Siebel Life Sciences Guide

Version 7.7 Rev. C
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1 What's New in This Release

What's New in Siebel Life Sciences Guide, Version 7.7, Rev. C

Table 1 lists the changes described in Revision C of the documentation to support version 7.7 of the software.

Table 1. What's New in Siebel Life Sciences Guide, Version 7.7, Rev. C

Topic	Description
Update to "Entering and Reviewing Data for 3500A Reports (End User)" on page 390	Added new fields for reporting adverse events on Form 3500A so that it complies with the new FDA mandate.

What's New in Siebel Life Sciences Guide, Version 7.7, Rev. B

Table 2 lists the changes described in Revision B of the documentation to support version 7.7 of the software.

Table 2. What's New in Siebel Life Sciences Guide, Version 7.7, Rev. B

Topic	Description
Electronic Signature Capture for dispersed samples. See Chapter 8, "Recording Calls in Pharma."	Users can capture signatures for samples disbursement within Siebel Pharma running on a mobile client.
Closed-loop marketing See Chapter 8, "Recording Calls in Pharma."	In the contact call record, sales representatives can note the professional's response to specific marketing campaigns. (The campaign manager can later review all responses to estimate the effectiveness of the campaigns.)
Managed care business plans. See Chapter 11, "Managing Managed Care Accounts."	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.
Routing time off territory records See Chapter 13, "Tracking Time Off Territory."	Routing rules can no longer be edited in the Siebel Remote Administration screen. If you need to edit routing rules, contact Siebel Expert Services.

Table 2. What's New in Siebel Life Sciences Guide, Version 7.7, Rev. B

Topic	Description
Protocol Versions Chapter 17, "Setting Up and Carrying Out a Clinical Trial."	Protocol versions are now administered and tracked through a dedicated view. When a new protocol version is applied, non-applicable subject visits are automatically deleted. Non-applicable subject visits are also deleted if the subject terminates the trial early.
Site Calendar Chapter 17, "Setting Up and Carrying Out a Clinical Trial."	The new Site Calendar displays all subject visits at a site, and site visits made by CRAs.
Rolling-up Subject Enrollment Information Chapter 17, "Setting Up and Carrying Out a Clinical Trial."	Subject information is automatically rolled-up from Sites to Regions to Protocols and directly from Sites to Protocols. Information for subjects and sites for which the clinical organization is not responsible (for example, trials outsourced to CROs) may also be rolled-up.
Associating Multiple Contracts with a Site Chapter 18, "Managing Sites and Clinical Contacts."	Multiple contracts may be associated with a site through a new Contracts view. The total contract value for a site is equal to the sum of the individual contract values.
Creating Site Visits Chapter 18, "Managing Sites and Clinical Contacts."	Site Visits are created and managed through a new Site Visits view.
Assessing Accounts Chapter 18, "Managing Sites and Clinical Contacts."	Accounts, such as hospitals, may be assessed to determine fitness to carry out a clinical trial.
Clinical Payments Chapter 19, "Setting Up and Making Subject Activity Payments."	Withholding Amounts and Percentages may be applied to payment activities to make sure all activities are completed before payment is made. Financial administrator can generate payments when payment activities are completed. Earned to Date and Paid to Date fields automatically roll-up from sites to regions and protocols, and from region to protocols.
Trip Reports Chapter 20, "Administering and Using Clinical Trip Reports."	Dynamic trip reporting based on visit types complete with different Actuate Trip Reports for different visit types. Trip reports can be approved or reject by manager before they are distributed.

Table 3 lists the changes described in Revision A of the documentation to support version 7.7 of the software.

Table 3. What's New in Siebel Life Sciences Guide, Version 7.7, Rev. A

Topic	Description
Medical Advanced Contracts. See Chapter 22, "Siebel Advanced Contracts."	Made minor changes to the text to improve document accuracy.

Table 4 lists changes described in the documentation to support version 7.7 of the software.

Table 4. New Product Features in Siebel Life Sciences Guide, Version 7.7

Topic	Description
Medical Advanced Contracts. See Chapter 22, "Siebel Advanced Contracts."	This new feature manages complex contracts. The feature keeps track of benefits, conditions, terms, and compliance history associated with the contracts.
Adverse Events and Complaints Management. See: 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, "Communicating with Customers for AECM." Chapter 29, "Closing Adverse Events and Complaints."	This new feature manages adverse events and product complaints for the regulated medical device and pharmaceutical industries. It manages information throughout the life cycle of a complaint: from capturing and investigating, through to reporting, resolving, and closing out.

2 Overview of Life Sciences

The Siebel Life Sciences product 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.

About Siebel Pharma

Siebel Pharma is a suite of eBusiness 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), Miller Heiman, 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 eBusiness 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 integrated with Microsoft Project
- 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

Many Siebel eBusiness Applications modules can be purchased and used with Siebel Life Sciences. In addition, optional modules specific to Siebel Life Sciences can be purchased to provide enhanced functionality for various business processes.

For information on the optional modules that can be used with Siebel Life Sciences, contact your Siebel 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 *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 5 lists the most frequently used Siebel Life Sciences screens and the functions of the views in those screens.

Table 5. 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
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 *Applications Administration Guide*
Agreements	Manage information about agreements, administrative contracts, and entitlements.	Chapter 22, "Siebel Advanced Contracts," in this guide and *Siebel Field Service Guide*
Analysis	Display prescriber, account, plan, payer, and territory-level sales and Rx data.	Chapter 12, "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 *Fundamentals*
Campaigns	Manage outbound communications with prospects targeted for a particular marketing effort.	*Siebel Marketing Installation and Administration Guide* and *Siebel Marketing User Guide*

Table 5. Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Clinical Programs	Manage information about clinical trial programs.	Chapter 17, "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 17, "Setting Up and Carrying Out a Clinical Trial" Chapter 18, "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 Professional Services Automation Guide*
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.	*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 Siebel administrator.	*Applications Administration Guide*
MedEd	Manage medical education events.	Chapter 14, "Managing MedEd Events," in this guide

Table 5. Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Objectives	Define objectives for contacts and accounts and monitor progress made toward meeting goals.	Chapter 15, "Setting and Achieving Objectives," in this guide
Opportunities	Manage formulary opportunities and affiliate contacts, accounts, and other information with a particular opportunity.	*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 19, "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 28, "Communicating with Customers for AECM," and Chapter 28, "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
Protocols	Maintain information about clinical trial protocols.	Chapter 17, "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 17, "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 12, "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

Table 5. Siebel Life Sciences Screens

Screen Tab	Functions	For More Information
Samples	Organize phases of samples workflow: shipments, orders, adjustments, inventory counts, and reconciliation.	Chapter 9, "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 18, "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 17, "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
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 17, "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 13, "Tracking Time Off Territory," in this guide
Time Sheets	Track employee time, by project, for compensation and billing purposes.	*Siebel Professional Services Automation Guide*

3 Getting Started with Life Sciences

This section covers the following topics:

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 *Applications Administration Guide*, the main guide for performing administrative tasks.

Applications Administration Guide covers the setup tasks that are common to all Siebel eBusiness 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 6 on page 30 before following the procedures in *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.

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

CAUTION: Do not perform system administration functions on your local database. 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 6 lists the administrative setup procedures that are specific to Siebel Life Sciences and procedures that might differ from those of the other Siebel eBusiness Applications. The table also directs you to documentation containing information about each task.

When setting up your application, use Table 6 in combination with the main resource, *Applications Administration Guide*.

Table 6. 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*
Define medical specialties	■ Defining medical specialties ■ Defining account specialties ■ Specifying a contacts'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 6. 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 9, “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 8, “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 9, “Managing Pharma Samples”
Configuring Time Off Territory	■ Configuring Time Off Territory approval process	■ Chapter 13, “Tracking Time Off Territory”

Table 6. Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
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 14, "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 17, "Setting Up and Carrying Out a Clinical Trial" Chapter 6, "Managing Products for Life Sciences" Chapter 18, "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 18, "Managing Sites and Clinical Contacts"
Setting Up Standard Payments	■ Setting up standard payment amounts in subject visit templates ■ Adjusting payment amounts and generating payments for sites	Chapter 19, "Setting Up and Making Subject Activity Payments"
Creating Trip Report Templates	■ Creating trip report templates ■ Approving trip report templates	Chapter 20, "Administering and Using Clinical Trip Reports"
Setting up Microsoft Project Integration	■ Setting up data exchange between Siebel Clinical Projects and Microsoft Project	Chapter 21, "Managing Clinical Projects"
Creating Project Templates	■ Creating project templates	Chapter 21, "Managing Clinical Projects"

Table 6. Siebel Life Sciences Administration Tasks

Administrative Task	Description	For More Information
Importing Data	■ Importing data with EIM ■ Importing, extracting, and routing syndicated data ■ Charting denormalized syndicated data	Chapter 16, "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 6. 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 Submit button ■ Changing read-only status of fields ■ MedEd special C++ classes	Appendix A, "Configuring Siebel Life Sciences"
Editing the epharma.cfg	If you are using Siebel Pharma Field Analytics, edit the epharma.cfg file to allow: ■ Integration of Pharma Analytics Home Page with Pharma Field Analytics ■ Importation of target list contacts into Siebel Pharma Field Analytics Client	The *Oracle Business Intelligence Infrastructure Installation and Configuration Guide* (Integrating Siebel Analytics Dashboards With Siebel Analytics 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 7 lists the default setting of the Manager List Mode user property for some Siebel Life Sciences screens and business components.

Table 7. The Default Setting for the Manager List Mode User 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*. This section 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 8 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 eBusiness Applications and currently conflicts with Siebel Life Sciences assignment rules. Siebel Life Sciences uses the assignment item type Industry SIC Code.

Table 8. 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 eBusiness 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 "Predefined Assignment Objects" on page 36.

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 "Indicating an Affiliation Between an Account and a Contact (End User)" on page 65.
- 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 that are assigned to their team members, regardless the assignment method, set the ASGN_DNRM_ "Y".

For more information, see "Charting Denormalized Syndicated Data" on page 432.

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 enable 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 Designer Administration 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 Integration Administration 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 Integration Administration 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 section, "To export DTE data maps from the server database to an XML file" on page 38.

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 section 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 section 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 section 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 42. Define medical specialities within the system and specify a contact's primary speciality.
- "Deleting a Contact" on page 44.
- "Administering Bricks" on page 44.
- "Associating a Contact with a Brick" on page 45.

End-User Procedures

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

- "Creating a Contact (End User)" on page 46.
- "Specifying the Best Time to Call (End User)" on page 48.
- "Indicating Affiliations Between Contacts (End User)" on page 49.
- "Indicating Affiliations Between a Contact and an Account" on page 49.
- "Viewing Pre-Call Information (End User)" on page 50.
- "Tracking Documentation Associated with a Contact (End User)" on page 52.
- "Other Tasks for Managing Contacts" on page 53. 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 *Applications Administration Guide*.

To define a specialty

1. Navigate to the Application Administration 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, you should merge the records into one in order to keep the database accurate. For more information on merging records, see *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 may want 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 61.

Defining a Brick

To define a brick

1 Navigate to the Data Administration 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 Data Administration 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 that are on the team of the subordinate person, please contact Siebel Technical Support.

Because the contacts shell is assigned to individual people (that is, employees) and not positions, this view does *not* show contacts that 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 44, and "Associating a Contact with a Brick" on page 45.
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 42 and "Setting Up Primary Specialties" on page 42.
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 98.
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 206.
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 44.

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 46
- Using the PreCall view, see "Viewing Pre-Call Information (End User)" on page 50

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 8, “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 managed-care organizations (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 49.	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 48.	
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 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 should be 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 "Creating Documentation Tracking Activities" on page 284.

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 *Applications Administration Guide*. For information about performing assessments (contact assessments are preformed the same way as account assessments), see *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 *Applications Administration Guide*.

5 Administering and Managing Accounts in Life Sciences

This section 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 57.

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 that 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 44.

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 61.

Scenario for Accounts

This section 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 section 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 58.
- “Deleting an Account” on page 58.

- "Generating Account Hierarchies" on page 59. 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 61.

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 61.
- "Specifying an Account Profile (End User)" on page 62.
- "Viewing Account Hierarchies in Roll-up Views (End User)" on page 63.
- "Creating Category Information for an Account (End User)" on page 65.
- "Indicating an Affiliation Between an Account and a Contact (End User)" on page 65.
- "Indicating Affiliations Between Accounts (End User)" on page 66.
- "Creating Subaccounts (End User)" on page 67.
- "Viewing Pre-Call Information (End User)" on page 69.
- "Tracking Documentation Associated with Accounts (End User)" on page 69. 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 into Siebel Life Sciences as accounts, but 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 61. For more information on adding competitive product information, see "Managing Competitor Information" on page 84.

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 *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 "About Configuring the Generate Hierarchy Button" on page 70.

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 *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 44.

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, please review the *Release Notes* on Siebel SupportWeb (see the issue about pop-ups off of shuttle applets in the General section).

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 58.

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 should 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 58.

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 *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 "Recording Calls in Pharma" on page 113.

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 "Creating a Contact (End User)" on page 46.

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 65.
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 67.

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 9 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 9. Access to Account and Subaccount Data

	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 66.

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 59.

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 65.
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 102.

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

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.
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 52.

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

Topics in this section are:

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 72.

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 74.

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 81.

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 16, “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 73.

Scenario for Managing Products

This section 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 section 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 74. Create a new product (called an internal product).
- "Specifying Additional Product Information" on page 82. 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 73. Create any competitive and complementary products (called external products).
- "Adding Products to Catalogs" on page 87.
- "Defining Price Lists" on page 83. Define a price list and then associate it with the new product.
- "Defining Decision Issues" on page 86.
- "Capturing Product Hierarchies for Medical Handheld" on page 87. 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 88.
- "Creating a Product Change Request (End User)" on page 88.

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 72.

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 74.

To create an external product

1 Navigate to the Product Administration 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 58.
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 74.
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 72.

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 10 on page 75 to categorize new products, or create market (therapeutic class) records.
- **Samples and promotional items settings.** Use the values described in Table 11 on page 76 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 142 or "Setting Up Lot Numbers for Medical Products" on page 345.

Product Categorization Settings

You categorize products or create market (therapeutic class) records using the Product Administration field values described in Table 10.

Table 10. 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 72.	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 76.

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 11:

- 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 142.

Table 11. (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 11. (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 Product Administration 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 73. 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 10 on page 75. If this product also exists in the external product table, select Competitor so that the products will match up correctly.

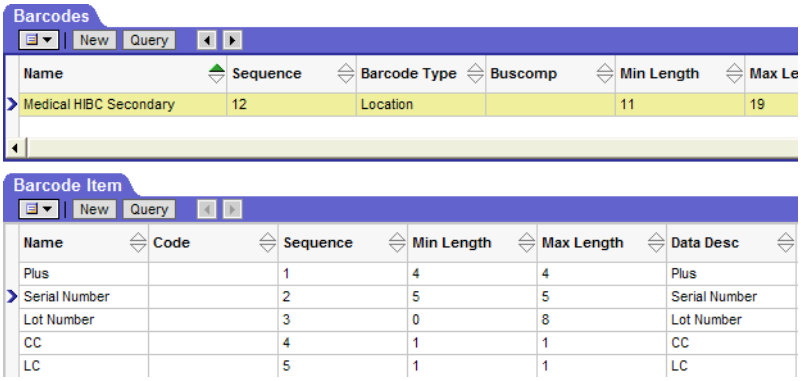
3 Drill down on the product.

4 Click the More Info view tab.

5 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 can be found in the Handheld Administration screen > Barcodes view.

Field	Comments
	
Frequency	This field is for Adverse Events and Complaints Management. Indicates how many times per 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 11 on page 76. For more information on defining lot numbers, see "Defining Lot Numbers for Samples" on page 142. ■ 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 89.
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 10 on page 75 and then Table 11 on page 76.
Manufacturer	This field is for Adverse Events and Complaints Management.

Field	Comments
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 10 on page 75.
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). *Note:* For Siebel Medical Handheld, only the primary parent is considered. Other parent products are ignored.
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 10 on page 75. 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 87
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.

Field	Comments
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 10 on page 75.
Short Days	This field is for Siebel Medical Handheld. An asset or lot for this product is short dated this many days before expiration.
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 82.

To make a product inactive

1. Navigate to the Product Administration 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 selecting the product in the Products list, and then making selections from the lower Show drop-down list. Using these subviews you can specify additional product features or associate product literature, other related products, and product comparison information.

To specify additional product features

1. Navigate to the Product Administration screen > Products view.
2. In the Products list, drill down on a product.
3. On the lower link bar, click Product Key Features.
4. In the Feature list, create a new record and complete the necessary fields.

To associate related literature

1. Navigate to the Product Administration screen > Products view.
2. In the Products list, drill down on a product.
3. On the lower link bar, click Product Literature.
4. Scroll down to the Product Literature list and create a new record.
5. In the Add Literature dialog box, select one or more records and click OK.

   The selected records are added to the Literature list.

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

To add information on related products

1. Navigate to the Product Administration screen > Products view.
2. In the Products list, drill down on a product.
3. On the lower link bar, click Related Products.
4. Scroll down to the Related Products list and create a new record.
5. In the Add Internal Products dialog box, select one or more products and click OK.

For more information on adding on other selections to the Add Internal Products dialog box, see To create an internal product or a market on page 77.

To add product comparison information

1. Navigate to the Product Administration screen > Products view.
2. In the Products list, drill down on a product.
3. On the lower link bar, click Product Comparison.
4. In the Product Comparison list, create a new record.
5. In the Add Product Comparisons dialog box, select one or more products and click OK.

   The products are added to the Product Comparison list.

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 Pricing Administration 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 74.

To associate a price list with a product

1 Navigate to the Product Administration 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 83.

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 *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 section 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 58.
- Creating records for competitors' products. For more information, see "Defining External Products" on page 73.
- Adding comparative and competitive literature files to the application. For more information, see the chapter on literature administration in *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 84 and "To define product features" on page 85.
- 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 85.

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 Product Features Administration screen > Product Features Administration view.

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

Some fields are described in the following table.

Field	Comments
Feature	The product comparison 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 58.

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 Competitor 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 84.
Rank	Enter the numeric rank of the feature as defined by your business process.

4 (Optional) Click the Competing Product Comparison view tab, create a new record and complete the necessary fields.

5 (Optional) Click the Literature view tab:

- Create a new record in the Competitor's Literature list and complete the necessary fields.
- Create a new record in the Comparative Literature list and complete the necessary fields.

6 (Optional) Click the Product Literature view tab, create a new record in the Product Literature list, and complete the necessary fields.

7 (Optional) Click the Product Literature view tab and select a product in the Product Literature list:

- In the Competitor's Product Literature list, create a new record and complete the necessary fields.
- In the Comparative Product Literature list, create a new record and complete the necessary fields.

For information on these fields, see the chapter on literature administration in *Applications Administration Guide*.

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 section, you must first add set up categories. (For general information about setting up categories, see the *Siebel eSales Administration Guide*.)

To create a decision issue

1 Navigate to the Data Administration 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

Products are added to categories within a catalog. 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. Access groups are assigned to a catalog to control visibility to users. For more information about access groups, see *Security Guide for Siebel eBusiness Applications*.

To add a product or lot number to a catalog

1 Navigate to the Catalog Administration screen.

2 Create a new record and complete the necessary fields.

3 Drill down on the hyperlink in the Name field.

4 In the Categories list, create a new record.

5 Use the buttons on the Categories list to create subcategories.

6 On the lower link bar, click Products.

7 Create a new record to the products list for each product or lot number you want to add to the category.

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 Product Administration 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 12.

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

Table 12. 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 section 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 Chapter 8, “Recording Calls in Pharma.”

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 92.
- **Targeting.** For more information, see "Targeting" on page 92.
- **Routes.** For more information, see "Routes" on page 92.
- **Activities.** For more information, see "Activities" on page 92.

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 93 and "Creating a Personal List (End User)" on page 96.

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 93 and "Creating and Applying Target Lists (End User)" on page 97.

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 the 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 94 and "About Defining a Route Plan (End User)" on page 98.

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 95 and "About Creating Activities" on page 102.

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 104.

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 107 and "Creating an Account Call (End User)" on page 109. For information on recording calls, see Chapter 8, "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 92.

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 96.
- **Record contact and account calls.** For more information, see Chapter 8, "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 "To create a target list from the List Management screen" on page 98.
2. **Apply target lists to other views.** For more information, see the *Applications Administration Guide*.

Scenario 3: Users Define Route Plans

This section 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 99.

2 **Add accounts to a route.** For more information, see "To add accounts to a route using the Accounts view tab" on page 100.

3 **Schedule account visits using routes.** For more information, see "Using a Route to Schedule Calls (End User)" on page 102.

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 8, "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 102.

2 **Create contact or account call.** For more information, see "Creating a Contact Call (End User)" on page 107 and "Creating an Account Call (End User)" on page 109.

3 **Set up a meeting.** For more information, see "Setting Up a Meeting (End User)" on page 105.

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 104.

Process of Planning Calls

This section 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 93**.** Personal lists determine which products appear in the Call Detail views in Siebel Life Sciences.

- (Optional) "Scenario 2: Users Create Target Lists" on page 93. 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 94. 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 95. 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 107.
- "Creating an Account Call (End User)" on page 109.

NOTE: After end users set up their personal list, they can record calls. For more information, see "Recording and Submitting Contact Calls" on page 120 and "Recording and Submitting Account Calls" on page 122.

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 8, "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 92 and the scenario "Scenario 1: Users Set Up Personal Lists" on page 93.

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.

Field	Comments
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 *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 92 and the scenario "Scenario 3: Users Define Route Plans" on page 94.

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 99.
- **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 102

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 100.
- **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 100.
- **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 101.

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 100 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 Step 6 on page 101 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 96.
- **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 8, “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 105.

- **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 13, "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 199.
- **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 265.
- **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 282.
- **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 297.
- **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 297.
- **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 and by importing from Microsoft Project files. For more information, see "Creating Activities and Tasks for a Project (End User)" on page 310.

For more general information on activities, see "Activities" on page 92 and "Scenario 4: Users Create Activities" on page 95.

NOTE: End users also use the Activities screen to record and submit details of contact and account calls. For more information, see Chapter 8, "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 *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 14, "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 105.

  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 106.
- **Add speakers for the meeting.** For more information, see "To add a meeting speaker" on page 106.
- **Add invitees for the meeting.** For more information, see "To add a meeting invitee" on page 106.

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 106. 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 106.
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 105.
   - 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.

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 105.
   - 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 105. For more information, see "Indicating an Affiliation Between an Account and a Contact (End User)" on page 65.

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 105.
   - 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 120.

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 96.

This section presents four different methods of creating contact calls:

- To create a contact call from the Activities screen on page 107
- To automatically schedule contact calls using the Schedule button on page 108
- To manually schedule a contact call in the Calls view tab on page 109
- To schedule a contact call in the Calendar on page 109

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 9, "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 120.

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 120.

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.

From the Contacts Screen Using the Schedule Button

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
- 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 per 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.

From the Contacts Screen (Manually)

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 120.

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 120.

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 120.

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 120.

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 96.

This section presents five different methods of creating account calls:

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 125.

For information on how to enter information in the Call Products Detailed, Attendees, and Activities lists, see "Recording and Submitting Contact Calls" on page 120.

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 125.

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 122.

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 122.

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 122.

8 Recording Calls in Pharma

This section 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 13 describes the specific actions that occur when clicking the Submit button in the view listed in the left column.

Table 13. 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. If samples were dropped, 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 samples were dropped, creates a Samples Transaction History record.
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 a an active transaction by moving the count in the latest inventory period.

Table 13. Effects of the Submit Button on Siebel Life Sciences Views

View	Access Path	Transaction Type	Clicking the Submit Button...
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 13. 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.
- 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 125 (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 126.

You should refer to the *System Requirements and Supported Platforms* on Siebel SupportWeb 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

Introduction

This section 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 118. 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 119. (Requires Siebel Pharma Campaigns.)
2. "Recording and Submitting Contact Calls" on page 120.
3. "Recording and Submitting Account Calls" on page 122.
4. "Remaking Electronic Signatures" on page 125. 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 105.

(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 107.

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 119.

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 107.

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 96.

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 142.
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 9, "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 96. 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.

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 96.
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 86.

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 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 119.

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 109.

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 96.

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 65.
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 96.
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 133.

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 122 or Step 5 on page 122 of the procedure "To record contact calls" on page 121.

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 Remake 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 remake receipt functionality.

This task is a step in “Process of Recording Calls” on page 119.

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 Remake Receipt.
3. Edit the name and address fields for the professional.
4. Click Sign.
5. Obtain the professional’s signature and click Save.

Configuring 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 13 on page 114 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 Update After Submit. Table 56 on page 440 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 14 lists LOVs that are required in the submit process. Do not delete or inactivate these LOVs.

Table 14. 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 9, “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 56 on page 440 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 1 on page 129 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 15 on page 130.

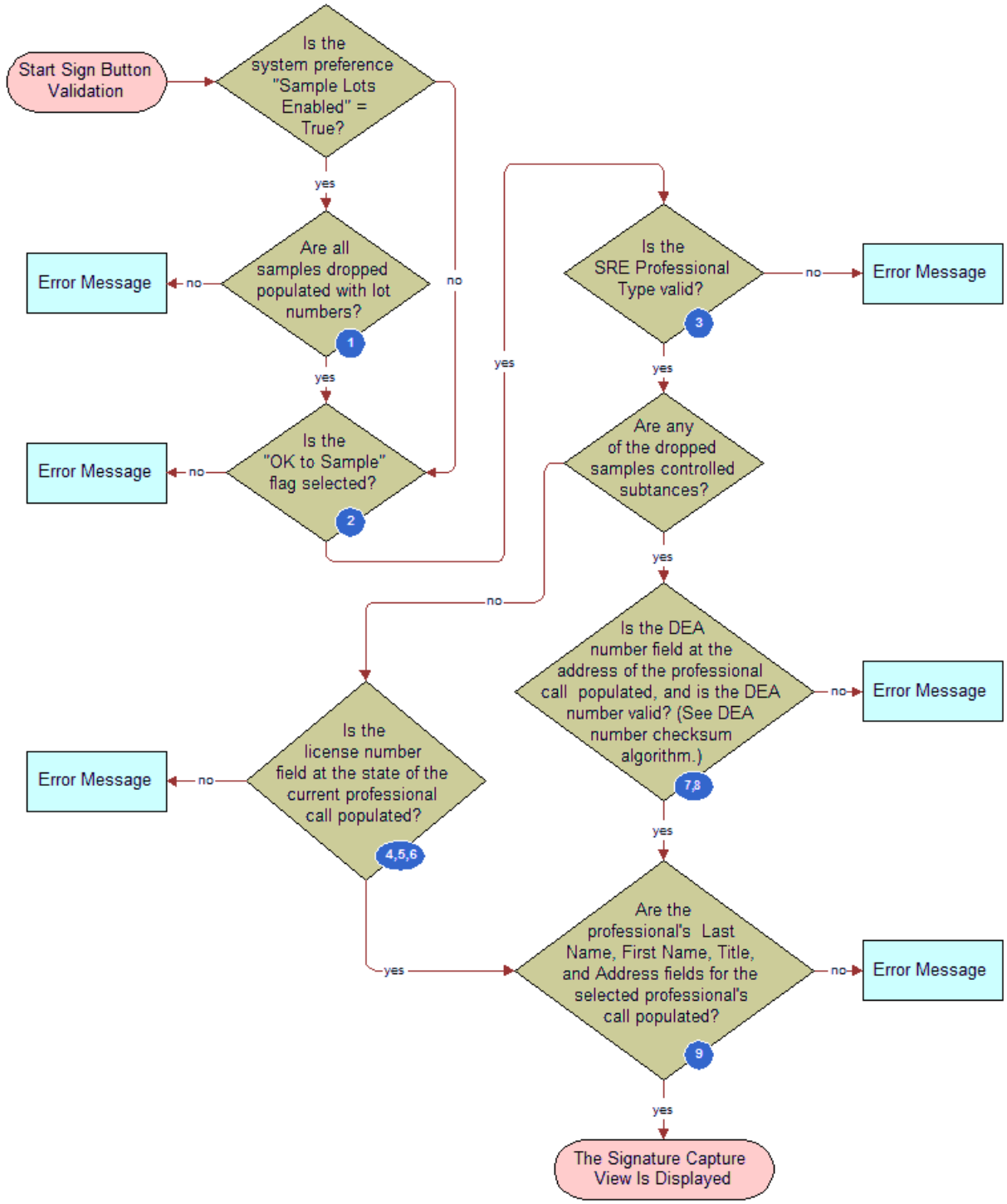


Figure 1. Default Validation Logic Flowchart for Sign Button

Table 15. 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 15. 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 16 on page 131.

Table 16. 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	Either single, double, 3D, or no border on the window	1

Table 16. 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

9 Managing Pharma Samples

This section 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 137.

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 an 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 2, 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.

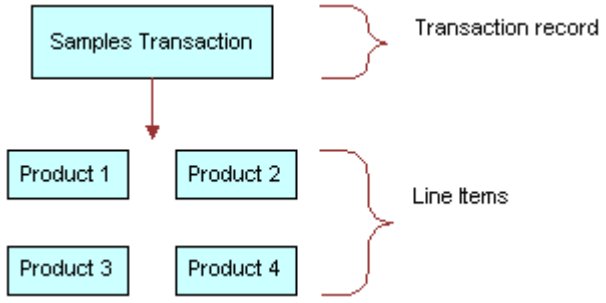


Figure 2. Transaction Record and Line Item Relationship

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 160.

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 160.

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 141.

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 17.

Table 17. 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 160.

How Siebel Samples Management Works with Calls

This section describes how Siebel Samples Management works with the Contact Call Detail and Account Call Detail views. For more information on recording calls, see Chapter 8, "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:

- 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 147.

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.
- 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 system preferences by navigating to the Application Administration 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 Product Administration 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 Product Administration 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 8, “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 142.
- **Set up and reconcile initial master inventory.** For more information, see "Establishing an Initial Inventory" on page 145.
- **Transfer inventory to end users.** For more information, see "Creating a Samples Transfer" on page 149.
- **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 151.
- **Manage electronic signatures.** For more information, see "Checking Electronic Signatures" on page 155.
- **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 158.
- **Add inventory to personal lists.** For more information, see "Creating a Personal List (End User)" on page 96.
- **Use the new samples in regular call reporting.** For more information, see Chapter 8, "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 149.
- **Request more samples.** For more information, see "Creating a Samples Order (End User)" on page 157.
- **Perform inventory adjustments.** For more information, see "Adjusting a Past Samples Transaction" on page 153.
- **Reconcile inventory periods as needed.** For more information, see "Reconciling an Inventory Period (End User)" on page 160.

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 21, "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 142.
- **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 145.
- **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 151.
- **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 155.
- **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 157.
- **Add inventory to personal lists.** For more information, see "Creating a Personal List (End User)" on page 96.
- **Use the new samples in regular call reporting.** For more information, see Chapter 8, "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 149.
- **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 158.
- **Perform counts and adjustments.** For more information, see "Adjusting a Past Samples Transaction" on page 153.
- **Reconcile inventory periods as needed.** For more information, see "Reconciling an Inventory Period (End User)" on page 160.

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 3 illustrates this process.

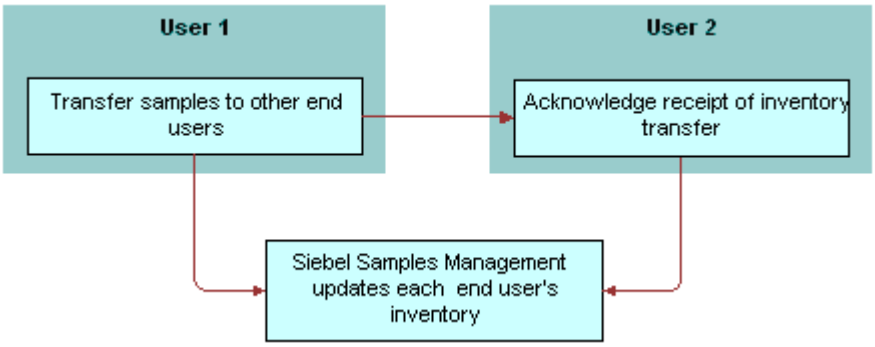


Figure 3. Process for Users to Transfer Samples to One Another

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 96.

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 that 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 Samples Receipts screen) 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.
- Receipts (transactions whose Type field is either Transfer In or Receipt) are added to the submitter's inventory counts.
- Samples transfers (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 Add and Adjust buttons are enabled and the Submit button is 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 147.

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 144.
- Define the products that will be disbursed as samples. For more information, see "Defining Internal Products" on page 74.
- Define the lot numbers for each product. For more information, see the procedure "To define lot numbers" on page 143.

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 144. For more information on reconciliation without lot numbers, see "Managing Inventory Tracking and Reconciliation Without Lot Numbers" on page 147 and "Enabling Inventory Reconciliation Without Lot Numbers" on page 436.

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 74.

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 74 paying specific attention to Table 10 on page 75 and Table 11 on page 76.

2. Navigate to the Samples Administration 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 74 paying specific attention to Table 10 on page 75 and Table 11 on page 76.
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 74 paying specific attention to Table 10 on page 75 and Table 11 on page 76.

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 74. 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 135 and "Defining Internal Products" on page 74 become active.

Setting the Samples Lots Enabled system preference to FALSE causes samples dispersed with lot numbers to not appear in the Samples History or the Inventory Count views. If you plan to disperse samples with lot numbers, the Samples Lots Enabled system preference should be set to TRUE to assure that all relevant data appears in these views.

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 *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 147.

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 137, 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 74 paying specific attention to Table 10 on page 75 and Table 11 on page 76.

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 74 and "About Samples Transactions" on page 141.

NOTE: End users do not need to perform the procedures described in this section 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 158. However, end users do need to perform the procedures described in this section 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 146.)
- **Submit adjustments.** Create and submit adjustments for the initial count. (See "To create and submit initial count adjustments" on page 147.)
- **Reconcile.** Reconcile the initial inventory period. (See "To reconcile the initial inventory period" on page 149.)

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. You can view this change using the My Samples History filter.

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 Product Administration screen.
- Implement product visibility. For more information, see "Retaining Sample Product Visibility" on page 436.

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 *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 the correct 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. 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 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 146).
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 146).
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 153.

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 the his or her inventory count. For more information, see "Acknowledging Receipt of a Samples Transfer (End User)" on page 158.

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 (because there is no recipient), and they are *not* added to the master inventory counts. However, the samples administrator can see returned samples transactions in the samples administration views. For more information, see "Monitoring Samples Activities" on page 151.

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 18 on page 152 to monitor samples activity across the enterprise.

To access monitor samples activities

1 Navigate to the Samples Administration screen.

2 On the link bar, click one of the view names listed in the left column of Table 18.

NOTE: The views discussed in Table 18 are read-only and appear only when you are connected to the server.

Table 18. 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 the 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 Samples Adjustment list. 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 18. 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 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.

   NOTE: To make it easier to find a transaction, sort the records in the Samples History list by the field you are using to identify the transaction. For example, if you know the Transaction #, sort the list by that field to locate the records you are looking for.

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 Pending Approval. 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 Last Name	The last name of the creator of the transaction.
Description	A description of the product or comment describing the transaction.
Last Name	The last name of the doctor. Used only if the transaction type is disbursement.
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.

Field	Comments
Transaction Type	Shows the type of transfer. Valid values include Transfer Out and Transfer In.
Transfer To/ From Last 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 18 on page 152 to monitor samples activity across the enterprise.

To display Signature Audit Administration

- Navigate to the Samples Administration 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 screen 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 Samples Administration screen > Sample Event Administration view.

Creating New Disclaimer Text for Signature Capture Display

The Disclaimer Administration screen 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 screen

1. Navigate to the Samples Administration 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 145.

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 158.

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 149
- By creating a samples order, see "Creating a Samples Order (End User)" on page 157

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 153.

To acknowledge receipt of a samples transfer

1 Navigate to the Samples screen.

2 On the link bar, click Received Samples.

3 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.

4 In Line Items list, modify the Received Quantity field if the value does not accurately reflect the quantity received.

5 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 a samples administration view. For more information on available administration views, see "Monitoring Samples Activities" on page 151.

6 From the Show drop-down list, select My Samples History.

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 153.

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 134.

Prior to starting inventory reconciliation, users must perform the steps outlined in Figure 4.

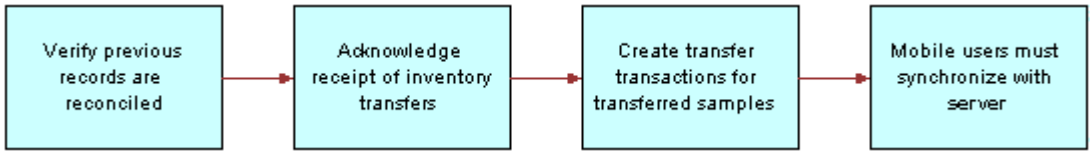


Figure 4. Inventory Reconciliation Prerequisites

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 157.
- **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 158.
- **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 149.
- **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 162.

The reconciliation process consists of the steps outlined in Figure 5.

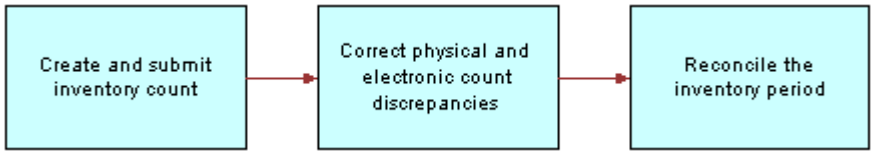


Figure 5. Inventory Reconciliation Process

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 161.

  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 163.

    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 155.

    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 164.

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 162.
- If the Difference field in all records is equal to zero, click Submit and follow the procedure "To reconcile an inventory period" on page 164.

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.

The number of discrepancies determines the adjustment method.

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 one or two 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 proceed with the procedure "To adjust a quantity in a samples transaction" on page 155.

- If more than two records require adjustments, enter a single adjustment transaction, with multiple line items, that adjusts all the quantities. Proceed to the following procedure, "To adjust multiple quantities with a new adjustment transaction" on page 163.

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 162: ■ 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.

2 From the Show drop-down list, select Reconciliation.

3 In the Unreconciled Inventory Periods list, select the inventory period that you want to reconcile.

4 Scroll through the records.

5 In the Unreconciled Inventory List, scroll through the records and verify that the value of the Difference field for each record is zero.

6 Click Reconcile.

The Samples Reconciliation view is cleared.

10 Creating Smart Calls

This section 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 165.

Scenario for Smart Calls

This section 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.

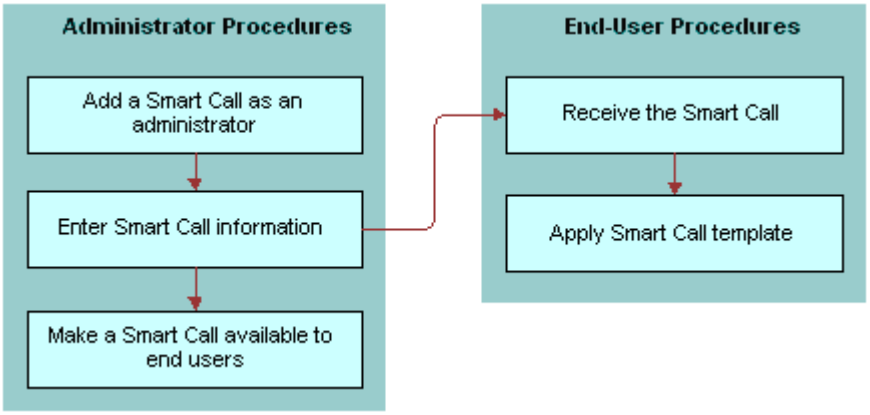


Figure 6. Administrator Creates Smart Call Templates

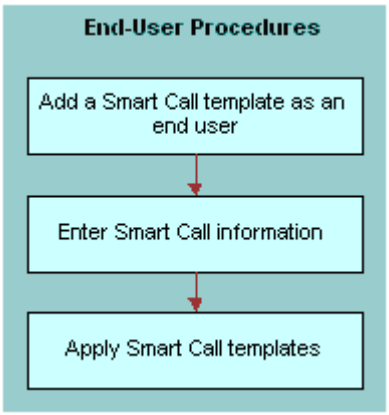


Figure 7. End User Creates Smart Call Templates

Administering Smart Calls

The following administrator procedures are described in this section:

- To create a Smart Call as an administrator
- To enter Smart Call information as an administrator on page 168
- To make a Smart Call template available to end users on page 169

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 169.

To create a Smart Call as an administrator

1. Navigate to the Application Administration 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 107 and "Creating an Account Call (End User)" on page 109.
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 Application Administration 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 Application Administration 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 169.

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 107 and "Creating an Account Call (End User)" on page 109.

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 107 and "Creating an Account Call (End User)" on page 109.
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 120 and “Recording and Submitting Account Calls” on page 122.

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 107 and “Creating an Account Call (End User)” on page 109.

Once a user applies a Smart Call template to a call, they 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

Topics in this section are:

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 19 on page 174 defines some terms that are used in this chapter and also in the application's user interface.

Table 19. 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 19. 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 176.

- "Entering Health Plan and Formulary Information" on page 177
- "Associating Contact Information to Health Plans" on page 179
- "Creating a Business Plan for a Managed Care Organization" on page 180
- "Entering Formulary Information for Managed Care Business Plans" on page 181
- "Performing Business and SWOT Analysis for a Managed-Care Business Plan" on page 182

■ “Associating Contacts and Accounts with Managed-Care Business Plans” on page 183

■ “Setting Objectives for the Managed-Care Business Plan” on page 184

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 176.

Who Owns the Formulary?

There are two approaches to setting up formularies in Siebel Life Sciences. The formulary can belong to:

- The MCO account, or
- The PBM account

Before deciding which type of account should own the formulary, review “Indicating Affiliations Between a Contact and an Account” on page 49 and “Entering Formulary Information for Managed Care Business Plans” on page 181, 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 19 on page 174 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 177.

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 19 on page 174 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 58.

5 Repeat Step 3 and Step 4 until you have created a record for every product on the formulary.

Associating Contact Information to 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 176.

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 176.

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 177.
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 12, "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 that 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 *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 15, “Setting and Achieving Objectives.”

12 Analyzing Syndicated Data

This section 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 section 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 section 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 section:

- "Defining Payer and Plan Information" on page 186.

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 236.
- "To create a data extraction rule" on page 239. Extract portions of data according to territory assignments.
- "To specify the data that is routed to mobile users" on page 240. Send the compressed data extracts to mobile users.
- (Optional) Updating responsibilities. For general information about responsibilities, see *Security Guide for Siebel eBusiness Applications*.
- Associating positions to bricks. See "Administering Bricks" on page 44.

End-User Procedures

The following list shows tasks end users typically perform using the Analysis screens:

- "Importing Syndicated Data Files (End User)" on page 187.
- "Analyzing Brick-Level Syndicated Data (End User)" on page 188.
- "Working with Sales, Rx, and Call Data (End User)" on page 189.

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 Application Administration 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 44.

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 Table 20 on page 190, 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 import syndicated data extracts" on page 187.

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 20.

NOTE: Analysis data is read-only. Data refresh cycles are determined by your company's business process and data availability.

Table 20 describes the functions of the views in the Analysis screen. Your responsibilities determine which views are available to you.

Table 20. 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 20. 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 20. 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.

13 Tracking Time Off Territory

This section 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 102.

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 section 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 194. 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 195.

The regional sales manager uses Siebel Time Off Territory to:

- "Viewing Time Off Territory Charts (End User)" on page 195. 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 195.

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.

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 *Applications Administration Guide*.
- Enter additional selections to the Reason drop-down list. For more information about Lists of Values, see *Applications Administration Guide*.

14 Managing MedEd Events

This section 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 199.

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 section 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 section 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:

1. "Establishing Funds for MedEd Plans" on page 200
2. "Creating Master MedEd Plans" on page 202
3. "Creating a MedEd Activity Template" on page 203
4. "Administering MedEd Literature" on page 205
5. "Designating MedEd Event Speakers" on page 206

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:

1. "Setting Up a MedEd Plan (End User)" on page 206
2. "Setting Up MedEd Events (End User)" on page 208
3. "Tracking Costs of MedEd Activities (End User)" on page 210
4. "Setting Up Sessions Within a MedEd Event (End User)" on page 212
5. "Inviting and Registering Prospective MedEd Attendees (End User)" on page 215
6. "Generating Correspondence for MedEd Event Invitees (End User)" on page 216
7. "Scheduling Calls to an Invitee (End User)" on page 216

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.

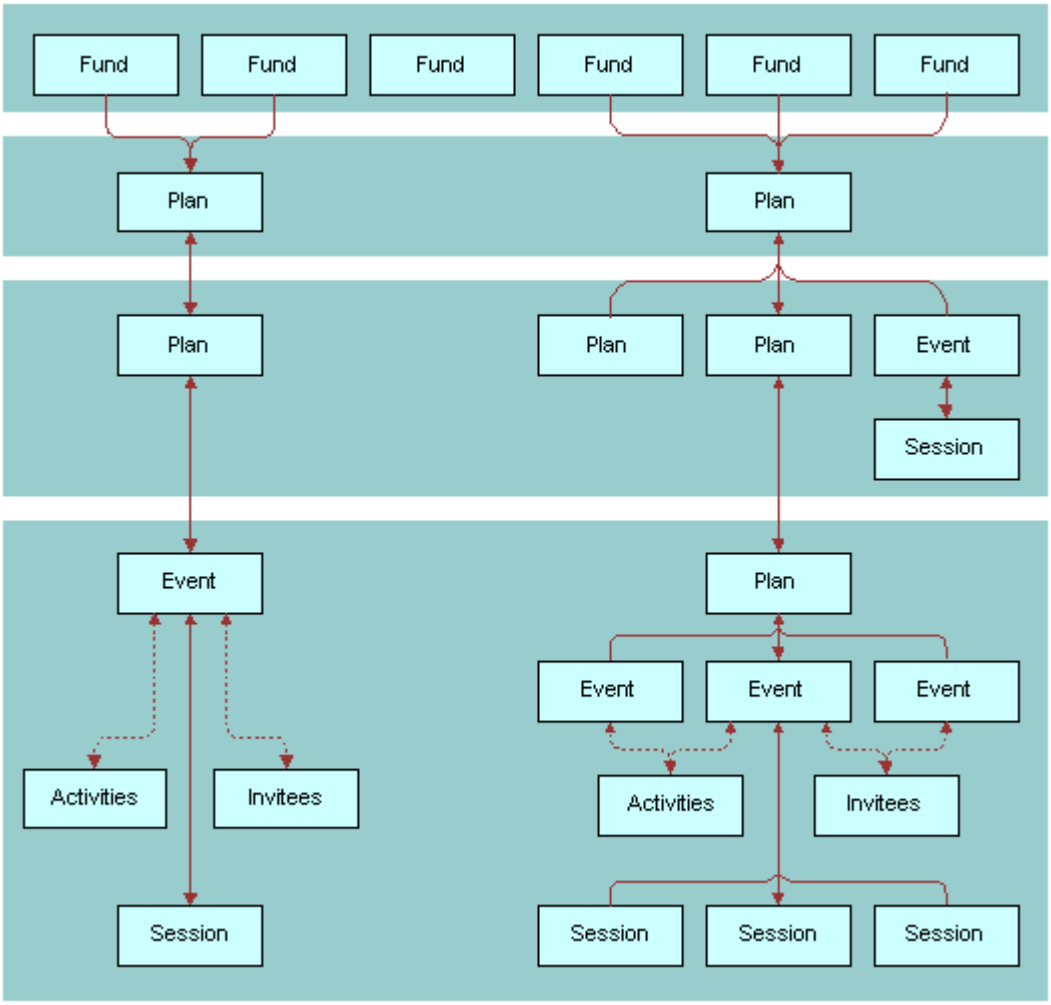


Figure 8. Relationships Between Funds, Plans, Events, Sessions, Activities, and Invitees

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 *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 202.

To verify that a fund is available for association with a MedEd plan

1. Navigate to the Data Administration 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 206.

To create a MedEd master plan

1. Navigate to the Data Administration 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 *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 21 lists the locations, field names, and values types of some MedEd drop-down lists.

Table 21. 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 Data Administration 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 21. 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 *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 specify literature for a MedEd session" on page 214.

To add a literature item to the application

- Follow the procedure for adding literature records in the *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 210.

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 *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 section, "Setting Up MedEd Events (End User)" on page 208.

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 Oracle Pharma Marketing Analytics product use these 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 Step 3 on page 209.
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 Step 4 on page 209.
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:

a Click the select button.

All available team members appear in the Event Team dialog box.

b For each team member: in the Cost Allocation field, 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%.

c Select your own record, specify a plan, and click OK.

Each MedEd Team member should log into Siebel Life Sciences and specify which MedEd plan will be charged for their portion of the event's costs.

4 In the Product field, click the select button, and in the Products dialog box that appears.

a Select the one or more products that will be discussed at the event.

b 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 203.

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 *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 206.

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 that 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.
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.

Field	Comments
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 46. 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 205.

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 204. 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 215.

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.

15 Setting and Achieving Objectives

This section 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 section 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 221
2. “Creating Recommended Activities for an Objective” on page 222
3. “Targeting Accounts to an Objective” on page 224
4. “Loading Actual Amount Fields Using EIM” on page 224

End-User Procedures

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

1. “Reviewing Objectives (End User)” on page 224
2. “Creating an Objective” on page 221

3 “Charting Objectives” on page 225

Creating an Objective

You must complete this task before performing the remaining tasks in this chapter. If you need an objective to recur, see “Creating Recurring Objectives” on page 222.

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 Designer Administration 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 221.

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 *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 16, “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.

16 Importing Data into Life Sciences

This section covers the following topics:

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 eBusiness 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 Table 25 on page 245.

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 section 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 228
2. “Importing, Extracting, and Routing Syndicated Data” on page 235
3. “Extracting Data for Mobile Users” on page 238

End-User Procedure

- “Importing Syndicated Data Files (End User)” on page 250

Importing Data with Siebel EIM

Siebel EIM manages the exchange of data between Siebel database tables and other corporate databases. This section 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 230. 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 (`default.ifb`).

   For general information about `default.ifb` 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 Syndicated Data Administration screen, you can define complex routing rules for syndicated data.

Table 22 shows the relationships between the data, interface tables, and base tables.

Table 22. Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
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

Table 22. Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
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
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

Table 22. Data and Related Interface Tables

Data	Interface Table	Base Table	Table Description
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 22. 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
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 22. 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 22. 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 22 on page 230:

- 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 which allows either full or partial table-level extraction. Using views in the Syndicated Data Administration 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* and *Security Guide for Siebel eBusiness Applications*.

The views that require syndicated data import are shown in Table 25 on page 245.

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 23 lists all of the foreign keys fields, their foreign key table, and a description of what the field contains for Siebel Life Sciences.

Table 23. 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 Table 23 on page 236. 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 sections.

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. 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 Syndicated Data Administration 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 Syndicated Data Administration 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.
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 24 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 24. 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

Table 24. Command Line Arguments for Environment Variables

	Argument and Meaning	Comments
/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 24 on page 242 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 section lists the Siebel Life Sciences views and business components that require data import and indicates which data values should be loaded into the syndicated data table.

Table 25 lists the views that require data import.

Table 25. Views and Business Components Requiring Data Import

Screen	View	Business Component
Accounts	Charts > Sales	Pharma Sales Consumption
	Charts > Profitability	Pharma Consumption

Table 25. 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 25. 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 26, and the Attribute by Data Source Matrix, shown in Table 27 on page 249, are provided to facilitate loading sales, Rx, profitability, and influence data. Table 26 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 26. 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 26. 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 27 indicates, by data source, the data values that should be loaded into the syndicated data table (S_SYND_DATA) attribute fields.

Table 27. 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	
RXBrk	Product NRx	Product TRx	Market NRx	Market TRx	
RXEVM	Product NRx	Product TRx	Market NRx	Market TRx	
RXPrf	Product NRx	Product TRx	Market NRx	Market TRx	
RXSMI	Product NRx	Product TRx	Market NRx	Market TRx	
RXSMM	Product NRx	Product TRx	Market NRx	Market TRx	
RXTer	Product NRx	Product TRx	Market NRx	Market TRx	
RXXPT	Product NRx	Product TRx	Market NRx	Market TRx	
RXZip	Product NRx	Product TRx	Market NRx	Market TRx	
SlsDirAct	Product Sales $	Product Sales Units			
SlsDirBrk	Product Sales $	Product Sales Units			
SlsDirTer	Product Sales $	Product Sales Units			
SlsDirZip	Product Sales $	Product Sales Units			
SlsIndAct	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	
SlsIndBrk	Product Sales $	Product Sales Units	Market Sales	Market Sales Units	
SlsIndTer	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	
SlsIndZip	Product Sales $	Product Sales Units	Market Sales $	Market Sales Units	

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*.

17 Setting Up and Carrying Out a Clinical Trial

Topics in this section are:

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.

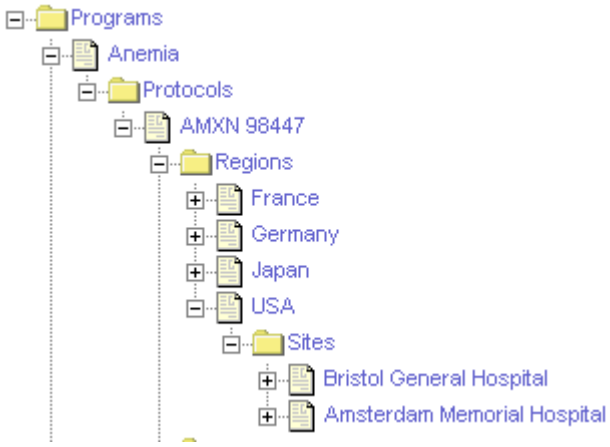


Figure 10. Siebel Clinical Hierarchical Relationships

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 section 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 254.

2 "Setting Up a Protocol" on page 255.

3 "Creating and Revising Protocol Versions" on page 256.

4 (Optional) "Setting Up Regions" on page 256.

5 "Defining a Subject Visit Template" on page 258.

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 261.

2 "Creating a Site (End User)" on page 263.

3 “Creating a Subject and Setting Up Visits and Visit Activities (End User)” on page 265.

4 “Applying Protocol Amendments (End User)” on page 269.

5 “Monitoring Subject Status and Enrollment Rates (End User)” on page 272.

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 and multiple versions of a protocol 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 Clinical Administration 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 move to 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 254.
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 256. 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.

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 Clinical Administration 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 255.

To create region records for a protocol

1 Navigate to the Clinical Administration 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 *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 271.
Protocol #	Only protocols where regions are required are listed in the Pick Protocol dialog box.
# Planned Sites	Number of sites planned for the region.
# Planned Subjects	Number of subjects planned for the region.
Protocol Region	A name for the region. This is automatically filled in with the protocol number and the region name.
Region	Geographic region to which the site belongs.
Team	Team members associated with the protocol to which the region belongs. 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, select a name in the Team picklist and click Position Rollup.

The team member is automatically added to the protocol to which the region belongs.

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

5 (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.

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 shown in Figure 11 is applied to a subject with a screen date of 11/20/2001, a rescreen date of 11/22/2001, and an enrollment date of 11/26/2001, the resulting visit schedule is as shown in Figure 12.

Visits

New | 1 - 5 of 5

Sequence	Visit Type	Name	Lead	Lead Units	Min	Max	Min/Max Units
1	Screening	Screening Visit	0	weeks	0	1	days
2	Re-screening	Re-Screening Visit	0	weeks	0	1	days
3	Enrollment	On Study Visit 1	1	weeks	1	1	days
4	Enrollment	On Study Visit 2	2	weeks	1	1	days
5	Enrollment	On Study Visit 3	3	weeks	1	1	days

Figure 11. Visits List

Subject

New | 1 of 1+ | Screen | Rescreen | Enroll

*Protocol #: CFRN 4563	*Subject Initials: JNC	Screening #: JNC:03/16/1940	Screen Failure Reason:
Region:	*Date of Birth: 03/16/1940	Eligible: ☐	Withdrawn Reason:
*Site #: 501	PI Last Name: Ellert	Informed Consent Dates:	Status: Enrolled
Account: Essex County Medical Association	PI First Name: James	Randomization ID:	Enrollment ID: 32012

More Info | Visits | Activities | Attachments

New | 1 - 5 of 5

Type	Name	Due	Version	Planned	Assigned To	Lock Assignment	Completed	Completed Date
Screening	Screening Visit	11/20/2001 9:00:00	Version 1	11/20/2001	LSMITH	✓		
Re-screening	Re-Screening Visit	11/22/2001 9:00:00	Version 1	11/22/2001	LSMITH	✓		
Enrollment	On Study Visit 1	12/03/2001 9:00:00	Version 1	12/03/2001	LSMITH	✓		
Enrollment	On Study Visit 2	12/10/2001 9:00:00	Version 1	12/10/2001	LSMITH	✓		
Enrollment	On Study Visit 3	12/17/2001 9:00:00	Version 1	12/17/2001	LSMITH	✓		

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 “Creating and Revising Protocol Versions” on page 256.

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 Clinical Administration 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.
Protocol 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 "Creating and Revising Protocol Versions" on page 256

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 259 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.

Field	Comments
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.
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.

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 19, “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 16, "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 *Applications Administration Guide*.

Field	Comments
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.
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 Position Rollup.

The team member is automatically added to the region that the site belongs to if the region required flag is checked and 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 "Creating and Revising Protocol Versions" on page 256.

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

For information, see "To associate contacts with a site" on page 281.

6 (Optional) Drill down on the Site # field and add extra information using the More Info tab view.

Some fields are described in the following table.

Field	Comments
Address	Select one of the principal investigator's addresses as the site address.
Contract Amount	Lists the sum of all contract amounts for the site. This field is read-only. For more information, see "Associating Contracts with a Site" on page 279.
# 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.

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 270).
Informed Consent	An informed consent date must be entered before a subject can be enrolled in the protocol. See Step 4 on page 267.
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.
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 269.

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 267 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 264.

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 Step 4 on page 267.
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 already been completed prior to when the template was amended.
9. Do one of the following:
   - Click No. If you click No, 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.
   - Click Yes. If you click Yes, the non-applicable visits are deleted.

NOTE: Screening and rescreening schedules are revised in the same way, except that informed consent dates are not necessary for these types of visit.

About Subject Enrollment Information Roll-Up

One of the key capabilities of Siebel Clinical in 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 subject-level information available may be check-marked as having No Site 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.

18 Managing Sites and Clinical Contacts

Topics in this section are:

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 Life Sciences’ 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 section 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 section 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 278. 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 278. 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 278. An administrator maintains records of contact license numbers and deletes erroneous or obsolete account and contact data.
- "Associating Contracts with a Site" on page 279. 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 279. CRAs create site visits to evaluation, initiate, monitor, and close-out sites.
- "Creating and Updating Site, Contact, and Account Records (End User)" on page 281. CRAs record details about contacts, accounts, and sites.
- "Assigning Employees to the Site Team (End User)" on page 281. Managers or CRAs add employees to the team associated with the site.
- "Creating Site Activity Plans (End User)" on page 282. 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 283. 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 284. 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 286. 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 258), trip report templates ("Creating a Trip Report Template" on page 297), contact and account assessment templates ("Creating Contact and Account Assessment Templates" on page 278).

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, duplicate the record and then edit the Protocol Title field.

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 *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 *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 42.

  NOTE: If the specialty type you need is not available, enter it by following the procedure, "To define a specialty" on page 43.

- Deleting contact and account records that were created in error or are obsolete. See "To delete a contact" on page 44 and "To delete an account" on page 59.

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.
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 Clinical Site Visits screen. From this view, it is possible for CRAs to view all their site visits and all follow-up activities that arise from the visits. It is also possible to view all site visits 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 get a pulse for what the most pressing issues are.

To create a site visit

1. Navigate to the Site Visits screen > Clinical Site Visits List view.
2. In the My Site Visits list, create a new record and complete the necessary fields.

   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 20, "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 262
- "To create a contact record" on page 262
- "To create a site" on page 263
- "To indicate an affiliation between contacts" on page 49
- "To indicate an affiliation between an account and a contact" on page 65
- "To indicate an affiliation between accounts" on page 66

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.

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 38.

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

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. Before closing the Access List dialog box, click Position Rollup.

   The employees are added to the team at the region and protocol levels.

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 278.

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.

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.
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.

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 create an assessment template" on page 278.

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 278.)

   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.

19 Setting Up and Making Subject Activity Payments

Topics in this section are:

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 21, "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 *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 section 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 289.
2. "Adjusting Payment Amounts and Generating Payments for Sites" on page 292. 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 290. Adjust payment amounts for individual sites.
2. "Marking Subject Activities Completed (End User)" on page 291.
3. (Optional) "Generating Ad Hoc Payments for Sites (End User)" on page 291.
4. "Generating Final Payments for Sites (End User)" on page 293.

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 258) 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 Clinical Administration 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 289), 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 291.

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 Date is set to the due date.
   - 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 292 to Step 8 on page 293 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 290), 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 Step 7 on page 293.

20 Administering and Using Clinical Trip Reports

Topics in this section are:

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 265.

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 section 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 297. Create a template for each type of site visit.
2. "Approving Trip Reports" on page 301. 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 297. 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 299. 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 296.)

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 258), clinical site templates ("Creating a Clinical Protocol Site Template" on page 278), and contact assessment templates ("Creating Contact and Account Assessment Templates" on page 278).

To create a trip report template

- Create an activity template of type Clinical Trip Report.

  For information about how to create activity templates, see *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 265.
3. Complete or edit other fields in the Trip Report form. See also Step 2 on page 300.

   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 *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 Step 1 on page 298.

2 Complete or edit fields in the Trip Report form. See also Step 3 on page 298.

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 298). 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 298).
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 299 to Step 3 on page 299 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 *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.

21 Managing Clinical Projects

Topics in this section are:

About Managing Clinical Projects

This chapter is meant to be used as a supplement to the documentation for Siebel Professional Services Automation, which is in *Siebel Professional Services Automation Guide* (Projects Management and Microsoft Project Integration chapters) and *Applications Administration Guide* (Professional Services chapter).

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. The Microsoft Project integration feature allows data exchange between Siebel Clinical Projects and Microsoft Project.

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 or import them from a Microsoft Project file. 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.

Exchanging Data with Microsoft Project

To create a Gantt chart of the project milestones, the PM exports the project data to a Microsoft Project file.

Process of Managing Clinical Projects

This section 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 305. These templates are used by many project managers carrying out similar clinical trials.
- "About Setting Up Employee Profiles" on page 306. 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 306. The position types and rate lists are required to allow subcontractors (and employees) to bill the project for their time.
- "Mapping Siebel Project Fields to Microsoft Project Fields" on page 307.

End-User Procedures

These tasks can be performed only after the administrator has completed the required preparatory work described in the preceding sections. These tasks may be carried out according to your company's business needs:

- "Creating a Project (End User)" on page 308.
- "Associating People and Accounts with Projects (End User)" on page 308. 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 310.
- "Monitoring Project Costs (End User)" on page 311.
- "Managing Risk (End User)" on page 311. Document project risks and resolution activities.
- "Exchanging Project Data with Microsoft Project (End User)" on page 312. For example, export project data to an MS Project file.

Creating a Project Activity Template

Activities can be created both within (Siebel) Projects screen and within Microsoft Project. If the study managers are primarily entering activities through the Projects screen, then creating project activity templates will be advantageous. If study managers are primarily importing activities from Microsoft Project file, then project activity templates need not be created.

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 258), clinical site templates ("Creating a Clinical Protocol Site Template" on page 278), trip report templates ("Creating a Trip Report Template" on page 297), and contact assessment templates ("Creating Contact and Account Assessment Templates" on page 278).

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 *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 *Applications Administration Guide*.

To create position types as products

1 Navigate to the Product Administration 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 Pricing Administration 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.

Mapping Siebel Project Fields to Microsoft Project Fields

If you want to exchange data between your project in the Siebel Clinical and an MPP file in Microsoft Project, you may need to set up mapping templates to define which Microsoft Project fields correspond to which Siebel Clinical project fields.

Some mapping templates have already been defined for you in the Project Mappings view of the Data Administration. However, you may want to create a new mapping template or copy and modify an existing one.

For more information, see about Microsoft Project Field Mappings for Professional Services in *Applications Administration Guide*.

To create a mapping template

1. Navigate to the Data Administration screen > Project Mappings view.
2. In the Project Mappings list, create a new record and complete the necessary fields.
3. In the Mapping Categories list, create a new record and from the Category drop-down list, select a mapping category.
4. In the Category Fields list, create a new record.
5. From the Microsoft Project Field Name drop-down list, select a field name.
6. In the Siebel Field Name field, enter the business component field name that will map to the Microsoft Project field.

NOTE: Continue to add information in the Mapping Categories list and Category Fields list until the mapping template is complete.

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 306.)

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 Professional Services Automation 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 Professional Services Automation 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 Professional Services Automation 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 310.)
- 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 311.)
- Import activities from a Microsoft Project file (See "Exchanging Project Data with Microsoft Project (End User)" on page 312.)

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.

Activities imported from Microsoft Project can be either standalone activities or task activities, depending upon how the mapping template has been set up.

For more information, see about creating activities and tasks for projects management in *Siebel Professional Services Automation 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 Professional Services Automation 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.

Exchanging Project Data with Microsoft Project (End User)

Resource, task, and summary task information from Microsoft Project data can be exchanged with Siebel Clinical Project. Some standard mapping templates are provided with Siebel Clinical and the administrator can create additional mapping templates (see "Mapping Siebel Project Fields to Microsoft Project Fields" on page 307).

Table 28 shows how features in Siebel Clinical Project map to features in Microsoft Project.

Table 28. Mapping Between Siebel Clinical Project and Microsoft Project

Siebel Clinical Project	Microsoft Project
Roles in the Team Workbook view	Resources
Activities in the Activities view, or Tasks in the Tasks view	Summary Tasks
Activities in the Activities view, or Tasks in the Tasks view	Tasks

CAUTION: Microsoft Project dependencies are not exchanged. To maintain dependencies in your Microsoft Project file, do not export your project from Siebel Clinical to Microsoft Project.

Export filters can be applied to restrict data exported from Siebel Clinical to Microsoft Project.

To exchange data between an MPP file and a Siebel Clinical project

■ See *Siebel Professional Services Automation Guide*.

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. Depending on the mapping template used, activities may be tasks and summary tasks imported from Microsoft Project.
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 *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 *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 Professional Services Automation Guide*.
Invoices	Use this view to create invoices for time and expenses logged against a project. For more information, see *Siebel Professional Services Automation Guide*.
Notes	Use this view to keep private and public notes about the project. For general information about the Notes view, see *Fundamentals*.

Table 29. Views in the Projects Screen

View	Comments
Orders	Use this view to create a product or material order and associate it with the project. For more information, see *Siebel Professional Services Automation 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.
Plan Integration	Use this view to exchange data between the Siebel Clinical project and Microsoft Project. For more information, see about Microsoft Project integration in *Siebel Professional Services Automation Guide*.
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 Professional Services Automation Guide*.
Subcontractors	Use this view to keep a list of subcontractors associated with the project. (See also "Partners" on page 314 in this table.)
Tasks	Use this view to create and modify tasks for the project. Depending on the mapping template used, tasks may be tasks and summary tasks imported from Microsoft 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 Professional Services Automation Guide*.

22 Siebel Advanced Contracts

This chapter describes Siebel Advanced Contracts. It includes the following topics:

About Advanced Contracts

Siebel Advanced Contracts may be used by Contract administrators, account managers, and customer service representatives. Agreement data is stored in Agreement records which may be created, revised, examined, and printed.

Important features in Siebel Advanced Contracts are:

- Benefits
- Conditions
- Compliance History
- Terms
- Benefit, Condition, and Term Templates

Contracts Terms Defined

This section defines agreements and related terms as used in the Siebel interface.

- **Agreements (used interchangeably with the term Contracts).** A document that defines the business relationship between two parties, including obligations to offer, provide, or produce specific products or services over a set period of time for a specific amount of money.
- **Entitlements.** Define coverage available to the customer under the terms and conditions of the agreement.
- **Benefits.** Define the services or products available to the customer under the terms and conditions of the agreement.
- **Conditions.** Are criteria determining whether the parties are entitled to the benefits defined by the contract.
- **Terms.** Are language terms not already included in the agreement.
- **Compliance.** Is the history of adherence to the terms and conditions of the agreement.

Common Agreement Types

The two most common types of agreements are:

- Service agreement

  A service agreement is a contract for service. For example, a customer purchases an MRI machine from a medical equipment manufacturer. The equipment manufacturer may negotiate a service agreement with the customer providing a special discounted rate for service on the MRI machine over a predetermined period of time.

- Sales Agreement

  A sales agreement is a contract that provides for special pricing and other benefits when products are purchased. For example, a medical supply company negotiates a sales agreement with a hospital for a rebate based on volume catheter purchases; if the hospital purchases more than 40 catheters in a quarter, it will receive a $3000 rebate.

Scenario for Advanced Contracts

The following scenario is designed to illustrate the functionality of Siebel Advanced Contracts. It shows a sample business process performed by the Contract administrator and the customer service representative or account manager.

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

Roles and Responsibilities

This section describes the responsibilities of the people involved in contract management.

Contract Administrator

The Contract administrator sets up the agreement templates (Entitlements, Benefits, Conditions, and Terms), administers the contract during its term, and manages its renewal.

Customer Service Representative or Account Manager

The customer service representative or account manager sells, documents, or sells and documents the contract. The customer service representative or account manager will create the draft agreement to represent the negotiated terms and conditions using entitlement, benefit, condition, and term templates created by the administrator. When appropriate, after the contract has been negotiated, updated in Siebel Medical, and approved by all parties, the contract manager makes it active.

Scenario

A medical device company has signed a sales agreement with a Group Purchasing Organization (GPO) that entitles the GPO to a 10% rebate on stent purchases made by its members each quarter when those purchases exceed 3000 units.

Independent from this contract, the administrator will create new term templates; for example, a term template stating that arbitration will be used to resolve disputes. The administrator will also create new benefit and condition templates. One benefit template, which could be used when creating the contract for this customer, would define a 10% rebate. The benefit template may be defined with associated conditions. In the case of this benefit template for the 10% rebate, the administrator may add a condition that the benefit is only delivered when more than 3000 stent units are purchased within a given quarter.

The account manager creates a new Agreement in Siebel Medical and adds the appropriate data. The account manager adds terms, benefits, and conditions to the agreement using templates or manually as described by the procedures in this chapter.

Once the agreement becomes active, the conditions governing the benefit will be evaluated, the compliance recorded (using the procedures described in this chapter or Siebel workflow), and, if appropriate, the benefit will be delivered.

The following topics describe the individual procedures for completing these tasks.

Process of Managing Advanced Contracts

This sample process represents the tasks that are carried out in the "Scenario for Advanced Contracts" on page 316.

Administrator Procedures

Refer to the Agreements chapter in *Siebel Field Service Guide* for procedures specific to administrator tasks. In addition, the following procedures are specific to Advanced Contracts.

- Creating Term Templates on page 318
- Creating Benefit and Condition Templates on page 318

The Contracts administrator is also responsible for setting up workflows. See "About Workflows for Advanced Contracts" on page 326.

End-User Procedures

Refer to the Agreements chapter in *Siebel Field Service Guide* for procedures specific to End-User tasks. In addition, the following procedures are specific to Advanced Contracts.

- Adding Terms to Agreements on page 323
- Adding Benefits to Agreements on page 323
- Adding Conditions to Benefits on page 324
- Verifying Compliance on page 325

Creating Term Templates

This section assumes you have administrator privileges.

In this example, the administrator is setting up the term templates for the entire company.

To create a term template

1. Navigate to the Contracts Administration screen.
2. Select Term Templates in the Contracts Administration screen.
3. Create a new record and complete the necessary fields.

   Some fields are described in the following table.

Field	Comments
Term #	The number of the term.
Term Name	A representative description for the term; for example, Term Length.
Type	The legal type of the term: standard, non-standard, or special.
Description	The actual term as it is used in the agreement.

Creating Benefit and Condition Templates

In this section, the Contract administrator will create templates for new benefits and conditions.

To create a new benefit template

1. Navigate to the Contracts Administration screen.
2. Select Entitlement Templates in the Contracts Administration screen.
3. Select an existing entitlement template or create a new entitlement template.

4 Select the Benefits tab to view Benefit templates associated with the selected entitlement template.

5 Create a new record and complete the necessary fields.

Some fields are described in the following table.

Field	Comments
Priority	The priority of the benefit in relation to other benefits.
Name	The name of the benefit; for example, Rebate on Stents.
Type	The type of benefit; for example, Credit or Rebate.
Schedule	The benefit schedule; for example, Quarterly.
Amount	The total amount of the benefit in the unit defined in the U/M field.
U/M	The unit in which the benefit is measured; for example, Percent.
Status	The current status of the benefit; for example, Active or On Hold.
Action Basis	The basis for evaluating or delivering the benefit; for example, if the Benefit is triggered by an invoice for a particular quantity of stents, Action Basis=Invoice.
Action Method	The action produced by the Action Basis; for example, if an allowance is administered by adjusting the invoice, Action Method = Adjustment.
Current Amount	The existing amount of the benefit including any adjustments already made, or the current liability for the benefit.
Description	A brief description of the benefit.
Benefit Basis	Used when the Benefit Amount is variable and is calculated based on another value; for example, 10% of Invoice Amount, Benefit Basis = Invoice Amount.
Benefit Price	Used when the Benefit Amount is variable and is calculated based on another value; for example, for a 5% discount, the Benefit Price specifies the starting price for Siebel Pricer.
Benefit Constraint	Indicates the maximum or minimum amount of the Benefit when it is calculated using Benefit Basis and/or Benefit Price.
Tier	Enables benefits to be defined differently for different tiers; for example 10% discount for Tier 1, 15% discount for Tier 2, where the volume of purchases determines the appropriate tier.
Division	Defines the Division to which the Benefit applies; for example, 10% rebate for all products purchased by the Cardiology Department of University Hospital.
Product Category	Indicates the product category associated with the benefit.
Product	Indicates the product associated with the benefit; for example, 1 free Xygo Lead for every 40 Lead purchases, Product = Xygo Lead.
Product Line	Indicates the product line associated with the benefit.

Field	Comments
Product Class	Indicates the product class associated with the benefit.
All Products	Indicates that All Products are associated with the benefit.
Level	Indicates the level at which the benefit applies; for example, Account, Agreement, Entitlement.
Comments	Used to capture additional comments related to the benefit.
Reset	Can be used to indicate that the benefit should be reset; for example, the benefit should be reset if exhausted, when the agreement is renewed or annually.
Conditions Relationship	Indicates all conditions must be met (“and”) or only one condition must be met (“or”) in order to deliver the benefit.
Adjustment Amount	Used when Action Method = Adjustment to indicate the amount of the adjustment.
Adjustment Currency	Indicates the currency associated with the Adjustment Amount.
Adjustment Exchange Date	Specifies the Exchange Date for the Adjustment Currency.
Amount Currency	Specifies the currency when U/M = Currency.
Amount Exchange Date	Specifies the exchange date for the Currency indicated by Amount Currency.
Count Method	Indicates whether the Current Amount should be incremented (to track the amount of benefit delivered) or decremented (to track remaining liability) when the benefit is delivered.

Creating a new condition template

1. Navigate to the Contracts Administration screen.
2. Select Entitlement Templates in the Contracts Administration screen.
3. Select an existing entitlement template or create a new one.
4. Select the Benefits tab to view Benefit templates.

   When you select the Benefits tab, the Conditions applet is also displayed.

5 Select a Benefit Template record, and in the Conditions list, create a new record and complete the necessary fields.

NOTE: There must be a benefit template selected in order to create a new condition. You may use AND, OR, and other expressions to define the condition.

Some fields are described in the following table.

Field	Comments
Order	The sequence of conditions.
Type	The condition type; for example Volume.
Subtype	The condition subtype; for example Product Line.
Operator	The logical operator used to define the condition; for example, when more than 3000 parts have been ordered (operator is >), or if membership = Gold (operator is =).
Target Amount	The target amount to be reached to satisfy the condition.
Target U/M	The unit in which the target amount is measured; for example Units.
Enforceable	Indicates that the condition should be enforced when determining benefit delivery. You might set this value to N (by clearing the check box) to learn more about the customer so that you could negotiate better contracts in the future without affecting benefit delivery.
Description	A brief description of the condition.
Status	The status of the condition; for example, Active or Exhausted.
Timing	The timing of the condition; for example, if Quarterly is chosen, the condition should be satisfied in one quarter.
Comments	Additional comments the sales representative, customer service representative, or Contract administrator may want to add to the condition.
Current Amount	The existing amount used to evaluate the condition; for example for this condition: revenue > $40,000, current amount is used to track the current revenue.
Range	Specifies a range around the target amount; for example +/- 10%.
Range U/M	Indicates the unit of measure for the Range amount.
Expression	Used to define complex conditions such as those with logical complexities or complex field combinations.
Adjustment Value	Used to adjust the benefit based on the condition; for example adjust benefit to 0% discount.
Adjustment U/M	Defines the unit of measure for the Adjustment Value.

Field	Comments
Mix %	Can be used to track expected purchases; for example, 20% Product A, 15% Product B, and so on.
Type of Calculation	Used to adjust benefit amount.
Tier	Used to associate a condition with a specific tier, enabling you to define different conditions to different tiers of customers.
Product	Used with Subtype = Product to specify the product associated with the condition.
Product Line	Used with Subtype = Product Line to specify the product line associated with the condition.
Product Class	Used with Subtype = Product Class to specify the product class associated with the condition.
Product Category	Used with Subtype = Product Category to specify the product category associated with the condition.
Target Currency	Defines the currency for the target amount when the target U/M is currency.
Target Exchange Date	Specifies the exchange date for the target currency when target U/M is currency.
Range Currency	Defines the currency for the range amount when Range U/M is currency.
Range Exchange Date	Specifies the exchange date for the range currency when Range U/M is currency.
Adjustment Currency	Defines the currency for the adjustment amount when the Adjustment U/M is currency.
Adjustment Exchange Date	Specifies the exchange date for the adjustment currency when Adjustment U/M is currency.
Condition Object Name	Specifies a business object containing the field used in evaluating the condition.
Condition Object Field	Specifies the field within the business object identified by the Condition Object Name to be used in evaluating the condition.
Count Method	Indicates whether the condition current amount should be incremented or decremented.

Adding Terms to Agreements

This section assumes that the agreement has already been entered into Siebel Medical. The example is based on information provided in the section "Scenario for Advanced Contracts" on page 316.

The following procedure describes how to create terms for an agreement.

To create terms for an agreement

1. Navigate to the Agreements screen in Siebel Medical, and select your agreement.
2. Click the Terms view tab.

   If it does not appear, click the down arrow next to the third-level view tabs to select it.
3. In the Terms view, you can either create a new term or add an existing term from a template:
   a. Click the Add button to add an existing term to the agreement.
      - Select a term to add to the agreement.
      - Use Ctrl+Click to select multiple terms in the list.
      - Use Ctrl+A to select all terms in the list.
   b. Click OK to add the selected Term(s) to the agreement.

   Alternatively:

   - Click the New button to create a new term, which does not exist in the current library of term templates, to the agreement and complete the appropriate fields.

Field	Comments
Section	The section number for the term.
Term Name	A representative description for the term; for example, Term Length.
Type	The legal type of the term: Standard, Non-Standard, or Special.
Description	The actual term as it is used in the agreement.

NOTE: Once terms are inserted into the agreement from Term Templates, they may be manually edited.

Adding Benefits to Agreements

Once the agreement has been created, the account manager creates specific benefits for the agreement. In this example as described in "Scenario for Advanced Contracts" on page 316, the benefit is a rebate.

To create a benefit for an agreement

1. Navigate to the Agreements screen in Siebel Medical, and select the agreement.

2 Click the Entitlements view tab.

3 Select an Entitlement or create a new Entitlement.

NOTE: Benefits and conditions are instantiated with entitlements.

4 Click the Benefits view tab.

5 In the Benefits view, you can either add a benefit from existing benefit templates or create a new benefit.

- Click the Add Benefits button to add a benefit from an existing benefit template.

  NOTE: You can use the Apply Template button to constrain the list of benefits based on the selected parent entitlement template.

- Click the New button to create a new benefit and complete the appropriate fields.

The fields available in the Benefits applet are described in "Creating Benefit and Condition Templates" on page 318.

NOTE: Adding an existing Benefit from a template with Conditions defined will instantiate both the Benefit and related Conditions.

Adding Conditions to Benefits

Once the benefit has been created, the sales representative may need to add conditions to the benefits. You can design many different types of benefits and conditions, such as a rebate when the customer purchases 3000 stents per quarter. Until that condition is met, the customer will not receive the benefit.

To add a condition to a benefit

1 Navigate to the Agreements screen in Siebel Medical, and select your agreement.

2 Click the Entitlements view tab.

3 Select your Entitlement or add a new Entitlement.

4 Click the Benefits view tab.

5 Select your Benefit or add a new Benefit.

The Conditions list is displayed below the Benefits list.

NOTE: Adding an existing Benefit from a template with Conditions defined will instantiate both the Benefit and related Conditions. See "Adding Benefits to Agreements" on page 323.

6 Click the New button to create a new condition, and complete the appropriate fields.

NOTE: You may use AND, OR, and other expressions to define the condition.

The fields available in the Condition applet are described in "Creating Benefit and Condition Templates" on page 318.

Verifying Compliance

Once conditions have been added to the benefits, you can use Siebel Workflow to automatically evaluate compliance, or you can verify compliance manually. Use the Compliance applet to track compliance to the conditions over time.

In this example, the contract manager verifies that the number of stents the customer has purchased this quarter (for example, 3002) exceeds the 3000 stents outlined in the condition in order to qualify for the 10% rebate.

To manually verify compliance

1. Navigate to the Agreements screen in Siebel Medical, and select your agreement.
2. Click the Entitlements view tab.
3. Click the Benefits view tab.
4. Select the Agreement, Entitlement, Benefit, and Condition being evaluated.

   The Compliance applet is displayed next to the Conditions applet.
5. Click the New button in the Compliance applet to create a new compliance record and complete the fields.

   Some fields are described in the following table.

Field	Comments
Verified	The date that compliance was verified. This field is automatically populated with the current date when you insert a new record.
Verified By	The username of the person verifying compliance. This field is automatically populated with the username of the person creating the record. You can use the pick applet to locate a different name.
Actual	The actual value used to evaluate the condition; for example, the number of stents ordered this quarter (3002), the value compared to the Target amount.
Achieved	A Yes or No field indicating if the condition has been achieved.
Comments	Additional comments you may want to add.

There are additional fields in the Compliance applet. They are described in Table 30.

Table 30. Additional Fields in the Compliance Applet

Field	Comments
Start Date	Used to track the start of the period over which the condition has been evaluated.
End Date	Used to track the end date of the period over which the condition has been evaluated.

About Workflows for Advanced Contracts

You can create workflows to suit your business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Designer Administration Guide*.

Siebel workflows are especially helpful in automating the following agreement-related business processes:

- Routing an agreement for approval.
- Evaluating agreement conditions in real time, for example, when an order is invoiced, and at scheduled intervals, for example, at the end of quarter.
- Delivering contract benefits if appropriate, for example, create invoice for a rebate or place an order for a give-away.
- Tracking condition compliance.
- Automating agreement renewal.

About Business Services for Advanced Contracts

To support automation of business processes related to the agreements, there are three new business services:

- Contracts Accumulator Service on page 326
- Contracts Resolver Service on page 327
- Condition Evaluator Service on page 330

Contracts Accumulator Service

This business service can be used in workflows to manage incrementing or decrementing an allowance pool.

Manage Running Total Method

Table 31. Input Arguments for Manage Running Total Method

Input Argument	Name	Description
Input 1	Count Method	Indicates whether the counter is incrementing or decrementing. Possible values are Increment or Decrement.
Input 2	Current Amount	Indicates the current value of the counter before the benefit amount is applied for this transaction.
Input 3	Valid Transaction Amount	Represents the amount of benefit to be applied and reflected in the running total. This may be calculated by the Contracts Resolver Service; see "Contracts Resolver Service" on page 327.

Table 32. Output Arguments for Manage Running Total Method

Output Argument	Name	Description
Output 1	Adjusted Current Amount	The updated running total, adjusted by Accumulator to reflect the amount of benefit applied (Valid Transaction Amount)

Figure 13 illustrates the Accumulator business service flow.

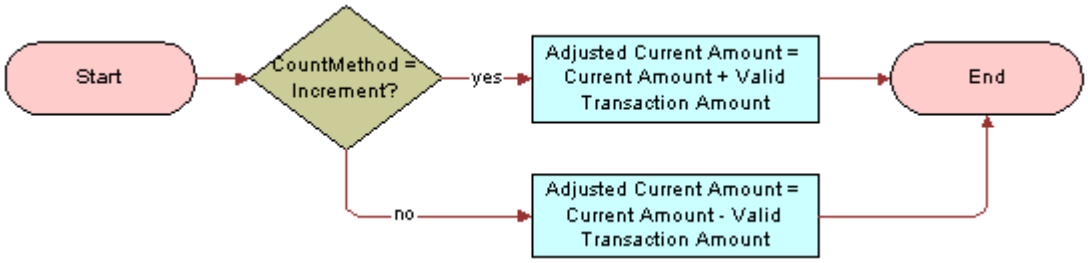


Figure 13. Accumlator Business Service Flow

Contracts Resolver Service

This business service can be used in workflows to resolve issues associated with managing an allowance or pool when the amount to be decremented is larger than the remaining allowance or pool.

Resolve Transaction Amount Method

Table 33. Input Arguments for Resolve Transaction Amount Method

Input Argument	Name	Description
Input 1	Current Amount	Indicates the current value of the counter before the benefit amount is applied for this transaction.
Input 2	Requested Transaction Amount	The amount of the transaction to be considered for the benefit. This value can be calculated by a user-defined Business Service or Workflow. **Example:** For a Benefit of 2% credit on all invoices, the actual dollar amount calculated by taking 2% of the total invoices is the Requested Transaction Amount.
Input 3	Amount	This argument represents the amount of the benefit or the threshold for the condition. For example, if you wanted to use the business service to manage a benefit, you set this input equal to the Benefit Amount field. If you want to use this business service to manage a condition, you set this input equal to the Condition Target Amount field.
Input 4	Count Method	Indicates whether the counter is incrementing or decrementing. Possible values are Increment or Decrement.

Table 34. Output Arguments for Resolve Transaction Amount Method

Output Argument	Name	Description
Output 1	Valid Transaction Amount	Resolver determines what portion of the requested benefit (Requested Transaction Amount) can be applied (Valid Transaction Amount).

Table 34. Output Arguments for Resolve Transaction Amount Method

Output Argument	Name	Description
Output 2	Remaining Transaction Amount	Resolver determines what portion of the requested benefit (Requested Transaction Amount) cannot be applied (Remaining Transaction Amount).
Output 3	Exhausted Flag	Indicates whether the amount of the benefit or the terms of the condition have been exhausted. You can use this setting to update the Status in either the Benefit or the Condition.

Figure 14 illustrates the Resolver business service flow.

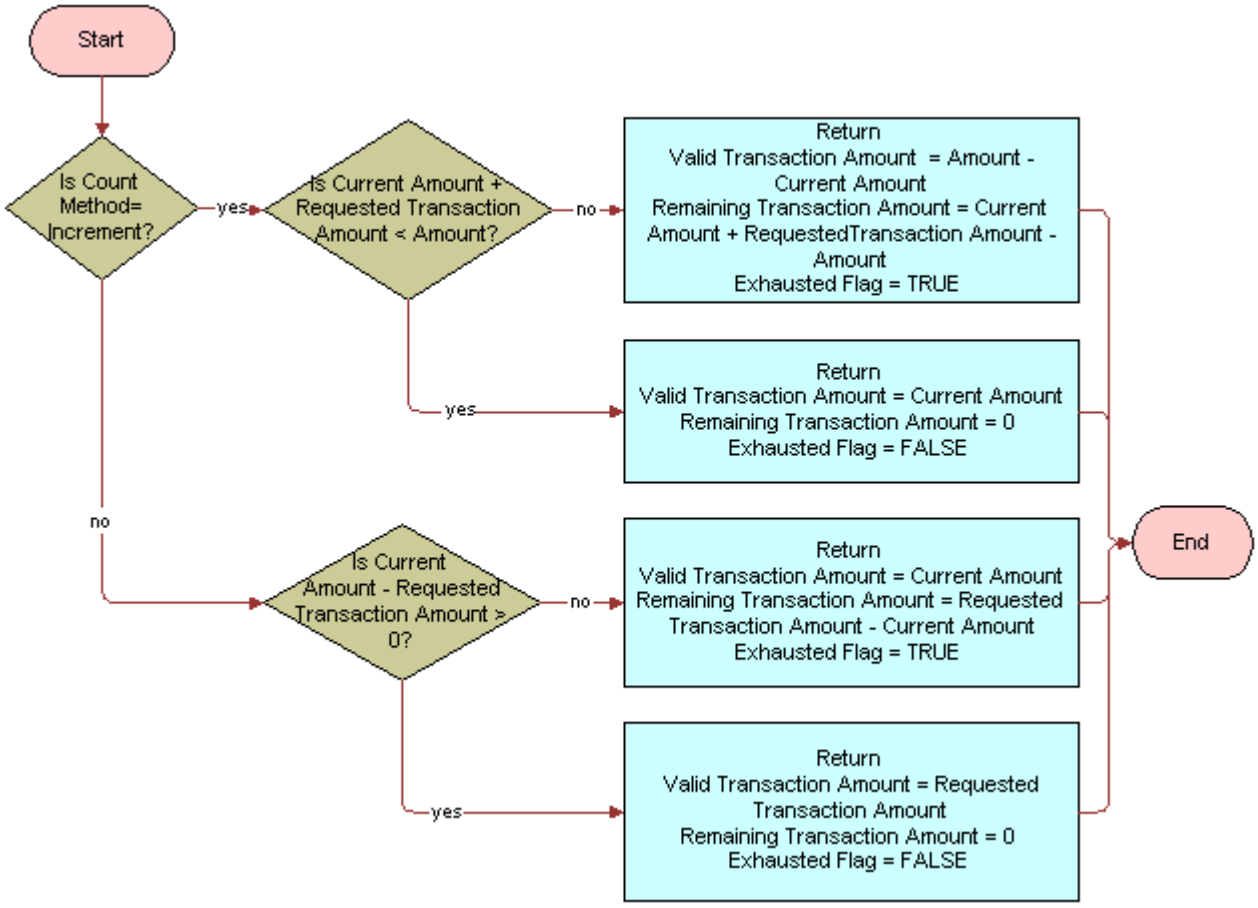


Figure 14. Resolver Business Service Flow

Condition Evaluator Service

This business service can be used in workflows to compare two values in order to determine if a condition has been met.

Evaluate Condition Method

Table 35. Input Arguments for Evaluate Condition Method

Input Argument	Name	Description
Input 1	Current Amount	Indicates the value used to evaluate if the condition has been met.
Input 2	Operator	The operator used for the calculation. Possible values are: = > < <= >= BETWEEN (< and >) BETWEEN (<= and >=)
Input 3	Target Amount	This is the value to which the Current Amount is compared. May specify minimum and maximum bounds separated by a colon (Min:Max) for BETWEEN operator. This may be used to compare to the Benefit Amount, the Condition Amount, or the Target Amount.

Table 36. Output Arguments for Evaluate Condition Method

Output Argument	Name	Description
Output 1	Compliance Flag	Indicates whether Condition has been met.

This business service compares the Current Amount to the Target Amount using the specified operator and sets the compliance flag.

About Configuring the Revise Button

When a user clicks the Revise button for an agreement:

- The agreement is revised, deep copied, and its version is incremented.

- Fields in the original agreement become read-only, according to the Read Only Upon Revise user property. See Table 37.

The read-only field behavior of the Revise button in the Agreements screen can be configured by editing the Read Only Upon Revise user property.

Table 37. How Read Only Upon Revise Determines Read-Only Behavior after Revision

Read Only Upon Revise =	Field Behavior of Original Agreement Record after Revise is Clicked
All	All fields are read-only
Partial	All fields except End Date, Valid, and Status are read-only
None	No fields are read-only

For information about editing user properties, see *Configuring Siebel eBusiness Applications*.

NOTE: Do not edit the Read Only Upon Revise Field user property.

About Configuring the Add Benefits Button

You can configure the Add Benefits button so that the available benefit templates are constrained by the parent entitlement record. This button is located in Agreements > Entitlements > Benefits. If you configure the Add Benefits button, only templates associated with the parent entitlement record will be displayed in the Benefit Template Popup Applet.

If you do not configure this button, the Benefit Template Popup Applet will display all available benefit templates instead of constraining the list to those associated with the parent entitlement template.

Set the following options to activate this user property:

- Name: Apply Template
- Value: Y

About Configuring the Entitle Button

The Entitle button is located in the Line Items view for Agreements. When you add a line item, you click the Entitle button to automatically associate entitlements with the line item based on the entitlement template associated with the product. See *Siebel Field Service Guide* for more information on the Entitle button.

You can edit the user property for the Entitle button so that it associates entitlements as well as the benefits and conditions associated with the Entitlement.

There are three possible values for the Method Invoked when the user clicks the Entitle button:

Value	Description
GetEntitlements	This associates the Entitlement with the line item.
GetBenefits	This associates the Benefits and Conditions with the line item.
AutoEntitle	This associates both the Entitlement and its child Benefits and Conditions with the Line Item.

23 Capturing Adverse Events and Complaints

Topics in this section are:

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 38 illustrates such a life cycle. Each step in the process represents a chapter in this book.

Table 38. 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	■ Ensure 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 38. 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 28, “Communicating with Customers for AECM”
- Chapter 29, “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 get escalated for investigation.

Siebel AECM Terms

Table 39 lists some important terms and abbreviations used in Siebel AECM.

Table 39. 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 39. 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 Actuate report created using data contained in the regulatory report record. Other regulatory reports like CIOMS can be configured using Actuate Report designer or other reporting tools.
Siebel AECM	The Siebel Adverse Events and Complaints Management module.
Signature capture	See User authentication.

Table 39. 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 *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 gets 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 338.

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 340
- Setting Up Codes on page 341
- Setting Up Lot Numbers for Medical Products on page 345

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 345
2. Escalating Adverse Events and Complaints as Product Issues (End User) on page 347
3. Adding Complaint-Specific Information to Product Issues (End User) on page 348

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 341.
- **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 may have already set these up for other reasons in Siebel Life Sciences. These set up 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 339.

Setting up Products, Product Lines, Categories, Assets, Activity Templates, Solutions, and LOVs

For information, consult Table 40.

Table 40. 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 73 and *Product Administration Guide*
Product Lines	Product Administration > Product Lines	*Product Administration Guide*
Categories	Catalog Administration	"Adding Products to Catalogs" on page 87
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	*Applications Administration Guide*

Setting Up Codes

About 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 41 lists where code fields appear in the Siebel AECM module.

Table 41. Code Fields in the Siebel AECM Module

Screen	View	Field Name	Notes
Service Requests	More Info	Codes	
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 MDV	Patient Codes	Only codes of type Patient can be entered.
		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 41. 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 42 is an example of the field values used to describe one code.

Table 42. 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]
Product Line	Blood analyzer, Dialysis system [1]

Table 42. Example Fields for a Code Classifying a Pump Error on a Blood Analyzer

Field	Example Value
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 "Process of Capturing and Escalating Adverse Events and Complaints" on page 339.

To set up codes

1 Navigate to Service Administration 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 eSales Administration 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	Service Administration screen > Lot Administration view
Siebel Pharma	Samples Administration screen > Lot Setup view

This task is a step in "Process of Capturing and Escalating Adverse Events and Complaints" on page 339.

To set up lot numbers

1. Navigate to Service Administration 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 74 paying specific attention to Table 10 on page 75 and Table 11 on page 76.
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 "Process of Capturing and Escalating Adverse Events and Complaints" on page 339.

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 "Process of Capturing and Escalating Adverse Events and Complaints" on page 339.

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 349.

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 339.

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		A1
Gender		A3
Age		A2
Date of Birth		A2
Weight		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 15.

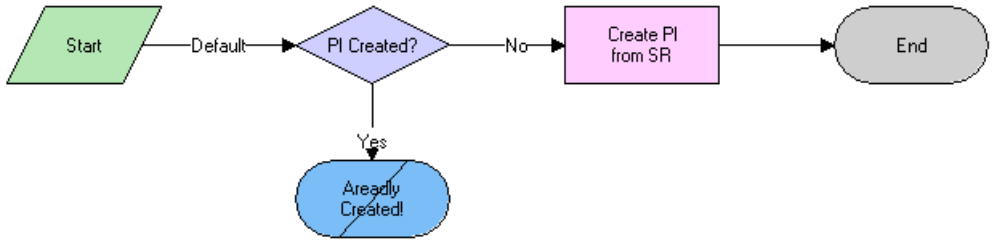


Figure 15. LS Medical Create PI from SR Workflow

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 Designer Administration 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 section 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:

- Chapter 23, “Capturing Adverse Events and Complaints”
- Chapter 25, “Recording Product Analysis for AECM”
- Chapter 26, “Managing CAPAs”
- Chapter 27, “Regulatory Reporting”
- Chapter 28, “Communicating with Customers for AECM”
- Chapter 29, “Closing Adverse Events and Complaints”

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 352.

Administrator Procedures

- Creating Product Issue Assessment Templates on page 353
- Creating Product Issue Activity Templates on page 353

End-User Procedures

- Reviewing and Editing the Product Issues (End User) on page 354
- Creating Multiple Product Issues Related to One Service Request (End User) on page 359
- Creating Product Issue Activity Plans (End User) on page 360
- Assessing if a Product Issue Is Reportable (End User) on page 361
- Completing Adverse Events and Complaints Reviews (End User) on page 361

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 353.

To create an assessment template

- Refer to *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 353.

To create a product issue activity template

1. Navigate to the Data Administration 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 *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 353.

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.	
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.	
Area	The general categorization area for the product issue. This field is constrained by Type.	
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.	
First Name	The first name of the investigator carrying out a particular clinical trial at a site.	
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.	
Mfg Report #	This field appears in the list applet. It also appears in the form in the Importer view.	

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.	
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.	
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.	
Reported FDA	Indicates if initial reporter sent a report to the FDA.	E4
SR #	The service request from which the product issue was created.	
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.	
Sub Area	This further refines the area categorization. (The Area field constrains this drop-down list.)	
Sub Status	The Status field constrains this drop-down list.	

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	
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
Common Device Name	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 362.
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 353.

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 353.

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 353.

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
Common Device Name	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 362. For more information about field lockdown, see Chapter 29, "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 Designer Administration 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 16.

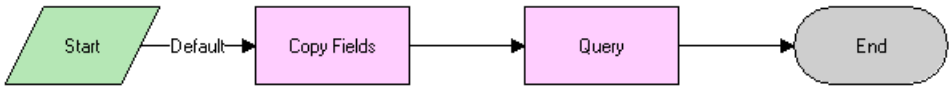


Figure 16. LS Medical Product Issue Create Related PI Workflow

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 17.

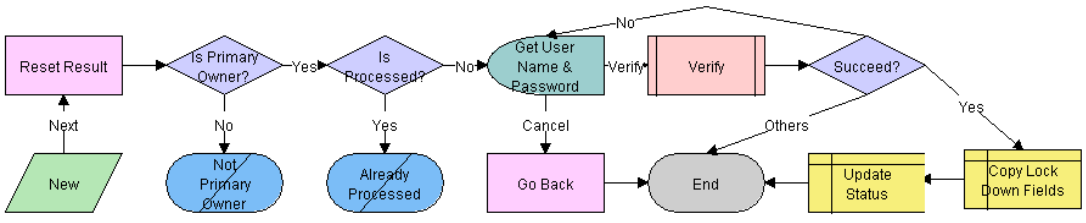


Figure 17. LS Medical Product Issue Review Complete Workflow

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 18.

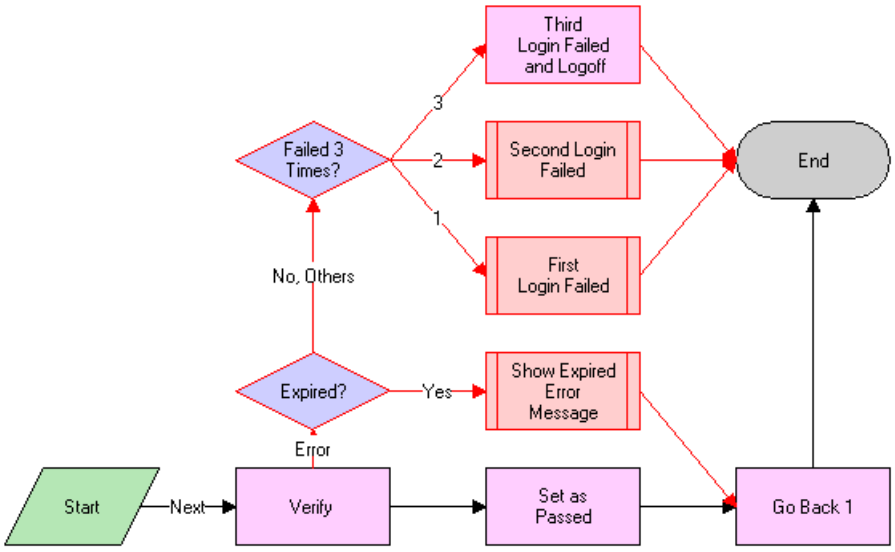


Figure 18. LS Medical User Verification Workflow

The workflow does the following steps:

1 Calls the Authentication business service to verify the user name and password.

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 43.

Table 43. 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 section 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:

- Chapter 23, “Capturing Adverse Events and Complaints”
- Chapter 24, “Investigating Adverse Events and Complaints”
- Chapter 26, “Managing CAPAs”
- Chapter 27, “Regulatory Reporting”
- Chapter 28, “Communicating with Customers for AECM”
- Chapter 29, “Closing Adverse Events and Complaints”

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 368.

Administrator Procedures

- Creating Product Analysis Activity Templates on page 369
- Setting Up Codes for Product Analysis on page 370

End-User Procedures

- Creating Product Analysis Records from a Product Issue (End User) on page 370
- Filling in Product Analysis Records (End User)
- Completing Product Analysis and Creating CAPAs (End User) on page 371
- Approving or Rejecting Product Analysis Records (End User) on page 373

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 369.

To create a product analysis activity template

1. Navigate to the Data Administration 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 *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 369.

To set up codes for Product Analysis

■ See "Setting Up Codes" on page 341.

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 369.

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 369.

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 369.

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 374.

This task is a step in "Process of Product Analysis Following a Product Issue" on page 369.

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 374.

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 374.

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 "Process of Product Analysis Following a Product Issue" on page 369.

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 gets deleted from Manager 2's Inbox when it is rejected by Manager 1).

For more information about the Inbox, see *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 Designer Administration Guide*.

LS Medical PA Submit Workflow

This workflow is initiated from the Submit button on the Repairs screen.

The workflow appears in Figure 19.

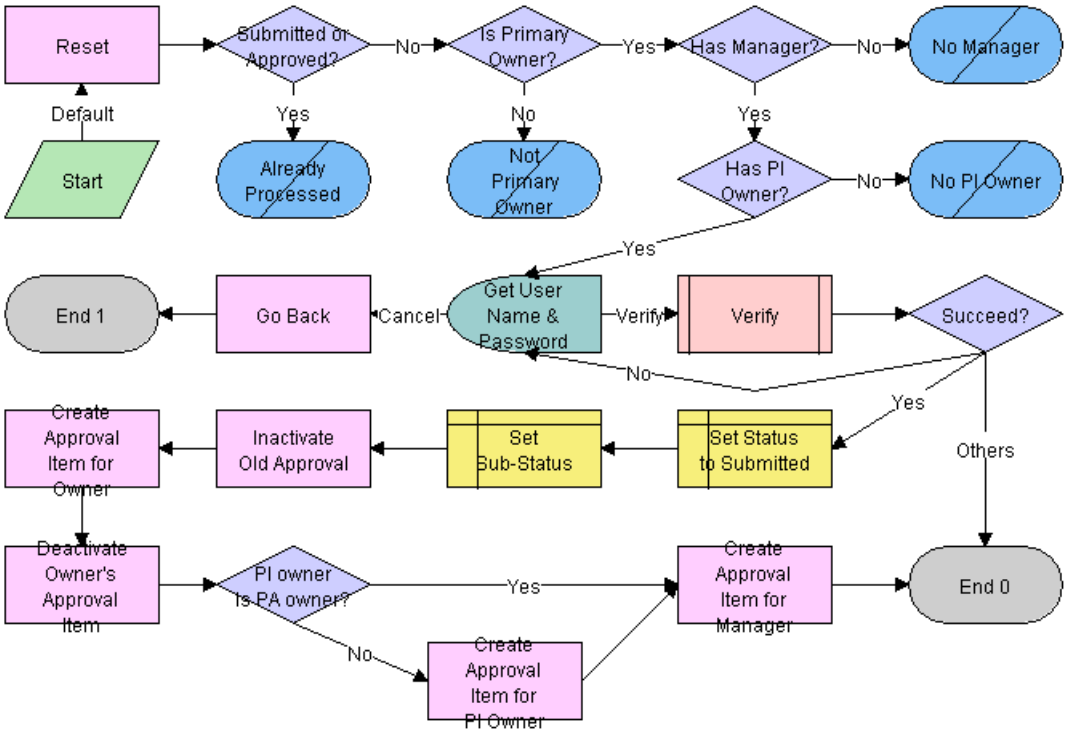


Figure 19. LS Medical PA Submit Workflow

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 20.

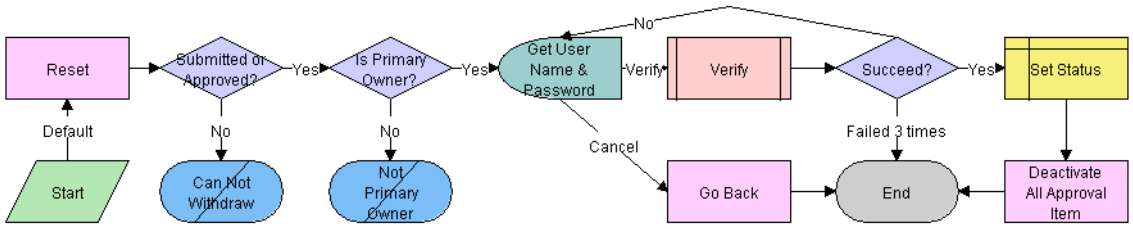


Figure 20. LS Medical PA Withdraw Workflow

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 section 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 44 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 44. 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 28, “Communicating with Customers for AECM”
- Chapter 29, “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 378.

Administrator Procedures

End-User Procedures

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 379.

To create a corrective action activity template

1 Navigate to the Data Administration 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 *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 "Process of Managing CAPAs" on page 379.

To set up codes for CAPAs

- See "Setting Up Codes" on page 341.

  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 "About Configuring Adverse Events and Complaints Capture" on page 349) for an example of a similar configuration.

This task is a step in "Process of Managing CAPAs" on page 379.

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 *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 *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 383.

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 374 for specific information on the product analysis approval workflows
- *Configuring Siebel eBusiness Applications* for information about how to configure buttons
- *Siebel Business Process Designer Administration Guide* for information about how creating workflows

27 Regulatory Reporting

This section 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 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 28, “Communicating with Customers for AECM”

■ Chapter 29, “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

There are four regulatory reports that can be created in Siebel AECM.

Table 45. 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 45. 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 387.

Administrator Procedures

- Setting Up Report Numbers on page 388

End-User Procedures

1. Creating and Populating New Regulatory Reports (End User) on page 389
2. Entering and Reviewing Data for 3500A Reports (End User) on page 390, or
3. Entering and Reviewing Data for MDV Reports (End User) on page 397
4. Running 3500A and MDV Reports (End User) on page 398
5. Generating Regulatory Report Numbers and Submitting Reports (End User) on page 399
6. Creating Supplemental or Follow-Up Regulatory Reports (End User) on page 401

Additional End-User Procedure

This end-user procedure is not part of the scenario described:

- Reopening a Regulatory Report (End User) on page 400

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 "Process of Regulatory Reporting" on page 388.

To set up report numbering scheme

1. Navigate to Group Administration 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 401.

This task is a step in "Process of Regulatory Reporting" on page 388.

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 411.

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 388.

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 US License Number.	G5
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.	G5
Combo Product	Define whether a suspect product comprises a drug-device, device-biological, drug-biological, or a drug-device-biological product.	G5
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.	G7
30-day	Select the check box to indicate the report is a 30-day report.	G7
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 388.

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 "Process of Regulatory Reporting" on page 388.

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 *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 46 lists the conditions for which the other sections get filled in.

Table 46. 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 388.

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 412.

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 388.

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 414.

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 "Process of Regulatory Reporting" on page 388.

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 398
   - "Generating Regulatory Report Numbers and Submitting Reports (End User)" on page 399
   - "Reopening a Regulatory Report (End User)" on page 400

Field Mapping for the MedWatch Report (Reference)

Table 47 shows how the fields in the Regulatory Reports screen map to the fields in the MedWatch 3500A report.

Table 47. 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)		
C1	Product	More Info (Products)
C2	Dose Per Unit	More Info (Products)
C2	Frequency	More Info (Products)

Table 47. 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
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)
D6	Implant Date	More Info (Products)
D7	Explant Date	More Info (Products)
D8	Reprocessed	More Info (Products)

Table 47. 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
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
F3	Importer	Importer
F3	Postal Code	Importer
F3	State	Importer

Table 47. 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
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
G3	Consumer	Manufacturer
G3	Foreign	Manufacturer
G3	Distributor	Manufacturer

Table 47. 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	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
H. Device Manufacturers Only		
H1	Death	Investigation
H1	Malfunction	Investigation

Table 47. 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
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
H8	Usage of Device	Investigation
H9	Correction #	Investigation

Table 47. 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
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 48 shows how the fields in the Regulatory Reports screen map to the fields in the MDV report.

Table 48. 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
Address Address 2 City State Postal Code Country	MDV	Address

Table 48. 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
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
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

Table 48. 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
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 #
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 #

Table 48. 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
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 411)
- Generate ("LS Medical Product Issue RR Submit Workflow" on page 412)
- Reopen ("LS Medical Product Issue RR Reopen Workflow" on page 414)

You can modify workflows to suit your own business model using Siebel Business Process Designer. For more information, see *Siebel Business Process Designer Administration 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 21.

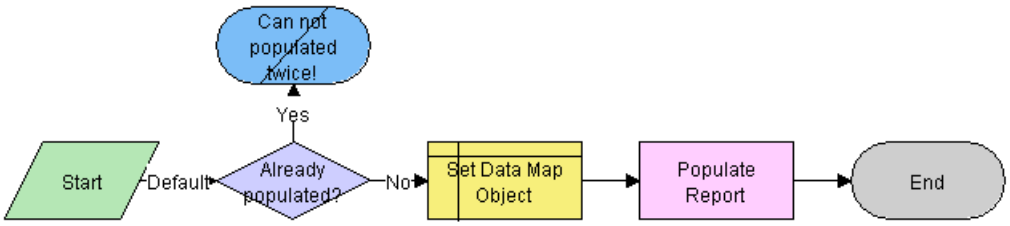


Figure 21. LS Medical Product Issue Populate Report Workflow

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 22.

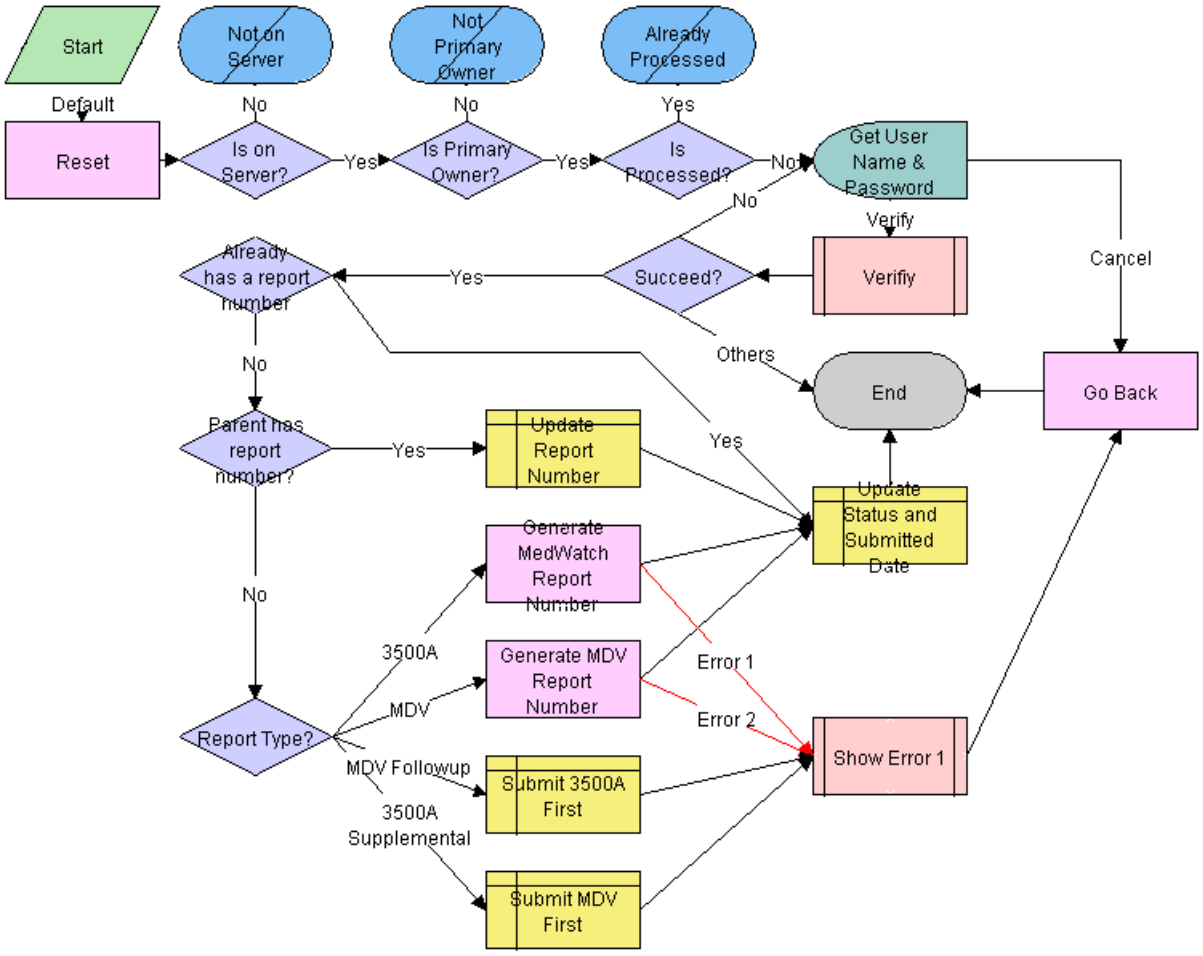


Figure 22. LS Medical Product Issue RR Submit

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	—	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 23.

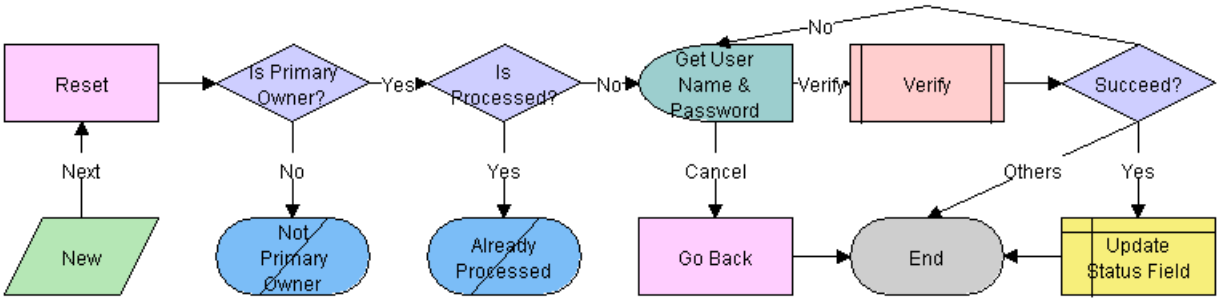


Figure 23. LS Medical Product Issue RR Reopen

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 Communicating with Customers for AECM

Topics in this section are:

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 29, “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 415. Your company may follow a different process according to its business requirements.

Administrator Procedures

End-User Procedures

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 "Process of Customer Communication in AECM" on page 416.

To set up proposals, correspondence, and presentations

■ See *Applications Administration 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 416.

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 *Applications Administration 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 416.

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 *Applications Administration 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 "Process of Customer Communication in AECM" on page 416.

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 *Applications Administration Guide*.

29 Closing Adverse Events and Complaints

Topics in this section are:

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:

- 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, “Communicating with Customers for AECM”

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

End-User Procedures

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 426.

This task is a step in "Process of Closure for AECM" on page 423.

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 426.

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 423.

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 *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 24.)

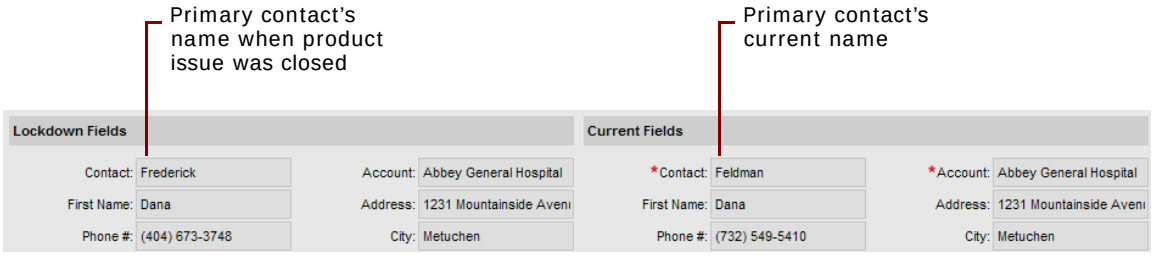


Figure 24. Lockdown Example

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 423.

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 Audit Trail, see *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 Designer Administration 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 25.

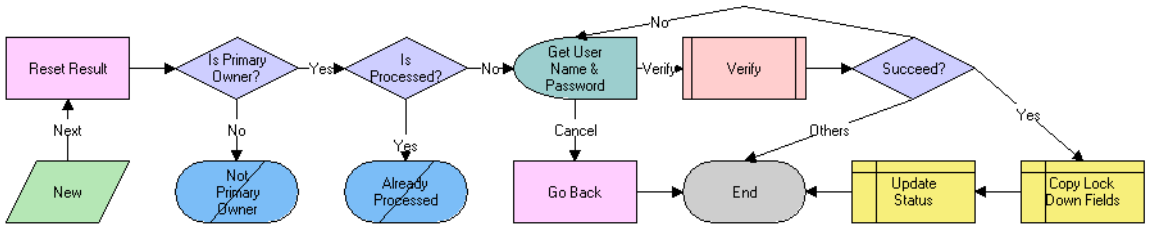


Figure 25. LS Medical Product Issue Close Workflow

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 26.

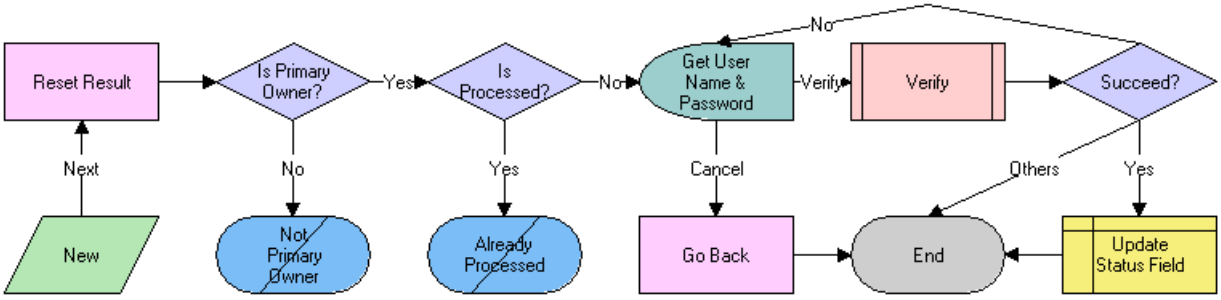


Figure 26. LS Medical Product Issue Reopen Workflow

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.

A Configuring Siebel Life Sciences

This appendix involves configuration of 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 eBusiness 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 49 and Table 50.

Table 49. 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 per business component.
Inactive	Optional	An indicator of whether the user property is active.
Comments	Optional	Comments describing the user property.

Table 50. 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 per 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 51 to each Opportunity business component.

Table 51. 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 57 on page 442.

- 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 57 on page 442 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 8, "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.

Charting Denormalized Syndicated Data

Siebel Life Sciences allows you to chart denormalized syndicated data. To take advantage of this enhancement, configuration is required at the business component, table, and applet levels.

Schema for Territory Data Files

The territory data files created by your syndicated data provider must have the following characteristics:

- They must be plain ASCII files.
- They must follow the schema described in Table 52.

Table 52. Territory File Schema

Field	Type	Length
Record Length	Alphanumeric	8
Territory Number	Alphanumeric	10
ME Number	Alphanumeric	10
Check Digit	Alphanumeric	1
Last Name	Alphanumeric	25

Table 52. Territory File Schema

Field	Type	Length
First Name	Alphanumeric	25
Middle Initial	Alphanumeric	1
Suffix	Alphanumeric	4
Title	Alphanumeric	5
Address 1	Alphanumeric	30
Address 2	Alphanumeric	30
Address 3	Alphanumeric	30
Address Indicator	Alphanumeric	1
City	Alphanumeric	28
State	Alphanumeric	2
Zip Code + 4	Number	9
Specialty	Alphanumeric	3
Called On Code	Alphanumeric	1
No Contact Indicator	Alphanumeric	1
Project Start Date	Alphanumeric	10
Current Week Date	Alphanumeric	10
Prior-To Date	Alphanumeric	10
Client Data	Alphanumeric	49
Programming Info	Alphanumeric	11
PRODUCT A	Alphanumeric	30
Week 9 Beg. Date	Alphanumeric	10
Week 9 End Date	Alphanumeric	10
Week 9 Activity Indicator	Alphanumeric	3
Week 9 Activity Indicator Name	Alphanumeric	10
Week 8 Beg. Date	Alphanumeric	10
Week 8 End Date	Alphanumeric	10
Week 8 Activity Indicator	Alphanumeric	3
Week 8 Activity Indicator Name	Alphanumeric	10
Week 7 Beg. Date	Alphanumeric	10
Week 7 End Date	Alphanumeric	10
Week 7 Activity Indicator	Alphanumeric	3

Table 52. Territory File Schema

Field	Type	Length
Week 7 Activity Indicator Name	Alphanumeric	10
Week 6 Beg. Date	Alphanumeric	10
Week 6 End Date	Alphanumeric	10
Week 6 Activity Indicator	Alphanumeric	3
Week 6 Activity Indicator Name	Alphanumeric	10
Week 5 Beg. Date	Alphanumeric	10
Week 5 End Date	Alphanumeric	10
Week 5 Activity Indicator	Alphanumeric	3
Week 5 Activity Indicator Name	Alphanumeric	10
Week 4 Beg. Date	Alphanumeric	10
Week 4 End Date	Alphanumeric	10
Week 4 Activity Indicator	Alphanumeric	3
Week 4 Activity Indicator Name	Alphanumeric	10
Week 3 Beg. Date	Alphanumeric	10
Week 3 End Date	Alphanumeric	10
Week 3 Activity Indicator	Alphanumeric	3
Week 3 Activity Indicator Name	Alphanumeric	10
Week 2 Beg. Date	Alphanumeric	10
Week 2 End Date	Alphanumeric	10
Week 2 Activity Indicator	Alphanumeric	3
Week 2 Activity Indicator Name	Alphanumeric	10
Week 1 Beg. Date	Alphanumeric	10
Week 1 End Date	Alphanumeric	10
Week 1 Activity Indicator	Alphanumeric	3
Week 1 Activity Indicator Name	Alphanumeric	10
PRODUCT B	Alphanumeric	30
Week 9 Beg. Date	Alphanumeric	10
Week 9 End Date	Alphanumeric	10
Week 9 Activity Indicator	Alphanumeric	3
Week 9 Activity Indicator Name	Alphanumeric	10
Week 8 Beg. Date	Alphanumeric	10

Table 52. Territory File Schema

Field	Type	Length
Week 8 End Date	Alphanumeric	10
Week 8 Activity Indicator	Alphanumeric	3
Week 8 Activity Indicator Name	Alphanumeric	10
Week 7 Beg. Date	Alphanumeric	10
Week 7 End Date	Alphanumeric	10
Week 7 Activity Indicator	Alphanumeric	3
Week 7 Activity Indicator Name	Alphanumeric	10
Week 6 Beg. Date	Alphanumeric	10
Week 6 End Date	Alphanumeric	10
Week 6 Activity Indicator	Alphanumeric	3
Week 6 Activity Indicator Name	Alphanumeric	10
Week 5 Beg. Date	Alphanumeric	10
Week 5 End Date	Alphanumeric	10
Week 5 Activity Indicator	Alphanumeric	3
Week 5 Activity Indicator Name	Alphanumeric	10
Week 4 Beg. Date	Alphanumeric	10
Week 4 End Date	Alphanumeric	10
Week 4 Activity Indicator	Alphanumeric	3
Week 4 Activity Indicator Name	Alphanumeric	10
Week 3 Beg. Date	Alphanumeric	10
Week 3 End Date	Alphanumeric	10
Week 3 Activity Indicator	Alphanumeric	3
Week 3 Activity Indicator Name	Alphanumeric	10
Week 2 Beg. Date	Alphanumeric	10
Week 2 End Date	Alphanumeric	10
Week 2 Activity Indicator	Alphanumeric	3
Week 2 Activity Indicator Name	Alphanumeric	10
Week 1 Beg. Date	Alphanumeric	10
Week 1 End Date	Alphanumeric	10
Week 1 Activity Indicator	Alphanumeric	3
Week 1 Activity Indicator Name	Alphanumeric	10

Enabling Inventory Reconciliation Without Lot Numbers

As discussed in Chapter 9, "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:

- Set the value of the Lots For Disperse Only system preference to TRUE
- Check the Lot# Tracking flag in the Product Administration screen
- Use Siebel Tools to reconfigure fields and replace business components

To enable inventory and reconciliation of samples without lot numbers

1. Navigate to the Application Administration screen > System Preferences view.
2. In the System Preference Name list, locate and select the Lots for Disperse Only record.
3. Change the field value to TRUE.
4. Verify that Sample Lots Enabled system preference is set to TRUE.
5. Navigate to Product Administration and check the Lot# Tracking flag.
6. Open Siebel Tools.
7. Choose View > Object Explorer > Flat tab.
8. Select Field, query for any Field with the value Picklist Pharma Samples Stocked Lots, and replace each occurrence with Picklist Pharma All Unexpired Lots.
9. Select Applet, query for any applet with the value Pharma Sample Stocked Lots Pick List Applet-CE, and replace each occurrence with Pharma Sample Lot for Picklist.
10. Select Applet, query for any applet with the value Pharma Stocked Lot Pick Applet and replace each occurrence with Pharma Sample Lot for Picklist.
11. Compile SRF.

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 53 lists the user properties that are general and can apply to any business component.

Table 53. 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 54 lists the user properties that are related to the following business components:

- Action (class CSSBCActivity)

- Calendar (class CSSBCCalendar)

Table 54. 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

Table 55 on page 439 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 55. 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 56 on page 440 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.

Table 56. 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 type 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.

Table 56. User Properties Related to Group 3 Business Components

User Property Name	User Property Value	Description
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.
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 Remake Reciept 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

Table 57 on page 442 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 57. 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.

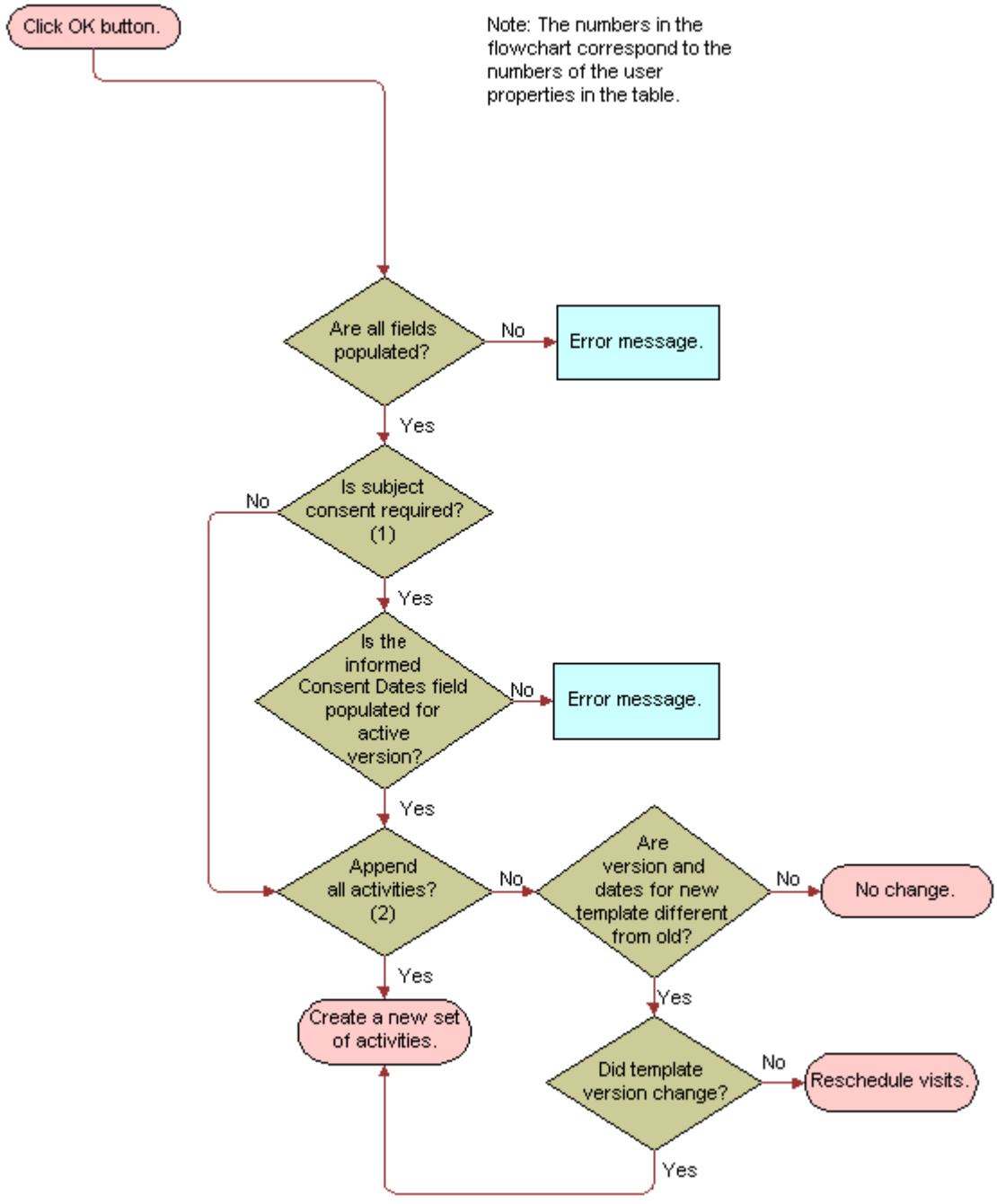
Configuring the Visit Generation Buttons

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 following flow chart illustrates the logic behind these buttons. The logic is the same for all three buttons, although content of the error messages does vary.



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.

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