

Hardware and Software
Engineered to Work Together

End-to-End E-Clinical Coverage with Oracle Health Sciences InForm GTM

A Complete Solution for Global Clinical Trials

The broad market acceptance of electronic data capture (EDC) technology, coupled with an industry moving toward more complex and global clinical trials, has fueled new demands for more efficient clinical data management solutions. Sponsors and sites need an e-clinical solution with a flexible platform that can consistently speed study design and accelerate study deployment, while scaling to global trials with large patient populations. As an EDC leader, Oracle delivers innovative technology and champions best practices that have proven effective through more than a decade of development, deployment, and services experience.

Oracle Health Sciences InForm Global Trial Management (GTM) helps clinical research coordinators, trial monitors, clinical data managers, and project managers work more efficiently and with greater accuracy throughout the clinical development process. Its intuitive user interface, multilanguage capabilities, and associated software modules deliver a robust solution to meet the needs of today's global electronic data capture user.

In addition, Oracle Health Sciences InForm GTM's scalable platform enables flexible, speedy study design and build, robust data management, and real-time data visibility, and provides user-driven reporting tools and advanced analysis capabilities. Further, interactive voice response systems, clinical trial management systems, imaging, and electronic patient reported outcomes can easily integrate with Oracle's e-clinical environment through the support of Web services and industry standards.

KEY BENEFITS

Oracle Health Sciences InForm GTM provides the ability to

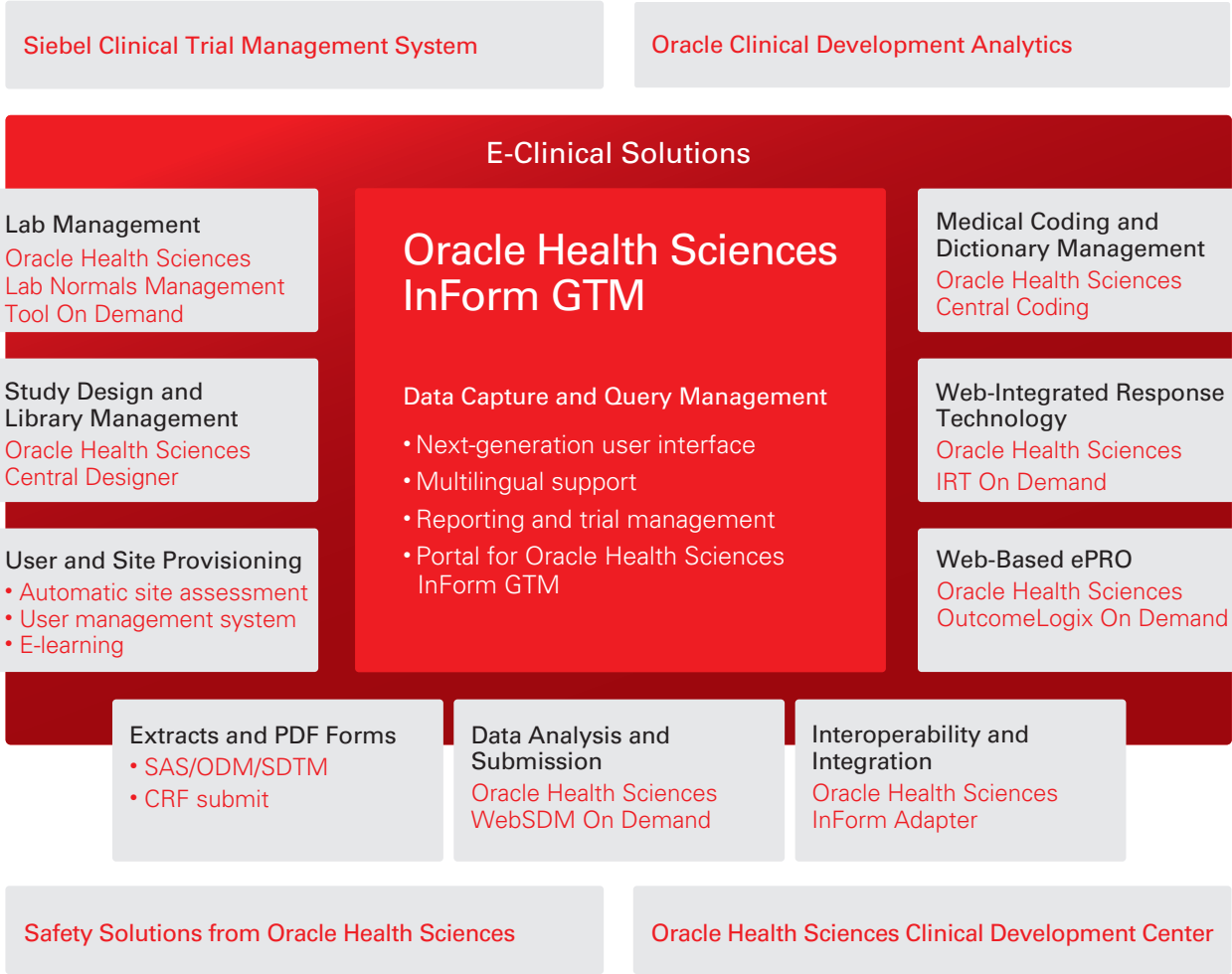
- Capture, manage, and analyze study data within a single platform
- Reduce input errors with built-in edit checks
- Save time and money by designing electronic case report forms (eCRFs) once and translating them into multiple languages
- Address discrepancies quickly and easily with query management functionality
- Achieve effective subject management with real-time access to trial data
- Accelerate training times with convenient and straightforward e-learning tools

Scalability and Performance Through Modularity

A modular services-oriented architecture (SOA) ensures scalability and allows best-fit solutions for different needs. Oracle Health Sciences InForm GTM can accommodate the full spectrum of study scenarios—from small-population, rapid turnaround studies to complex, multiyear trials, or postapproval observational programs—across tens of thousands of subjects.

The modular design provides scalability and performance and allows organizations to

- Conduct complex global trials without sacrificing performance
- Make design changes to live studies without impacting other trials
- Upgrade studies independently to a newer software version
- Locate studies and their databases on different servers and in different domains to help optimize performance
- Run detailed reports without impacting transactional performance at sites or sponsor locations
- Enhance data and system security through the use of a separate application and database environment for each study



KEY FEATURES

- A flexible system architecture for scalability and performance
- A study design and library management environment that reduces build time
- Integrated, multitrial medical coding
- Role-appropriate monitoring and data review workflows
- Query workflows that enable fast discrepancy resolution
- On-demand data access and advanced reporting
- A single study environment for multilanguage or regionally based trials
- A user-friendly interface for efficient navigation and effective workflow
- Support for CDISC standards

Streamline Study Design and Reduce Build Time

Oracle Health Sciences Central Designer, used with Oracle Health Sciences InForm GTM, helps streamline the process for designing and building EDC studies by

- Increasing study design efficiencies
- Improving component reuse and the application of standards including Clinical Data Acquisition Standards Harmonization (CDASH)
- Enhancing communication and workflow

Accelerate Study Deployment

Deploying integrated EDC studies reliably and consistently requires a proven system architecture and methodology. With unsurpassed experience in deploying thousands of trials worldwide, Oracle Health Sciences offers

- State-of-the art hosting facilities with disaster recovery and world-class global support
- Centralized site management and provisioning across trials and applications, streamlining access and identity management and tracking site readiness
- Standardized third-party integration offerings that leverage common technology and industry standards

Access End-to-End Solution Coverage

The Oracle Health Sciences clinical solutions help automate and standardize the integration of Oracle Health Sciences InForm GTM with other Oracle best-of-breed solutions including

- Oracle Health Sciences Central Coding. A centralized cross-trial Web-based medical coding and dictionary management environment.
- Oracle Health Sciences IRT On Demand. A flexible Web-based randomization, trial supply management, and forecasting solution.
- Oracle Health Sciences Clinical Development Center. Integrate, manage, and analyze clinical information.
- Oracle Health Sciences OutcomeLogix On Demand. Comprehensive, easy-to-use Web-based electronic patient-reported-outcome (ePRO) solution.
- Oracle Health Sciences safety solutions. An integrated suite for lifecycle pharmacovigilance and risk management.

Capture and Access Study Data, Easily and Securely

Clinical researchers want to spend as little time as possible sitting in front of a computer. Oracle Health Sciences InForm GTM has become one of the most widely used EDC tools in the industry by providing

- An easy-to-use Web-based application with a modern user interface and intuitive navigation
- Optimized system performance for rapid user interaction
- Support for multilingual studies, including Japanese
- Online edit checks to reduce data entry errors
- Efficient data discrepancy resolution through online query process
- Easy batch loading of external source data

Reduce Time to Database Lock

The Oracle Health Sciences InForm GTM platform offers unique functionality that enables teams to establish optimized workflows designed to reduce time to database lock through

- Real-time access and reporting on all study information
- Quick and easy processes for creating and closing queries for improved data quality
- Functionality that supports midstudy design changes
- User-driven filters and reports that simplify preparation for source verification and data review
- Complete support for remote online source verification
- An integrated medical coding environment for coding drug and adverse event terms across trials globally with Oracle Health Sciences Central Coding
- Multistudy coding support for the World Health Organization Drug Dictionary (WHO-DD), the Medical Dictionary for Regulatory Activities (MedDRA) and its Japanese version (MedDRA-J), and J Drug
- Import and export support for Clinical Data Interchange Standards Consortium Laboratory Data Model (CDISC LAB), Operational Data Model (ODM), and Study Data Tabulation Model (SDTM)

Deploying integrated EDC studies reliably and consistently requires a proven system architecture and methodology. Only Oracle Health Sciences offers unsurpassed experience in both building EDC studies and deploying thousands of trials worldwide.

RELATED PRODUCTS

Oracle Health Sciences InForm GTM works with the following best-of-breed solutions to efficiently manage the clinical development process:

- Oracle Health Sciences Central Coding
- Oracle Health Sciences Central Designer
- Oracle Health Sciences IRT On Demand
- Oracle Health Sciences Clinical Development Center
- Oracle Health Sciences Empirica products
- Oracle Health Sciences InForm Adapter

Gain Immediate Access to Critical Data

Medical monitors, biostatisticians, and other stakeholders need continuous, real-time access to all facets of study information—from the number of patients enrolled at each site to the statistical trends on patient data. With Oracle Health Sciences InForm GTM, users gain immediate access to detailed reporting and data review capabilities through

- On-demand, user-driven dashboard-style reports via an Internet portal
- Immediate access to reports available on study-go-live date
- Out-of-the-box standard reports for reviewing operational data
- A simple, nontechnical, ad hoc reporting capability for generating reports, graphs, and charts
- Ad hoc export options including: Microsoft Excel, Portable Document Format (PDF), Extensible Markup Language (XML), and comma-separated values (CSV)
- On-demand data extracts (such as SAS, RDE) for customers using Oracle hosting services

Implement Industry Standards

As an active member in CDISC and other standards committees, Oracle is committed to providing products that

- Include a certified CDASH library
- Support CDISC LAB and ODM standards for data exchange
- Support SDTM data set delivery for analysis and submission

Why Oracle Health Sciences InForm GTM for EDC?

Leveraging a decade of experience helping life sciences companies capture, analyze, and manage clinical data, Oracle Health Sciences sets the standard for what companies look for in an EDC solution.

- **Proven Usability.** The Oracle Health Sciences InForm GTM environment has been used in more than 4,000 trials worldwide, providing a familiar and intuitive user interface that allows both sites and sponsors to efficiently capture and manage clinical information. The roles-based functionality within Oracle Health Sciences InForm GTM makes it easy for clinical researchers, data managers, monitors, biostatisticians, and key stakeholders to streamline their process workflows and access the real-time information needed to conduct trials.
- **Trusted Performance and Scalability.** Oracle Health Sciences InForm GTM is built on a tiered system architecture that provides consistent, reliable performance for any size study. Life sciences companies can quickly ramp up on EDC because of the system's inherent scalability. Today, Oracle Health Sciences InForm GTM is a trusted EDC solution with a proven track record of helping customers.
- **Flexible System Configurability.** The Oracle Health Sciences InForm GTM environment is one of the most flexible EDC platforms on the market today, enabling life sciences companies to configure the system to address their unique business needs, such as making connections with third-party systems, conducting studies in developing countries, developing adaptive trials, and running Phase I, II, and III clinical studies as well as large-scale Phase IV registry trials. Customers can also implement midstudy design changes quickly without disrupting trial activities.
- **The Ownership Experience.** Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry. It can scale to meet the demands of the smallest to the largest companies. With Oracle Health Sciences, clients enjoy lifecycle project management, study design and implementation, site and user provisioning, out-of-the-box integrations, hosting and application management, user training, and 24x7 global support. Clients looking to bring applications directly into their enterprise can also leverage Oracle Health Sciences' full range of mentoring programs, training offerings, and implementation services to transfer knowledge in-house.



An EDC solution must provide the right level of functionality and services to successfully implement clinical studies and meet the specific needs of different organizations—while also maintaining reasonable costs. Oracle Health Sciences InForm GTM sets the standard for EDC solutions by allowing companies to streamline the capture, analysis, and management of clinical data.

CONTACT US

For more information on Oracle Health Sciences InForm GTM, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.

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Visit oracle.com/corporate/contact/global.html to find the phone number for your local Oracle office.



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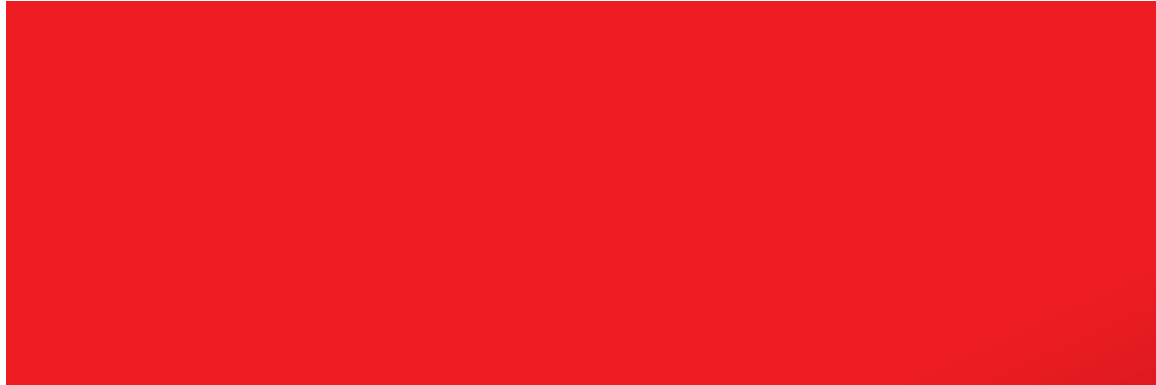
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