POWERING CLINICAL STUDIES WITH ORACLE CLINICAL

ORACLE HEALTH SCIENCES

ORACLE CLINICAL PROVIDES SPONSORS AND CROS A SINGLE APPLICATION AND INFRASTRUCTURE FOR EDC AND CDMS BUILT ON PROVEN TECHNOLOGY FOR SCALABILITY. BENEFITS INCLUDE:

- IMPROVED SITE PRODUCTIVITY AND OPERATIONAL EFFECTIVENESS
- LOWER COST OF OWNERSHIP
- TECHNOLOGY ENABLEMENT TO MAXIMIZE THE IT INVESTMENT

More than 250 pharmaceutical, biotechnology, medical device, and contract research organizations have relied on Oracle Clinical to conduct more than 10,000 clinical trials, making it a proven clinical research solution. Oracle Clinical's operational effectiveness, lower cost of ownership and technology enablement increase ROI with each study.

Oracle Clinical and Oracle Remote Data Capture provide a single application and infrastructure for electronic data capture and clinical data management, while leveraging the renowned Oracle database. Oracle Clinical enables management of all clinical trial data in a single system, improving accuracy, visibility, and data integrity.

Improved Operational Efficiency and Productivity

Oracle Clinical improves operational efficiency with full support for modeling flexible studies where users can incorporate complex trial design scenarios. These could include multiple treatment arms with different assessment schedules, multiple randomization points, and repeating treatment cycles, all defined by rules through the study definition interface. The system also provides the ability to define multiple potential pathways a patient might take through a complex study.

Oracle Clinical's ability to easily model flexible trials provides a significant reduction in time and costs to set up a complex trial.
Oracle Clinical' global library enforces standards and consistency throughout. It supports electronic data capture and hybrid studies by using the same study definitions and page layouts for both electronic and paper environments. Streamlined study management functionality allows staff to assign multiple patients to a study book, while also providing complete control over protocol amendments. The rollout of amendments to sites can now be carefully staggered and scheduled in accordance with local regulatory timelines. It is designed to provide a seamless experience for sites to capture and process clinical data.

Lower Total Cost of Ownership

Oracle Clinical is the only clinical data management solution that is fully integrated with a front-end electronic data capture system – Oracle Remote Data Capture. Because it shares its data model with Remote Data Capture, users have access to a single study definition, allowing them to design, build, and validate a study only once. Centralized data management means that data can be entered into either system, and all of the data can be accessed in both Oracle Clinical and Remote Data Capture.

This single application and infrastructure for EDC and CDMS lowers the cost to own and operate a clinical data management system.

Technology Enablement Reduces Risk and IT Burden

Oracle Clinical is built on the latest Oracle database technology, delivering superior performance across all clinical trials and reducing risk from technology changes. A zero-footprint client to enable ease of site deployment and uptake. Oracle Clinical provides maximum system uptime and availability to ensure continuous operations and security of clinical

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**TECHNICAL
SPECIFICATION:**

Database Server:
Oracle11gR1, Sun
Solaris (64-bit), HPUX
Itanium (64-bit),
Windows 2003 Server

Middle Tier: Oracle
AS10gR2 Application
Server, Windows 2003
Server

Client: Internet Explorer
7, Windows Vista,
Windows XP, Windows
2000, Windows 2003

data.

Its proven scalability and performance has helped life sciences organizations successfully conduct thousands of clinical studies. These have included studies across all development phases and vast patient populations, with submissions approved across many therapeutic areas and geographies.

Oracle Clinical Capabilities

Study Design and Management: With the study design and management subsystem, users can design protocols and amendments as well as specify how patient data is tracked. The protocol design includes study objectives, investigator and site information, enrollment plans, drug treatment regimens, randomization schedules, and visit definitions. Oracle Clinical features sophisticated site, patient, and visit tracking to:

- Assign and maintain information on investigators and sites
- Visualize the planned, projected, and actual patient enrollment and study timelines
- Develop detailed visit schedule specification and tracking, including the identification of missing and late case report forms (CRFs)
- Manage and track treatment blind breaks
- Track patient availability and withdrawal information
- Insert amendments transparently within minutes by adding values through quick picks and removing attributes by selecting a "do not collect" box, with no recompiling or copying of objects required

Study Data Definition: The study data definition subsystems enable a single study to be defined and conducted at several worldwide locations concurrently with minimal additional effort. The essential subsystems include global library management, study data definitions, a data validation facility, and lab reference range management.

Study Conduct and Validation: Obtaining "clean" data is faster and simpler with Oracle Clinical. You can capture and edit data plus edit the screen layout to parallel the CRF layout. Oracle Clinical's unique data validation dramatically reduces time spent identifying and finding data problems via a library of procedures that can be used and reused continually. During this process, each data problem identified creates a discrepancy record that can be tracked and summarized. Data, validation checks, and discrepancies are all synchronized so changes made to any unique component are automatically reflected in all areas of the system. Oracle Clinical also supports the data clarification form (DCF), which enables customized report creation and submission to external sources such as investigators.

Data Access and Reporting: Oracle Clinical stores all data results in a universal format. For example, for a company conducting 10 clinical trials and collecting 30 different modules/types of data per trial, Oracle Clinical makes it possible to manage a stable structure with predefined tables, rather than 300 separate tables (30x10).

This universal format means that study setup, data collection, and data extract do not require specialist database design skills. Users can also:

- Automatically create views corresponding to each CRF and automatically extract data into SAS for analysis
- Create custom views combining data from multiple CRFs
- Create various data snapshots for interim analysis during normal data processing
- Query the data through an online query facility
- Include locked or frozen data, as well as discrepancy status information, in extracted data

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The Oracle Difference

Oracle's combination of data management and health science domain expertise offer significant benefits to the industry. Because Oracle understands every aspect of clinical data management in a changing market, Oracle Clinical can help organizations create solutions for their particular data management and business challenges.

Oracle's commitment to the health sciences has resulted in acknowledged leadership and vision. Oracle Health Sciences includes a dedicated organization of consultants and technical support personnel worldwide as well as partnerships with other industry leaders.

Reduce project risk and cost with Oracle Consulting Services

Consultants from Oracle Health Sciences are part of a global consulting organization with extensive domain expertise and in-depth experience implementing Oracle's health care and life sciences solutions. Oracle's consultants complement Oracle Health Sciences products to provide a comprehensive solution. They can help organizations:

- *Reduce project risk and improve quality* with Oracle's distinctive resources and expertise
- *Lower total cost of ownership* with Oracle's complete solution
- *Realize faster time to business value* by leveraging Oracle's unique library of consulting assets and accelerators

Oracle Health Sciences' consultant team is 100% dedicated to Oracle Health Sciences products and have many years of experience implementing these healthcare and life sciences solutions. It is composed of a global team of product experts who leverage their close ties to Oracle's product strategy and development teams, utilize standard Oracle methodologies (OUM aware and certified), participate in numerous international standards-setting bodies (such as HL7 steering committee, CDISC), and embrace a partner-friendly strategy. All while backed up by the power of Oracle Corporation's global consulting organization. Oracle Health Sciences consultants are uniquely positioned to ensure project success.

Contact Us

For more information about Oracle Clinical, please visit the Oracle Health Sciences applications website or call your local Oracle office or +1.650.506.7000 to speak to an Oracle representative.

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