

Siebel Life Sciences

Siebel eClinical 7

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Clinical trials are being influenced by a number of factors – increasing competition, expanding clinical pipelines, increasing development cycles, high costs of drug development, and a more stringent regulatory environment. Pharmaceutical companies, as a result, are faced with the tremendous challenge of conducting clinical trials in an expeditious and cost-effective manner while maintaining the highest quality standards. The key criteria for successful clinical trial management include:

- Superior planning, flawless execution and real-time status tracking of trials
- Ready access to historical information, both clinical and financial
- Excellent relationships with clinical investigators and highly productive clinical research associates (CRAs)

To help our customers successfully manage their clinical trials, Siebel Systems has developed Siebel eClinical, the most comprehensive suite of Web-based, eBusiness applications available today for clinical trial management. Siebel eClinical is designed to help pharmaceutical companies, medical device companies and clinical research organizations (CROs) optimize planning and execution of clinical trials, better manage investigator relationships, and track real-time clinical trial status to enable better decision making and faster time to market.

Siebel eClinical

Siebel eClinical enables companies to quickly deploy a Web-based clinical trial management system to both internal users such as project managers and monitors, and external users such as sites and CROs. Siebel eClinical empowers pharmaceutical companies to expedite clinical trials and maximize revenues by:

- Enabling efficient planning, execution and tracking of clinical studies across multiple geographies and therapeutic areas
- Improving relationships with clinical investigators and site coordinators
- Enhancing employee productivity and effectiveness
- Allowing information sharing with sales, marketing, medical affairs, and other internal departments
- Enabling faster and better decision making through an integrated systems approach with EDC, IVRS, payments, and supplies integration

Siebel eClinical Functionality

Siebel eClinical delivers complete trial management tools for CRAs, study managers, clinical directors, investigators, site-coordinators and CROs leading to a more effective use of resources, better decision-making, and a faster time-to-market.

Siebel eClinical provides comprehensive project planning and resource management functionality, site and investigator profiling, activity and calendar management, trial status and management reports, subject enrollment tracking, and efficient identification and targeting of clinical trial sites and investigators.

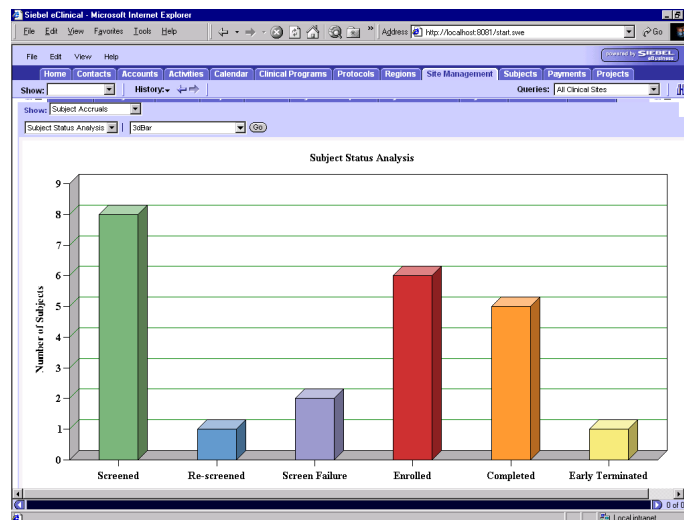


Figure 1 Enrollment Rate Analysis chart enables management to track enrollment at a site or across a protocol.

Global Trial Management

Siebel eClinical enables comprehensive clinical trial management by allowing users to capture and track clinical information at multiple levels of the clinical trial hierarchy. The highest level supported in Siebel eClinical is the Clinical Program, which may be used to track the therapeutic area of a clinical trial. Users can associate multiple compounds and protocols to a clinical program. Information from individual sites aggregates up to the protocol and program levels, allowing users to better organize and access clinical information.

Siebel eClinical provides users the option to track studies by various geographic regions and countries allowing them to more effectively manage global trials. Additionally, Siebel eClinical supports multiple currencies and time zones facilitating global deployment of the application.

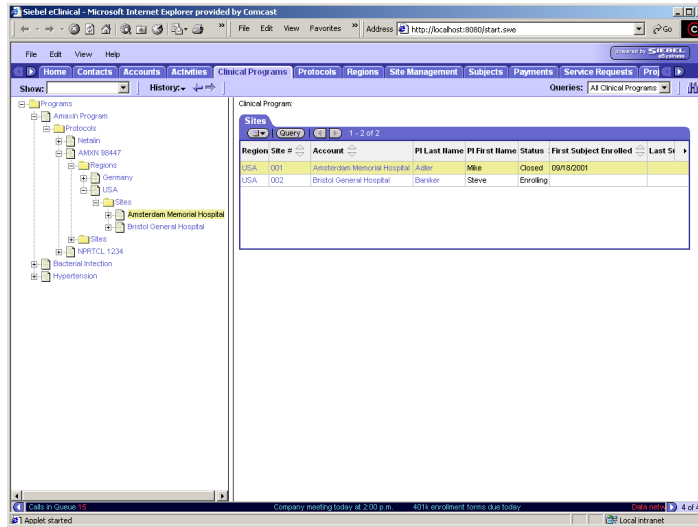


Figure 2 The explorer view allows easy access to clinical trial information.

Project Planning and Resource Allocation

Siebel eClinical empowers clinical teams to effectively plan clinical trial projects, develop trial action plans, track and control the entire trial process. This powerful functionality allows users to closely monitor project development status and benchmark it against performance milestones and critical events. The robust assignment capability allows organizations to load balance resources using various criteria based on their business requirements. Siebel eClinical also enables the project management team to manage tasks, activities, and resources efficiently through integration with Microsoft Project.

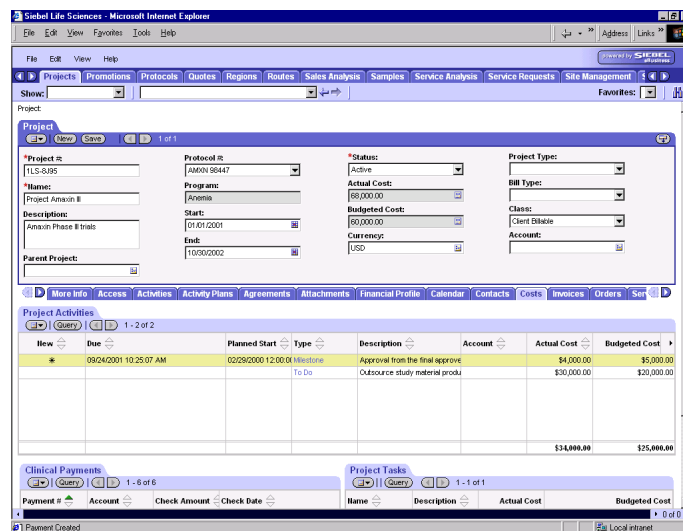


Figure 3 Siebel eClinical allows efficient planning and tracking of clinical trials.

Investigator and Site Management

Siebel eClinical enables users to access and manage comprehensive profiling information about their investigators and sites. Information such as multiple addresses, site and contact affiliations, certifications, activities, past performance and notes enable employees to maximize their effectiveness during interactions with sites and investigators. Users can see the complete history of trial involvement of their target investigators and sites to help with recruitment of sites for future trials. Users can share investigator and site profile information with other study team members, enabling productive collaboration.

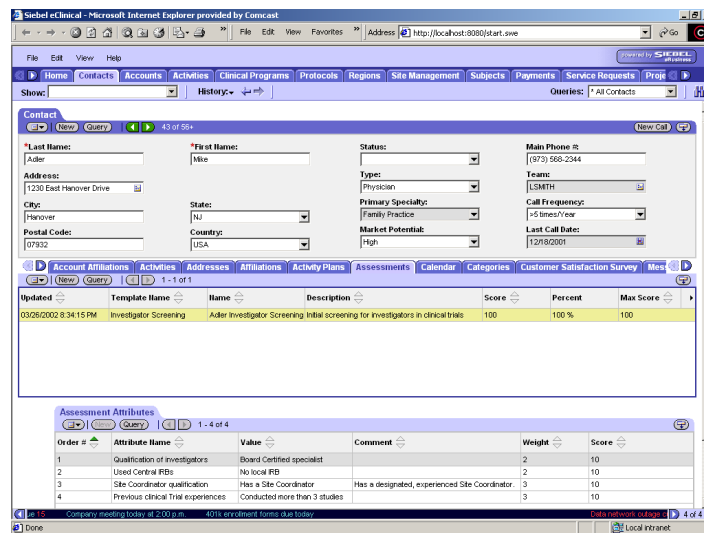


Figure 4 Siebel eClinical allows comprehensive profiling of investigators.

Study Management

The Siebel Protocol Builder module provides a powerful tool for trial sponsors to automatically create, manage and track subject visits according to protocol specifications. Using visit and activity templates, study managers can transform a written protocol into a visit scheduler that can be applied to subjects by site personnel over the Internet. Visits can be re-scheduled within the range specified by the protocol. Out-of-range re-scheduling is warned by the application to minimize protocol violation. The same feature can be used by CRAs to monitor protocol adherence at the site. Siebel eClinical supports Protocol Amendments by version control coupled with tracking of the corresponding IRB approval dates.

Correspondence

Siebel eClinical has built-in functionality that dramatically lowers the cost and effort of managing communications with sites and subjects. Through integration with Microsoft Office, Siebel eClinical enables users to automatically send addressed letters, notes,

and other correspondence to one or more contacts. Users can save time by using company-supplied letter templates or customized letters, and have the option to print the letters themselves or submit them to a fulfillment center.

Siebel eClinical is fully integrated with Microsoft Outlook and Lotus Notes enabling email communication with both external and internal users.

Document Tracking

Siebel eClinical helps study managers, CRAs and investigators to streamline and simplify the clinical document tracking process. Users can track regulatory and other trial documents during various stages of the trial including site-initiation and close-out. Siebel eClinical consists of several built-in reports that enable users to quickly identify the status of the documents and take action if necessary, so as to ensure regulatory compliance and to expedite the trial.

Site Visits and Trip Report Management

The Siebel Trip Reports module allows CRAs to plan, execute and track site visits. CRAs can produce high quality trip reports using standard templates created by clinical managers. Pre-built templates such as templates for site initiation, monitoring, and close-out visits help drive consistent business processes based on a company's own Standard Operation Procedures. Siebel eClinical helps CRAs to efficiently track open issues and follow-up items, leading to better site management and stronger investigator relationships. Siebel eClinical also provides a central repository for all trip reports allowing managers to easily review, approve, track and archive trip reports.

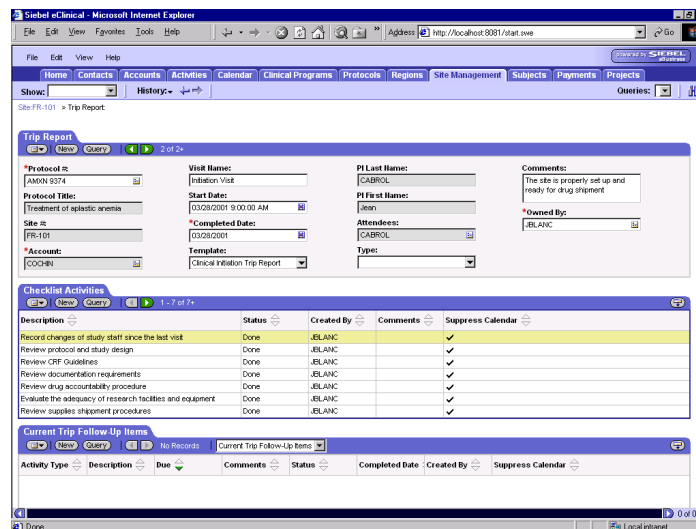


Figure 5 Siebel eClinical allows easy generation and tracking of Trip Reports.

Subject and Investigator Recruitment

The campaign management functionality facilitates subject and investigator recruitment by enabling customers to conduct multichannel advertising campaigns, including telephone, web and e-mail campaigns to recruit potential subjects and investigators. Campaign respondents may be directed to call a designated telephone number or to visit a web site to obtain more information about the trial and undergo a pre-screening process. Potential subjects who pre-qualify may then be directed to the appropriate investigator site for further follow-up, resulting in lower recruitment costs and shorter recruitment period.

Investigator Payment Management

The Siebel Payments module allows trial sponsors to create, monitor, and track clinical trial-related payments to investigators. The clinical study team is able to provide detailed information to site personnel and investigators about their past and current payments, and inform them about the upcoming payments. Streamlined payment generation process simplifies calculation of payment amounts based on completed visits or pre-determined milestones, enabling sponsors to pay more quickly while increasing investigator satisfaction.

Clinical Project Cost Tracking

The Siebel Project Cost Tracking module provides a dashboard for monitoring all costs associated with running clinical trials. Actual costs of investigator payments, subcontractor fees, project tasks and project activities can be tracked against budgeted costs on a single view.

Site Portal

Siebel eClinical provides a personalized internet portal for site coordinators and clinical investigators to screen and enroll subjects, schedule subject visits, record visit status, update and view subject status, and view up-to-the-minute payment information. The Site Portal can also include a calendar, which allows sites to view their past, current, and future subject visits on the web in monthly, weekly, or daily format.

The Site Portal also provides site coordinators and clinical investigators with access to answers to frequently asked questions and the ability to request medical information.

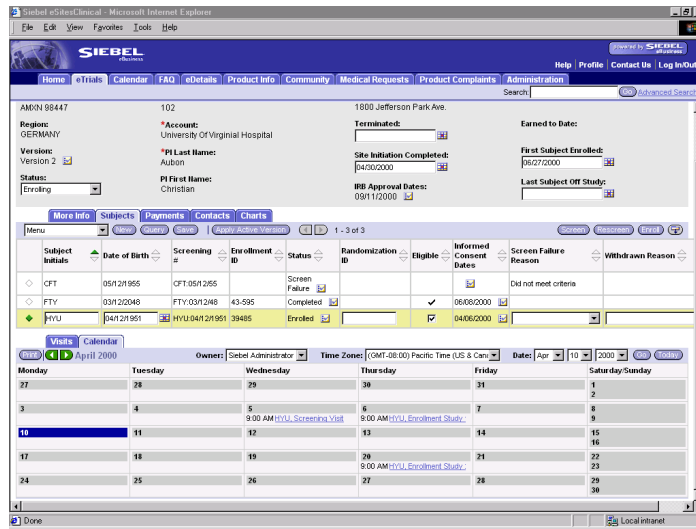


Figure 6 The Site Portal allows site-coordinators to track subject visits and status.

Deployment to Contract Research Organizations (CROs)

Sponsors who wish to track outsourced trials can deploy Siebel eClinical to CRO users. Sponsors can choose to deploy Siebel eClinical either as a zero-footprint Web-client where CRAs access the application through a network connection or as a disconnected client where CRAs access the application through software installed on their laptops. The Web-client option is a low cost deployment option that enables sponsors to access clinical information immediately upon being updated by CRO employees.

Regulatory Compliance

Siebel eClinical facilitates compliance with regulatory guidelines for electronic records. Specifically, the application consists of audit trail and security, access and authorization features that enable compliance with 21 CFR Part 11. The internal software development processes, testing and documentation controls ensure accuracy, reliability, reproducibility and consistent performance of the application.

Siebel eBusiness Platform

Siebel eClinical is built on the foundation of Siebel eBusiness platform that supports the delivery of the best clinical trial management application at the lowest total cost of ownership. The major features of this platform include:

- [The Smart Web Architecture](#). This unique technology combines a zero-footprint, browser-based Web client – meaning there is no software installed on the desktop – with high levels of interactivity traditionally available only in

Windows applications. Therefore, organizations choosing to deploy Siebel eClinical to users as a zero-footprint client will benefit from cost savings associated with administering a pure Web client and from the rich, interactive, productive experience available only from a desktop application.

- [The Siebel N-tiered Architecture](#). Siebel eBusiness platform is based on a true n-tiered architecture, in which user interface, logic, and data are clearly delineated into separate logical layers. The architecture provides Siebel eClinical customers to deploy the application in various modes including a truly disconnected mode, where mobile users such as remote CRAs can access the application even when they are not connected to the network.
- [Configurable and Upgradeable](#). Siebel eClinical is highly configurable allowing customers to customize the application to their specific-business processes. The automated upgrade functionality drastically reduces the effort and time involved in upgrading to a newer version of the application, resulting in reduced deployment times and lowest total cost of ownership.
- [Application Network Support](#). This feature ensures that Siebel eClinical is interoperable with the many applications within a pharmaceutical organization's systems environment, including data management systems, electronic data capture systems, adverse event management systems, and homegrown legacy systems.



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