Rising costs, increasing regulatory requirements, and complexity of clinical trials has increased the time, and cost to introduce new products to market. This is driving life sciences companies to focus on streamlining processes and enhance the quality of clinical information. Oracle’s solutions for clinical trial management enable an integrated approach for managing the entire clinical trials value chain.

Companies need to manage multiple trials often across the globe. Clinical trials management is complex and requires the integration of information across the enterprise and from outside partners. Competition for top investigators is increasing while its becoming difficult to identify, enroll, and retain clinical trial subjects. With large amount of clinical trial data being generated from multiple sources consolidation, analysis, and reporting poses enormous challenges. Oracle’s complete solution enables life sciences companies to improve operational efficiencies and outcomes of clinical trials. With clinical trial management applications from Oracle, companies are able to significantly enhance their ability to:

- Manage hundreds of simultaneous trials in a regulatory compliant manner
- Improve efficiency and quality of clinical data
- Streamline clinical analysis, reporting and submission
- Maintain a single source for adverse event data submission and reporting

**Manage hundreds of simultaneous trials in a regulatory compliant manner**

With clinical trials being conducted across the globe, there is a need for having tools to efficiently manage concurrent trials, strengthen relationships with principal investigators, rapidly enroll qualified participants, identify problems early, and take corrective actions quickly. Oracle’s Siebel Clinical Trial Management System enables you to take advantage of the world’s leading CRM application to efficiently manage clinical trials. A centralized trial management database provides users with the most relevant and appropriate information in real-time. Armed with the most current and relevant data, clinical users are able to spot problems earlier and take corrective actions sooner, thus reducing overall trial costs.

With Siebel Clinical Trial Management System your ability to collect, track, and analyze information about principal investigators is greatly enhanced. This enables you to identify those with the greatest chance of running your clinical trials successfully. It further provides many automated tools to help researchers and project managers to keep trials on track.

Siebel Clinical Trial Management System lets you improve relationships with principal investigators, enhance employee productivity and effectiveness, and achieve faster patient enrollment, better trial quality, and lower trial costs.

**Improve efficiency and quality of clinical data**

Data is central to the clinical trial process. It serves as the basis for product submission, approval, labeling, and marketing. However, clinical trial data can come from a variety of sources and multiple systems, which make it difficult to obtain a comprehensive view of important data elements. Oracle’s combination of broad coverage and deep functionality offers major benefits in clinical data management.
Oracle Clinical is Oracle’s clinical data management application that is fully integrated with front-end electronic data capture (EDC), using Oracle Clinical Remote Data Capture. With a combined functionality to support clinical data management and electronic data capture, Oracle Clinical improves both efficiency of data collection and data accuracy. It provides an efficient, scalable electronic data capture system that emulates paper-based methods. The application lets you standardize and control data definitions and data usage across global operations, expedite multinational regulatory approval processes, and reduce cycle times in clinical trial processes. These capabilities speed data collection and data cleaning processes, reducing the time and money spent on clinical trials.

Oracle Thesaurus Management System facilitates rapid coding of medical terminology and provides a centralized repository of dictionary terms and associated verbatim. Due to its integration with Oracle Clinical and Oracle Adverse Events Reporting system, it provides consistency in coding used to describe and categorize data across multiple applications.

Streamline clinical analysis, reporting and submission

Since clinical trials are now being conducted globally the collection, consolidation and analysis of data, for regulatory filing, poses numerous challenges. This is because the systems used to support clinical trials create isolated silos of information. With Oracle Life Sciences Data Hub you can now integrate information from multiple systems. It brings together both clinical and non-clinical data to streamline analysis reporting and submission. It resolves the issue of integrating silos of information created in multiple clinical trials with a single, compliant infrastructure for data access, transformation, persistence and distribution. It improves productivity, shortens reporting time, and aids compliance.

Maintain a single source for adverse event data submission & reporting

The ability to maintain a single information source on any type of complaint reported during clinical trials or related to product complaints is crucial. It enhances the capability of the company to monitor product safety and compliance and quickly generate and submit reports to authorities. Oracle Adverse Event Reporting System (AERS) is a comprehensive solution for product safety monitoring and compliance. Oracle AERS supports the capture, management, reporting and analysis of serious adverse events and product complaint cases from all sources. Its seamless integration with Oracle Clinical and Oracle Thesaurus Management System prevents duplicate effort and reduces discrepancies. Oracle solution offers integrated complaint and adverse event capabilities, which provides the industry direct integration of adverse events reporting to clinical data management system. This creates a unique single source of truth for both adverse event submission and reporting.

Oracle’s end-to-end solution

Oracle is committed to life sciences industry. Oracle offers a complete clinical data management, electronic data capture, clinical trial management, and adverse event reporting solutions. Oracle provides a scalable, reliable, and secure infrastructure, with built-in capabilities for improving operational efficiencies and outcomes in clinical trials. Look to Oracle to help manage large number of trials high volumes of data, and stringent reporting requirements worldwide while helping you reduce costs and time for completing trials.

Contact Us

To learn more, call +1.800.ORACLE1 to speak to an Oracle representative or visit oracle.com/industries/healthcare

Outside North America, visit oracle.com/corporate/contact to find the phone number for your local Oracle office.