

Comprehensive Enterprise Trial Management and Monitoring in the Cloud



Reduce Trial Costs while increasing study speed and Data Quality with Oracle Health Sciences Trial Management and Monitoring Cloud Service

KEY BENEFITS

- Easily implement strategic, risk-based monitoring
- Make fast and accurate decisions with real-time performance metrics
- Facilitate multi-channel communications and compliance
- Improve investigator targeting and recruitment
- Increase process efficiency and staff productivity
- Implement modular capabilities
- Achieve time-to-value in just a few days

KEY FEATURES

- Enterprise-class, clinical trial management system
- Centralized trial management database
- Fully configurable user interface
- Support for any device and any browser
- Built-in performance analytics
- Easy-to-use reports and dashboards
- Workflow automation, alerts, and notifications
- Data sharing across internal and external systems
- Out-of-the-box support for more than 20 languages

Oracle Health Sciences Trial Management and Monitoring Cloud Service, comprised of Oracle's Siebel Clinical Trial Management System (CTMS) enables effective management of critical clinical trial activities and improved relationships with investigators, from early to late-stage clinical trials. With real-time visibility into clinical trial progress and significant utilization rates of clinic and staff resources, this solution can help to lower costs, while increasing study speed and data quality. These services are part of the foundation for Oracle Health Sciences' integrated, holistic approach to risk-based monitoring.

Oracle Health Sciences Trial Management and Monitoring Cloud Service is fully integrated with Oracle Health Sciences InForm Cloud Service and with Oracle Health Sciences Clinical Development Analytics (CDA). This "monitoring cloud" enables actionable insight into clinical trials to accelerate clinical development while reducing trial cost and risk.

This proven, flexible, and scalable cloud-based solution can help:

- Easily implement holistic and strategic risk-based monitoring following FDA, EMA, TransCelerate, or one's own best practices
- Make fast and accurate decisions with real-time enrollment and site performance metrics in a centralized trial management database
- Facilitate multi-channel communications and compliance through automated workflows and notifications
- Improve investigator targeting and recruitment with built-in investigator intelligence
- Increase process efficiency and staff productivity through comprehensive performance analytics and mobility
- Implement your risk based monitoring strategies
- Achieve time-to-value in just a few days



Enterprise-class trial management solution provides a centralized, single source of truth for managing study operations and all relevant relationships.

“Oracle Siebel Clinical Trial Management System Cloud Service dramatically simplifies how we manage study data and communicate with clients, especially in studies involving multiple CROs.”

– PPD

Improve 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. Unlike paper-based solutions, Oracle Health Sciences Trial Management and Monitoring Cloud Service ensures that clinical studies are conducted with greater efficiency, with all users operating against single source of truth for all clinical operations data.

Companies need a centralized repository for their investigator and site contact information that provides flexibility to assign contacts to one or more entities, track movement of personnel across accounts, and capture information in an easy-to-use interface. This information needs to be accessible across multiple business functions to facilitate communication, payment, assessment of performance, and tracking of enrollment and monitoring activity.

Oracle Health Sciences Trial Management and Monitoring Cloud Service leverages the deep functionality and flexibility of the Oracle Siebel life sciences customer relationship management (CRM) platform. Managing trial contacts, such as clinical investigators, institutions, sites, and internally assigned study resources, the cloud service leverages automated workflows, pre-built templates, and checklists to improve real-time decision-making for study and site performance. The software enables holistic and strategic monitoring, while facilitating site payments, processing, and tracking. This reduces trial risk and cost, as well as improves quality, compliance, and site performance. Additionally, the software can be deployed in a modular fashion to solve specific business problems (such as monitoring trip reports).

“Ovum designates a market leader as having established a commanding market position with a product that is widely accepted as best of breed and worthy of a place on most technology selection shortlists. Oracle’s support for, risk-based monitoring and integration with its Oracle Health Sciences Clinical Development Analytics product differentiates its offering from the rest of the market.”

– OVUM HEALTH SCIENCES

Lower Your Total Cost of Ownership

Oracle Health Sciences Trial Management and Monitoring Cloud Service provides a lower total cost of ownership (TCO) through predictable cloud infrastructure costs, reduced IT management time and effort, and improved compliance processes and controls. The cloud service provides customers with world-class security and compliance as well as 24x7 application availability via a web browser. Additionally, the cloud service offers accelerated implementations, reduced downtime for upgrades, and proactive patches and updates.

Benefit from Siebel Open User Interface

The open, next generation, browser client for desktop and mobile platforms features a smart, efficient user interface (UI) with a modern look and feel for desktop browsers on any hardware platform, as well as for mobile browsers on any tablet or smart phone. Optimized for usability and productivity across devices, the standards-based open UI is easy to deploy and maintain.

Personalize the User Experience

With the release of Siebel Open UI and various other enhancements, Oracle Health Sciences Trial Management and Monitoring Cloud Service now supports any browser, any device, anywhere. This flexible, user-friendly interface is fully configurable to improve the user experience, thereby increasing productivity.

Oracle Health Sciences Trial Management and Monitoring Cloud Service enhances the end user experience by providing automated workflows to guide end users including:

- Task Based UI
- iHelp
- SmartScripts

Use the updated Open UI out-of-the-box. Or, use your own cascading style sheets and change the look of the user interface. Customization possibilities include:

- Desktop styles
- Themes, branding
- Customer dashboard
- Web self-service options
- Industry-specific customizations, such as for sales or service

Customer Dashboard:
view top information on
a single screen



Web Self-Service: empower
customer self help



Themes: style for
familiarity or brand



Industries: plan, perform,
and track field sales and
service activities

“Following adoption of Oracle Siebel CTMS, Novotech is now able to manage highly complex trials across any number of sites and countries with the same ease of reporting and management control as the smallest single site study. This also offers real-time web based reporting to clients anywhere in the world.”

– NOVOTECH CRO

Gain Robust Global Trial Management

Oracle Health Sciences Trial Management and Monitoring Cloud Service 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.

The software offers a single repository for Standard Operation Procedures (SOPs) and business practices for improved processes and controls. Services can be rapidly expanded to support extended business operations through cloud or on premise integrations with Oracle Health Sciences CDA. An enterprise-class, clinical trial management system, Oracle’s Health Sciences Trial Management and Monitoring Cloud Service replaces paper-based, manual processes to improve quality, speed, and productivity throughout clinical operations. The cloud service has the ability to grow and change with one’s business needs. It can help to lower costs while increasing study speed and data quality, significantly increasing utilization rates of clinic and staff resources.

Oracle Health Sciences Trial Management and Monitoring Cloud Service provides:

- A centralized trial management database to track and manage study operational data
- Real-time study status enabling efficient study and enrollment tracking
- Support for over 20 languages, time zones, and currencies

Enhance Support for Risk Based Monitoring Strategies

Oracle Health Sciences Trial Management and Monitoring Cloud Service provides support for risk based monitoring processes throughout a study lifecycle. The solution offers capabilities to define and document risk during study planning, perform targeted Source Data Verification (SDV), and track investigator site protocol-specific-training throughout the study.

- Utilize risk assessment via the TransCelerate RACT tool
- Create and track protocol specific training plans for investigator site users
- Define SDV plans

The flexibility of the partial SDV capabilities allow customers to: define critical visits and pages to be monitored for all subjects, designate specific subjects for full SDV categories, and set criteria to trigger SDV for individual subjects.

Optimize Investigator Relationships and Site Performance

Leading clinical organizations are applying the customer relationship management (CRM) paradigm to manage interactions with their investigators. Using Oracle Health Sciences Trial Management and Monitoring Cloud Service 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 can identify those investigators most suitable for a trial. By facilitating communications to the study team and by providing investigators with timely, accurate payments, the software can also be

used to provide investigators with personalized services. The results are improved investigator relationships, faster enrollment, better trial quality, and lower trial costs.

Employ Built-In Performance Analytics for Increased Efficiency and Productivity

Oracle Health Sciences Trial Management and Monitoring Cloud Service and Oracle Health Sciences Clinical Development Analytics are the only solutions in the industry to offer integrated and cloud-based trial management, performance analytics, and risk based monitoring functionality to increase efficiency and productivity, while reducing risk.

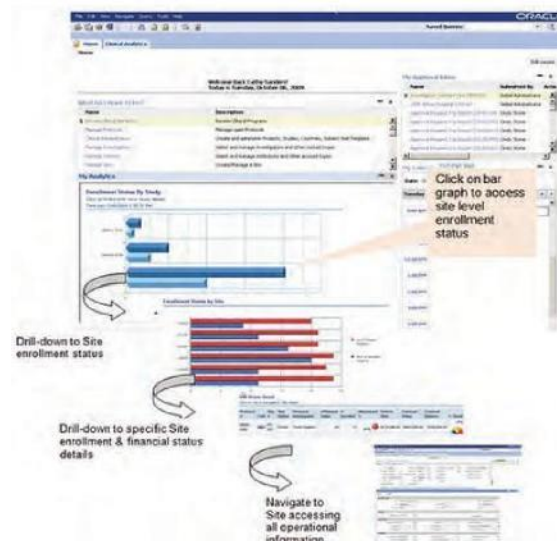
Oracle Health Sciences Trial Management and Monitoring Cloud Service offers built-in analytics leveraging Oracle Health Sciences CDA to enhance study monitoring and actionable reporting. These built-in analytics provide a role-based, user-friendly, analytic model of enterprise information and metrics, including embedded, best practice calculations and key performance indicators. Analytics are further supported by integration with Oracle Health Sciences CDA.

The following capabilities provide real-time visibility into clinical trial progress and offer actionable insight for fast, informed, decision-making that accelerates clinical development and reduces trial cost and risk:

- Easy-to-use reports and dashboards
- Reduction in redundant reports and reduced need for highly manual data gathering and manipulation
- Rapid identification of top and bottom performing sites and resources
- Detailed and timely discrepancy reporting enabling early identification of trends and ability to take corrective action, such as increased site or staff training, or changes to the data design

Leveraging CDA, one can easily define and deploy automated alerts and notifications.

- Set conditional Indicators based on your SOPs
- Get immediate notification of problems/milestones
- Keep a legend to ensure common understanding
- Use conditional Indicators to trigger proactive alerts



Built-in analytics leveraging CDA Analytics to enhance study monitoring and deliver actionable reporting

Facilitate Workflow Automation

Oracle Health Sciences Trial Management and Monitoring Cloud Service facilitates multi-channel communications and compliance through automated workflows and notifications. workflow automation alerts, and notifications reduce delays and latencies. They enable the fast data sharing electronically with stakeholders, providing them with higher-quality data and the ability to take the appropriate actions.

Enable System Integration

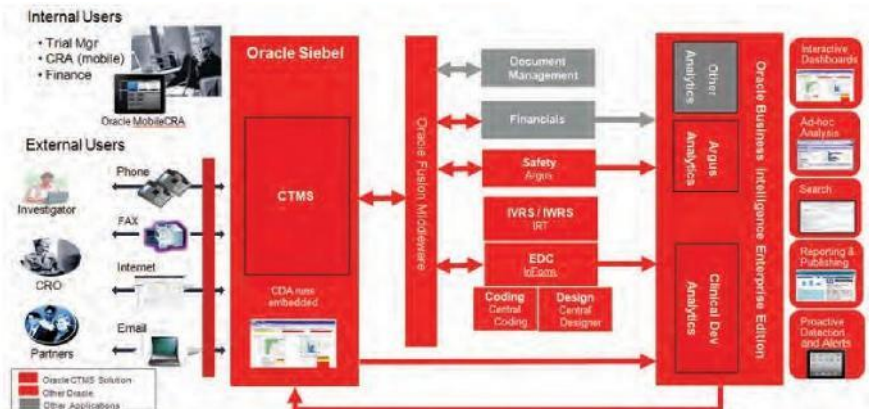
The outsourcing trend has dramatically increased the need for sponsors and CROs to share information. With Oracle Health Sciences Trial Management and Monitoring Cloud Service, information can be shared across internal and external systems.

Oracle Health Sciences Trial Management and Monitoring Cloud Service integration capabilities further enable data sharing and visibility, providing higher data quality and timeliness. The software provides out-of-the-box integration with Microsoft Office suite, MS Project, and Sharepoint. It allows organizations to connect to other applications as a source or destination system.

Health Sciences Trial Management and Monitoring is integrated into the cloud, as well as hybrid cloud to on premise, with other Oracle Health Sciences applications to support an end-to-end business process, including:

- Oracle Health Sciences InForm and Oracle Health Sciences InForm Cloud Service
- Oracle Health Sciences Clinical Development Analytics

Oracle Health Sciences Trial Management and Monitoring Cloud Service offers world-class architecture designed to integrate with both Oracle and third-party applications, using open technology standards. Real-time data sharing and enhanced cross application automation are enabled with the ability to leverage the OBIEE analytics platform to run CDA and other clinical and business analytics application. Oracle Health Sciences Trial Management and Monitoring Cloud Service is commonly seen as a central hub with touch points to many internal systems





CONTACT US

For more information about Comprehensive Enterprise Trial Management and Monitoring in the Cloud, visit oracle.com/healthsciences, email healthsciences_ww_grp@oracle.com or call +1.800.633.0643 to speak to an Oracle representative.

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Integrated Cloud Applications & Platform Services

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