierarchies" on page 518

■ "Creating Sales Territories" on page 519

■ "Creating Alternate Sales Force Hierarchies" on page 521

Creating Primary Sales Force Hierarchies

Oracle Pharma Sales Analytics provides a prebuilt sales hierarchy configuration that determines the rollup and visibility of sales, Rx and call activity data for the different levels of users within a sales organization. This configuration includes prebuilt aggregation tables and de-duplication of data at each level of the sales hierarchy to support accurate analysis and improved performance. The primary sales force hierarchy is configured as a position hierarchy within the Siebel Pharma application, with the sales territory level position at the bottom of the position hierarchy. This topic details the tasks that application administrators must perform to configure the position hierarchy for use in Oracle Pharma Sales Analytics.

To create a primary sales force hierarchy

1 Navigate to the Administration - Group screen > Positions view.

2 In the Positions list, click New to create the Top level Position in the Sales Force Hierarchy.

3 Complete the fields in the following table for the new position.

Field	Comments
Division	Division for the primary sales force hierarchy.
Position	Position associated with the primary sales force hierarchy.
Position Type	Select the position type from the drop-down list.

4 For the each of the levels that are below the sales hierarchy repeat Step 2 and Step 3 down to the sales territory level position.

5 In the Parent Position field for each of these records, select the Position for the level above the
current Position.

The prebuilt Oracle Pharma Sales Analytics configuration supports the following sales hierarchy
levels.

Table 59.   Sales Hierarchy Levels

Level	Description	Cardinality to Parent
Organization	Top level of the sales organization that is sometimes referred to as *Franchise*. For example, *Respiratory Franchise* refers to a sales force commissioned to promote respiratory products. This level does not have any parents.	None
Sales Force	Child of Organization. Refers to a sales force promoting products within a sales organization.	M:1
Area	Child of Sales Force. Refers to a large geographic sales area, such as US East, US West, or US South.	M:1
Region	Child of Area. Refers to a sales geographic region.	M:1
District	Child of Region. Refers to a sales geographic district.	M:1
Territory	Child of District. Refers to a sales geographic territory composed of ZIP codes, bricks, contacts, or accounts.	M:1

All of these levels must be created as positions and linked to a position hierarchy to populate
correctly the Oracle Business Analytics Warehouse.

6 The bottom territory level position in the hierarchy must be the position associated with the
assignment rule definition for the sales territory alignment, as described in
.

Creating Sales Territories

Sales territory alignments are used within Oracle Pharma Sales Analytics to assign sales and Rx data
to the appropriate sales territory level positions. A sales territory alignment is the relationship
between each sales territory position and a set of ZIP codes, bricks or accounts, or contacts. This
territory alignment relationship is created and managed as a set of assignment rules in the
Administration - Assignment screens within the Siebel Pharma application.

The following procedure details the task that application administrators must perform to configure
the assignment rules in Oracle Pharma Sales Analytics.

To create a new assignment rule

1 Navigate to the Administration - Assignment screen > Assignment Rules List view.

2 In the Assignment Rules list, click New to create a new assignment rule.

3	In the Objects to be Assigned field, select either Account or Contact from the Assignment Object dialog box, and click OK.

4	In the Rule Group field, select Default Rule Group from the Pick Rule dialog box, and click OK.

5	In the Activation field, enter the rule activation date.

6	In the Criteria list, click New to create a new Criteria.

7	In the Rule Criterion field, select one of the assignment criteria from the following table.

NOTE: A territory can have one or more criteria defined for it, depending upon the territory alignment requirements (for example, you can assign both account ZIP code and contact ZIP code to the same territory).

Assignment Criteria	Assignment Type	Description	Cardinality
Account ZIP Code	ZIP Code	Assigns an account ZIP code or group of ZIP codes to a sales territory.	M:M
Contact ZIP Code	ZIP Code	Assigns a contact primary address ZIP code or group of primary address ZIP codes to a sales territory.	M:M
Account Brick	Brick	Assigns an account brick or group of bricks to a sales territory.	M:M
Contact Brick	Brick	Assigns a contact primary brick or group of bricks to a sales territory.	M:M
Account	Account	Assigns an account name or groups of contacts to a sales territory.	M:M
Contact	Contact	Assigns a contact name or group of contact names to a sales territory.	M:M

8	In the Comparison Method field, select Compare to Object.

9	For each assignment criterion entered, click New, and add the appropriate records for the criteria within the given territory.

For example, for an account ZIP code criteria create a new record for each ZIP code range, and enter values in the ZIP Code Low and ZIP Code High fields.

10	Click the Position Candidate detail view tab.

11	In the Position Candidates list, click New, and select the appropriate position for the given territory.

12	Repeat the process for each sales territory that must be defined.

Creating Alternate Sales Force Hierarchies

Oracle Pharma Sales Analytics supports the ability to analyze Rx script data and compare it with alternate sales force organizational structures. These alternate sales force hierarchies can support co-marketing sales organizations where Rx scripts might be 100% allocated to both sales forces, as well as Mirror Sales Forces where Rx Script allocation may be shared between the Sales Forces.

You can assign scripts to each alternate sales representative by:

■ Using a report or metadata calculation based on the attribute of the W_POSITION_D dimension table

■ Creating a new set of aggregation tables to de-duplicate scripts

The alternate sales force hierarchies are configured as an additional set of positions and alignment rules within the Siebel Pharma application. This topic details the tasks that application administrators perform to configure these positions and alignment rules.

NOTE: The allocation of Rx scripts to alternate sales force positions uses an allocation percentage that is stored in the S_POSTN.OWNER_ALLOC_PCT column in the Siebel Pharma transactional database. This database column is not exposed in the standard Siebel Pharma Application. To complete the steps for creating the alternate sales force hierarchies, add the OWNER_ALLOC_PCT column to the position business component, and expose it in the Position List Applet using Siebel Tools.

To create an alternate sales force hierarchy

1   Navigate to the Administration - Group screen > Positions view.

2   In the Positions list, click New to create the top-level position in the sales force hierarchy.

3   Complete the fields in the following table for the new position.

Field	Comments
Division	Division for the alternate sales force hierarchy.
Position	Position associated with the alternate sales force hierarchy.
Position Type	Select the position type from the drop-down list.

4   For each of the levels below the Sales Hierarchy, repeat Step 2 and Step 3 down to the Sales Territory level position.

5 In the Parent Position field for each of these records, select the Position for the level above the
current Position.

The prebuilt Oracle Pharma Sales Analytics configuration supports the following sales hierarchy
levels.

Level	Description	Cardinality to Parent
Organization	The top level of the sales organization that is sometimes referred to as *Franchise*. For example, *Respiratory Franchise* refers to a sales force commissioned to promote respiratory products. This level does not have any parents.	None
Sales Force	Child of Organization. Refers to a sales forces promoting products within a sales organization.	M: 1
Area	Child of Sales Force. Refers to a large geographic sales area, such as US East, US West, or US South.	M: 1
Region	Child of Area. Refers to a sales geographic region.	M: 1
District	Child of Region. Refers to a sales geographic district.	M: 1
Territory	Child of District. Refers to a sales geographic territory composed of ZIP codes, bricks, contacts, or accounts.	M: 1

6 Create all levels for the sales hierarchy as positions, and link them to a position hierarchy to
populate the Oracle Business Analytics Warehouse correctly.

7 For the territory level position in this new alternate hierarchy, set the Position Type field to either
mirror, swat, or *job share* as appropriate for the alternate sales force.

NOTE: Select these position types for the territory level positions in the alternate sales force.

8 In the new Owner Allocation field that has been exposed in the Position List Applet, enter the
percentage allocation of scripts as a decimal for the alternate territory level position.

The Pharma Sales Analytics ETL populates the value from the Owner Allocation Percentage field
to a column in the Position Dimension that can then be used to calculate measures and
aggregates for Rx script allocations.

9 After the alternate sales force positions and hierarchy have been created, you must create an
additional alignment rule for the alternate sales territory as an assignment rule.

For more information about creating these additional Assignment Rules, see "Creating Sales
Territories" on page 519.

NOTE: The alternate sales force territory level position must be selected as the candidate
position for these assignment rules.

Creating Target Lists Using Oracle Business Intelligence

Target List Creator enables the automatic import of customer lists derived from an Oracle BI query into Siebel List Management. This functionality is enabled through the Oracle Business Intelligence Presentation Services and can be used from Oracle BI Interactive Dashboards or Oracle BI Answers integrated with the Siebel Enterprise application.

NOTE: This functionality is certified and tested with the Siebel Pharma Mobile Web Client and Oracle Pharma Sales Disconnected Analytics application, as well as the Siebel Pharma Connected Client and Oracle Pharma Sales Analytics application.

This topic describes the following:

- "About Target List Creator" on page 523

- "Creating a Siebel Target List Using Oracle Pharma Sales Disconnected Analytics Answers" on page 525

- "Configuring Oracle Pharma Sales Disconnected Analytics Integration with Siebel Pharma Mobile Web Client" on page 526

- "Using Target List Creator with Siebel Pharma Applications in Connected Mode" on page 527

About Target List Creator

The following topics outline the components and functionality of the target list creator:

Components

The following components support the Target List Creator functionality:

- **Create Target List view.** Oracle Business Intelligence Presentation Services includes a report view called Create Target List that displays a link used to initiate a business service in the Siebel Pharma application.

- **LS Analytics Target Service business service.** The Siebel Pharma application includes a business service called LS Analytics Target Service that provides the data integration capability.

When Target List Creator is used in an offline mode, Oracle BI Disconnected Analytics Client and Oracle Pharma Sales Disconnected Analytics application need to be installed and configured along with the Siebel Pharma mobile web client and application.

When Target List Creator is used in connected mode, both the Oracle BI Presentation Services and Siebel Web Engine (SWE) must reside on the same machine so that the Create Target List link can be used within an Oracle BI report. The Oracle BI Open Intelligence Interface also needs to be installed and configured on the Siebel Pharma application server to enable connectivity between the Siebel Pharma business service and the Oracle BI Server. For more information, see *Siebel Analytics Installation and Configuration Guide*.

Functional Overview and Process

The following outlines the functionality and general process steps of the Target List Creator components:

1 When a user clicks the Create Target List link in an Oracle BI Interactive Dashboard report, a JavaScript function prompts the user to enter a name for the new list. The function then passes this name and the logical SQL for the Oracle BI Query through the Siebel Pharma application's SWE to the LS Analytics Target Service business service.

2 The LS Analytics Target Service business service:

a Verifies that the field representing the row Id of the target object is the first column selected in the query. For example, if you create a target list for Contacts, then in the default configuration the Contacts.ROW_ID column must be the first column in the query.

b The Oracle BI presentation columns that represent the Row Id values are configured in user properties for the LS Analytics Target Service business service. The Account Row Id Fields user property maps to the Oracle BI presentation column for the Siebel Account Row Id. The Contact Row Id Fields user property maps to the Oracle BI presentation column for the Siebel Contact Row Id. If the Oracle BI presentation columns used to store the Row Id values differ from the default configuration, then the column mappings for the user properties can be changed through Siebel Tools.

c Then a new target list header record is created in the Siebel Pharma application's database. The List Name is set to the Name entered by the user in the Oracle Business Intelligence dialog box and passed from Oracle Business Intelligence to SWE.

d The LS Analytics Target Service business service then uses the Oracle BI ODBC DSN (OpenDataBase Connectivity Data Source Name) name defined in the Siebel Pharma application's AnalyticsDataSrc to connect back to the Oracle BI server.

e The business service executes the logical SQL passed from Oracle Business Intelligence, iterates through the results, and creates a new List Item for each record.

f The validate targets user property on the business service can be turned on to provide additional validation by ensuring that the record in Oracle Business Intelligence already exists in the user's local Siebel database. Possible values for the user property are N or Y. The default value is N.

NOTE: The business component used for the contact target items is List Mgmt List Member, while the business component used for account list items is SLM List Member - Account. Both of these business components must be present in the List Mgmt business object.

3 After the list is created, the application automatically navigates to the view set in the Business Service's Redirect View User Property. This view must be associated with the List Mgmt Business Object and must have the List Mgmt Lists Business Component as its primary business component. The default view is My List Mgmt Lists View.

Creating a Siebel Target List Using Oracle Pharma Sales Disconnected Analytics Answers

The Target List Creator functionality supports offline usage with Oracle Pharma Sales Disconnected Analytics. This topic details what you must do to create a target list and import it into list management from Oracle Pharma Sales Disconnected Analytics Answers, which is accessed from within the Siebel Pharma Mobile Web Client.

To be able to perform this task, make sure that:

■ The integration between the Siebel Pharma Mobile Web Client and Oracle Pharma Sales Disconnected Analytics is set up correctly

■ The Oracle Business Intelligence Disconnected Client is running

■ The local data set for Pharma Sales Disconnected Analytics is synchronized

To create a target list and import into list management

1 In the Siebel Pharma Mobile Web Client, navigate to the Answers > Answers screen.

2 Select Pharma Promotional Effectiveness from the list of Subject Areas.

3 Create a query that contains ROW_ID in the first column. For example, select the following columns:

   a From the Contacts folder: ROW_ID, Full Name.

   b From the Contacts - Contact Profile folder: Market Potential, Primary Specialty.

4 Filter the contacts on the Market Potential and Primary Specialty columns as appropriate.

   NOTE: ROW_ID is mapped to the INTEGRATION_ID column in the underlying Data Warehouse dimension table. This column stores the value of the Siebel Pharma application's Row Id for the Contact. This is a required field and must be the first field in the query. No other field is required to make the Create Target List work.

5 Click the Results tab to list all the contacts who meet the criteria.

6 From the Add View drop-down list, select Create Target List to add the Create Target list view to the report.

7 Save the report with the added Create Target List view.

8 While still in the Results screen, click the Create Target List to invoke a dialog box prompting for the name of the new Target list.

9 Enter a name for using this Target List in the Siebel Pharma Application, and click OK.

The Target List is created, and the application navigates to the Siebel Pharma Application's List Management screen to display the new Target List.

The new Target list can now be applied in multiple views within the Siebel Pharma Application. For more information about applying target lists, see Creating and Applying Target Lists (End User) on page 107.

NOTE: The name of the target list must be unique. If a target list already exists with the same name, the application returns an error when the Create Target List is used. To reuse an existing name, go to List Management in the Siebel Application, and delete the list that exists with that name.

Configuring Oracle Pharma Sales Disconnected Analytics Integration with Siebel Pharma Mobile Web Client

To use the Target List Creator with the Siebel Pharma application in offline mode, Oracle Pharma Sales Disconnected Analytics must be integrated correctly with the Siebel Pharma Mobile Web Client. The following tasks explain how to configure and verify the integration between Oracle Pharma Sales Disconnected Analytics and Siebel Pharma Mobile Web Client.

Install Oracle Pharma Sales Disconnected Analytics

To install Oracle Pharma Sales Disconnected Analytics, see *Siebel Analytics Installation and Configuration Guide.*

Configure the Siebel Pharma Mobile Web Client .CFG Settings

The Target List Creator functionality requires a number of settings to be configured correctly in the Siebel Pharma Mobile Web Client .CFG file.

Make the following changes to the Siebel Pharma Mobile Web Client .CFG file (ePharma.cfg):

■ In the LOCAL section, change UseExternalCachedContent to FALSE.

■ In the SIEBEL section, change EnableFQDN to FALSE.

■ In the Datasources section, set AnalyticsDataSrc to the name of the ODBC DSN configured for the local Oracle BI Server being used with Oracle Pharma Sales Disconnected Analytics. The default name for this ODBC DSN is AnalyticsWeb.

Configure the Oracle Pharma Sales Disconnected Analytics OLTP Database Connection

Oracle Pharma Sales Disconnected Analytics uses an ODBC DSN to connect to the Siebel Pharma Mobile Web Client local database and authenticate users.

To configure ODBC DSN to connect to the Siebel Pharma Mobile Web Client and authenticate users

1 Create a new ODBC System DSN called *SIEBEL_OLTP* of type Adaptive Server Anywhere 8.0

2 Obtain the local SQL Anywhere server name by placing the mouse over the SQL Anywhere icon on the Windows task bar when the Siebel Pharma Mobile Web Client is open.

3 Enter the local server name in the Servername field under the Database tab of the System DSN ODBC configuration window.

4 Enter the path to the local Siebel Pharma DBF file in the Database File under the Database tab of the System DSN ODBC configuration window.

Verify Oracle Pharma Sales Analytics Host and Dashboard URL Configuration

Verify that the NQSHost hostname entry in Siebel Integration Administration is set up correctly to work with the integrated Siebel Pharma Mobile Web Client.

To verify NQSHost hostname entry in Siebel Integration Administration

1 Log in to the Siebel Pharma Mobile Web Client as an Administrator.

2 Navigate to the Administration - Integration screen > WI Symbolic URL List view.

3 Search for NQHOST in the Virtual Name field, and verify that the Name field contains the *localhost:9762* value.

4 Verify that the Oracle Pharma Sales Disconnected Analytics dashboard screens have the correct values in the URL fields:

    a Click the View toggle drop-down list on the Host Administration list, and choose Symbolic URL Administration.

    b Search for the records with the following Names, and make sure that each of their URL fields has `http://NQHOST/Analytics/sawd.dll` correctly set:

        ePharmaHomePageAnalytics1
        ePharmaHomePageAnalytics2
        ePharmaHomePageAnalytics3
        ePharmaHomePageAnalytics4
        SISMLSDistrictManagerDashboard1
        SISMLSSalesRepDashboard1
        SiebelAnswers

Using Target List Creator with Siebel Pharma Applications in Connected Mode

You can also use the Target List Creator with the Siebel Pharma application and Oracle Pharma Sales Analytics in connected mode. This topic lists the tasks that you must carry out to verify the Siebel Pharma application's configuration to support using the Target List creator in connected mode:

■ "Configuration Changes to the Siebel Application" on page 528

■ "Configuring the Application's Server Component Parameters and Enterprise Profile" on page 528

Install and Configure the Oracle Business Open Intelligence Interface

The LS Analytics Target Service business service uses an ODBC DSN to connect back to the Oracle BI Server and execute the Oracle BI logical SQL passed into it. This ODBC DSN needs to be setup using the Oracle BI Open Intelligence Interface (ODBC) client, and requires that this client be installed on the Siebel Pharma application server. To install and configure the Oracle BI Open Intelligence Interface, see *Siebel Analytics Installation and Configuration Guide*.

Configuration Changes to the Siebel Application

To enable the LS Analytics Target Service Business Service to be called from the Siebel Web Engine (SWE), the Business Service name has to be present as a ClientBusinessService user property for the Siebel application being used.

To verify the LS Analytics Target Service business service

The LS Analytics Target Service business service is configured as part of the Siebel Life Sciences application.

1   In Siebel Tools, find the Siebel Life Sciences application record in the Application objects list.

2   In the Application User Prop list verify that the following entry exists:

```
ClientBusinessService10 = LS Analytics Target Service
```

Configuring the Application's Server Component Parameters and Enterprise Profile

The Oracle BI Open Intelligence Interface ODBC DSN connection must be configured as a new data source profile for the Siebel Enterprise and must be associated with the Siebel Application's Object Manager configuration.

To configure a new data source profile and associate with AnalyticsDataSrc

1   Log in to the Oracle's Siebel Application as an administrator.

2   Navigate to the Administration - Server Configuration screen > Enterprises view.

3   Click the Profile Configuration view tab.

4   Search for the AnalyticsDataSrc in the list. If it does not exist, then copy the existing ServerDataSrc record, and rename the copy to AnalyticsDataSrc.

5 Update the following parameters with the values indicated:

DSDLLName = sscdsacon

DSConnectString = AnalyticsWeb

DSTableOwner = <blank>

6 Click the Component Definitions view tab.

7 In the Component list, search for the appropriate Application's Object Manager. For example, for Siebel Pharma, search for ePharmaObjMgr_ENU.

8 With the Component selected, click the Menu button on the Component List applet, and then click Start Reconfiguration.

9 Search for *OM - Named Data Source name* in the Component Parameters list applet.

10 Append the current list at the end with AnalyticsDataSrc.

11 Click the Menu button on the Component List applet, and then click Commit Reconfiguration.

12 Log out of the application.

13 Log in to the server manager, and restart the component by executing the following commands:

shutdown comp ePharmaObjMgr_enu

startup comp ePharmaObjMgr_enu

14 Log in to the application again.

The Create Target List functionality is enabled.

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