

# ORACLE CLINICAL

## ORACLE<sup>®</sup> HEALTH SCIENCES

- Smoothly transitions from paper to electronic data capture trials
- Annotated CRFs provide intuitive means of creating submission-ready annotations
- Improved randomization, leveraging the built-in functionality of the Oracle database
- Built-in automated test environment
- Accepts CDISC-compliant transactions
- Provides customizable information flex fields in CRF header/footer
- Extends existing audit trail features to ensure industry compliance
- Data extract provides denormalized, easy-to-read view of study data
- Industry-proven and backed by the world's leading application software company

*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 the market-leading clinical research solution. Oracle Clinical's scalability, ease of implementation, and built-in compliance increase your return on investment with each study you initiate.*

### Industry Challenges

In the past decade, the pharmaceutical industry has encountered many new challenges. The industry has seen an increase in competition, safety concerns, generic drug manufacturers, prescription substitution, and consumer and market sophistication, combined with ongoing trends such as globalization, outsourcing, consolidation, and unrelenting demand for new products. In addition, the industry must comply with increasingly stringent regulatory guidelines and government controls on prescriptions and pricing.

Today's successful companies are exploiting advances in genetic sciences, combinatorial chemistry, and high-throughput screening to discover more lead compounds than ever before. This inevitably increases the pressure on clinical development and poses a constant challenge to keep up with the pace of change.

**Globalization:** Globalization of clinical trials means even greater complexity, especially in data management. Expediting the multinational regulatory process without sacrificing quality is critical. For clinical data to be defined, managed, and interpreted consistently worldwide, companies must be able to standardize, disseminate, and control data definitions across concurrent global operations.

**Flexibility:** All clinical trials organizations require flexible and scalable applications for high-integrity information management. Oracle Clinical works for all organizations that conduct clinical trials, enabling them to conduct trials according to their own specific needs.

**Efficiency:** With Oracle Clinical, organizations gain a competitive advantage in that they can integrate their existing information resources and attract established and complementary solution partners.

**Competition:** Competition today requires organizations to seek business efficiencies but also to fundamentally change the research process itself. This requires the ability to improve product development cycles and reduce product time to market.

### Faster Time to Market

Organizations must also fundamentally change the way they contribute value to the

information surrounding the process of bringing new drugs and therapies to market. The sophisticated Oracle Clinical solution helps you get to market faster in a complex business and regulatory environment. Focused on providing superior functionality, improved operational efficiencies, and lower information management costs during the product clinical trials cycle and regulatory approval processes, Oracle Clinical delivers a significant time-to-market advantage. Leveraging the inherent advantages of Oracle's database, tools, industry-specific solutions, consulting services, and technical support, Oracle Clinical further helps speed your time-to-market cycle while reducing costs.

### **Oracle's Vision and Leadership**

Oracle provides the best and most comprehensive solutions to meet clinical research needs. We maintain a separate product development organization for pharmaceutical applications, providing a single point of accountability and ensuring that Oracle Clinical continues to address evolving industry needs. In addition, our commitment to continued leadership and delivering stellar global support includes a dedicated organization of consultants and technical support personnel worldwide as well as partnerships with other industry leaders.

### **A Strategic Partnership**

Oracle's guiding principle in this market is flexibility. When you implement Oracle Clinical, you've done more than install a piece of technology – you've integrated a comprehensive business solution that will satisfy your present requirements and scale to meet your future needs.

### **The Solution**

Oracle Clinical's combination of broad coverage and deep functionality offers unmatched benefits. And 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.

**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. You 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
- Execute more than 70 parameter-driven reports immediately or in batch mode, allowing users to monitor and track information in a flexible, user-friendly environment with online preview before printing

### Elements of the Oracle Solution

**Technical Support:** Oracle offers 24x7 technical support with analysts recruited from the industry who have in-depth knowledge of Oracle Clinical.

**Consulting Services:** Oracle has professional consultants dedicated to the pharmaceutical, biotechnology, medical device, and clinical research industries. They are experienced in rapidly and successfully implementing Oracle Clinical in a wide range of business situations.

**KEY BENEFITS**

Oracle Clinical enables organizations to design, implement, and conduct clinical research in a safe and compliant manner.

**RELATED PRODUCTS AND SERVICES**

Oracle products that can be used with Oracle Clinical as part of your clinical research application solution:

- Oracle Discoverer
- Oracle Adverse Event Reporting System
- Oracle Thesaurus Management System
- Oracle Remote Data Capture
- Oracle SiteMinder
- Oracle TrialMinder

Hundreds of Oracle Clinical customers have relied on Oracle Consulting to implement and validate their Oracle Clinical solutions.

**TECHNICAL SPECIFICATION**

- Database Server: Oracle9i (9.2.0.6), Sun Solaris, HP-UX PA-RISC, Windows 2000 Server, Windows 2003 Server
- Middle Tier: Oracle9i Application Server/Oracle Application Server 10g, Oracle Portal, Windows 2000 Server, Windows 2003 Server
- Client: Internet Explorer 5.5 or later, Windows XP, Windows 2000

**Customer Education:** With sales, consulting, support, and educational personnel, Oracle is dedicated to delivering value and industry solutions for our clients on a global basis. Oracle offers several education courses covering the full range of Oracle Clinical's functionality.

**User Group Participation:** Oracle Clinical users can subscribe to a user group that provides feedback, suggests enhancements, and recommends direction for future product development.

**Key Component in the Integrated Oracle Clinical Research Suite**

Oracle Clinical is the core of an integrated suite of clinical research solutions that also includes systems for adverse event reporting, thesaurus management, electronic data capture, and clinical trial management. The integrated nature of Oracle Clinical lets you manage all of your clinical trial data in a single system, improving accuracy, visibility, and data integrity.

**Seamless Transition from Paper-Based to Electronic Data Capture**

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 (RDC). Because it shares its data model with RDC, you design, build, and validate your study only once. Data can be entered into either system, and all of the data can be accessed in both Oracle Clinical and RDC.

**Enhanced Graphic Layout Editor: Build PDF Screens**

The 'Graphical' Oracle Clinical Layout Editor (GLE) provides the ability to generate layout-enhanced data collection forms rendered in PDF format. The GLE can be leveraged to use the same CRFs in paper-based and electronic data capture studies, making Oracle Clinical and Oracle Remote Data Capture the strongest solution in the market for hybrid studies.

**Create Annotated CRFs**

Oracle Clinical provides the powerful capability to create annotated CRFs. The CRF annotation tool enables you to select from an extensive set of metadata information (e.g., question name, SAS name, CRF name), create successive copies of a CRF with different metadata, and save each as a separate PDF file.

**Contact Us**

For more information about Oracle Clinical, please visit [http://www.oracle.com/industries/health\\_sciences/index.html](http://www.oracle.com/industries/health_sciences/index.html) or call +1.800.ORACLE1 to speak with an Oracle representative.

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