

SIEBEL CLINICAL TRIAL MANAGEMENT SYSTEM



KEY BENEFITS

- Centralized trial management database
- Improved investigator relationships
- Increased clinical research associate productivity

Oracle's Siebel Clinical Trial Management System offers a new and innovative approach to managing clinical trials. The approach focuses on strengthening relationships with trial participants, especially investigators and subjects, by using customer relationship management (CRM) software solutions.

Improving Clinical Trial Efficiency with Optimized Processes

Costs for conducting clinical trials are rapidly increasing due to the growing number and complexity of clinical trials, accompanied by longer trial duration. Clinical organizations can no longer manage trials using uncoordinated, manual, and paper-intensive methods of the past. They need a better approach – one that streamlines trial management, reduces trial length, and lowers expenditure.

One of the major gaps in current clinical trial management approaches is suboptimal relationship management. Clinical organizations must do a better job in managing relationships with trial participants, especially investigators and subjects.

Delivering key benefits, Oracle's Siebel Clinical Trial Management System is built upon a CRM paradigm. CRM strategies offer a new, innovative approach to managing clinical trials. The approach focuses on strengthening relationships with trial participants, especially investigators and subjects, by using CRM software solutions. CRM solutions enable robust processes that enhance collaboration and information sharing across the many different teams involved in clinical trials. The result is closer, more productive participant relationships. CRM solutions also gather and maintain a wealth of valuable data that can be leveraged for a variety of other purposes, such as marketing, sales, and pharmacovigilance.

Robust Global Trial Management

Clinical trials are increasingly global in nature, conducted concurrently across multiple geographies. Making trial information accessible to the right people at the right time with the right level of detail becomes ever more critical. Siebel Clinical Trial Management System enables global clinical organizations to maintain a centralized trial management database while providing users with the most relevant and appropriate information based on their specific roles and responsibilities. Thus, real-time trial information is available not only to clinical research associates managing individual sites, but also to regional managers responsible for geographic areas and to global trial managers managing global trials. Armed with the most current and relevant data, clinical users are able to spot problems earlier and take corrective actions sooner, reducing overall trial costs.

Improve Investigator Relationships and Site Performance

Finding eligible subjects with the right health profile for a trial is often time-consuming and daunting, and failure to line up enough patients in time often accounts for days lost during clinical trials. In addition, the quality of data collected on each trial subject can vary significantly from site to site.

Identifying the investigators with the right subject demographics is a critical first step. Investigators with outstanding track records on meeting enrollment and performance targets bring tremendous value to clinical organizations. Competition to secure the service and loyalty of these prized investigators has intensified in the past few years. Leading clinical organizations have started applying the CRM paradigm to manage interactions with their investigators. Using Siebel Clinical Trial Management System as a centralized repository for all investigators, organizations can collect and track all relevant information about their investigators, from personal profiles to disease specialties, and from past trial experiences to current trial performance.

By analyzing comprehensive investigator data, clinical organizations are able to identify the investigators most suitable for a trial. Furthermore, Siebel Clinical Trial Management System can be used to provide personalized services to investigators by facilitating communications to the study team and by providing investigators with timely and accurate payments. The results are improved investigator relationships, faster enrollment, better trial quality, and lower trial costs.

Improve Clinical Research Associate Productivity

Despite recent developments in information technology, clinical trials are still laden with manual processes and inefficiencies. Valuable time is wasted on labor-intensive tasks such as tracking study documents and maintaining contact interaction records, causing repetitive data entry for the same information in multiple systems. Siebel Clinical Trial Management System document tracking provides clinical research associates with an efficient alternative to track regulatory and other study documents during various stages of the trial, spanning from site initiation to site closeout and at various levels, from site to country to protocol. Workflows and alerts available as part of Siebel Clinical Trial Management System allow relevant users to be notified for specific interventions such as document review or renewal.

Siebel Clinical Trial Management System activity management provides clinical research associates with a powerful tool to actively maintain contacts with sites, and to manage issues through to resolution. Using the Siebel Clinical Trial Management System trip report tool, clinical research associates can schedule site visits based on investigators' availability, site enrollment, or completed work. Prebuilt visit report templates help drive consistent business processes based on regulatory mandates and companies' standard operating procedures.

Siebel Clinical Trial Management System also provides an easy and efficient way to create and submit visit reports. Using various productivity tools within the system, several leading pharmaceutical, biotechnology, medical device, and contract research organizations have reported improved process efficiencies, thus significantly improving clinical research associates' productivity.