ORACLE CLINICAL

OVERVIEW

ROBUST CLINICAL DATA MANAGEMENT SOLUTION

- Smoothly transition from paper to EDC trials
- Annotated CRFs – provides an intuitive means of creating submission-ready annotations
- Improved randomization – leverage the built-in functionality of the Oracle Database
- Built-in automated test environment
- Accept CDISC compliant transactions
- Flex fields - provide customizable information fields in header/footer of CRFs
- Auditing – extends existing audit trail features to ensure industry compliance
- Data Extract - denormalized, easy-to-read view of study data
- Industry Proven
- Backed by the world's leading application software company

More than 200 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 and consolidation. 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 greater complexity, especially in data management. The key issue is expediting the multinational regulatory process without sacrificing quality. For clinical data to be defined, managed and interpreted consistently worldwide, companies need to 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 and allows individual organizations to conduct trials according to their own 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 companies not only to seek business efficiencies, but also to fundamentally change the research process itself. Pharmaceutical, biotechnology, medical device and clinical research organizations must respond by improving product development cycles and reducing product time-to-market. Your competitors face the same issues. Who will solve them first? Who will survive?

Faster Time to Market

Competition in the pharmaceutical, biotechnology, medical device and clinical research industries today requires more than just improved business efficiencies. Companies in these industries must fundamentally change the way they add value to the information that supports the process of getting new drugs and therapies to market. Oracle Clinical is a sophisticated solution that helps you meet your biggest challenge: how to get to market faster in today's complex business and regulatory environment. Oracle Clinical is focused on providing superior functionality, improved operational efficiencies, and lower information management costs during the process of getting a product through the cycle of clinical trials and regulatory approval. Oracle Clinical is the solution to your clinical data management demands, using the inherent advantages of Oracle's database, tools, industry-specific solutions, consulting services and technical support to help you accelerate and lower the costs of your time-to-market cycle. With Oracle Clinical, you gain a significant time to-market advantage that allows you to cope with the increasing pressures of new competitors, generic drug manufacturers, outsourcing, consolidation and the unrelenting demand for new products.

Oracle's Vision and Leadership

Oracle has organized its clinical research business to provide the best and most comprehensive solutions possible for the companies that face these pressures. We maintain a separate product development organization for pharmaceutical applications. This gives customers a single point of accountability and ensures that Oracle Clinical continues to meet the industry's evolving business needs. We are fully committed to providing high quality global support with a dedicated organization of developers, consultants, and technical support personnel worldwide. We continue to extend our solution by developing other product modules and by building partnerships with industry leaders to ensure our continued leadership.

A Strategic Partnership

When you implement Oracle Clinical, you've done more than install a piece of technology – you have integrated a comprehensive business solution designed to meet your requirements for faster time-to market, improved business processes, streamlined operations, and reduced costs. And not just for today. Oracle's guiding principle in this market is flexibility, providing solutions that can satisfy your present requirements and scale to meet your future needs.

The Solution

Because Oracle understands every aspect of clinical data management in a changing market, Oracle Clinical can help organizations create solutions for their specific data management and business challenges. Its combination of broad coverage and deep functionality offers unmatched benefits in all aspects of clinical data management.

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. No recompiling or copying of objects is 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 and edit the screen layout to parallel the CRF layout. Oracle Clinical’s unique data validation dramatically reduces the time spent identifying and finding data problems. This is accomplished through 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 that when a change is made to any unique component, the system automatically reflects the change in all areas. Oracle Clinical also supports the Data Clarification Form (DCF), which enables customized reports to be created and sent to an external source such as an investigator.

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 (30 x 10). This universal format means that study set-up, 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 You can execute more than 70 parameter-driven reports immediately or in batch mode, to allow users to monitor and track information in a flexible, user friendly environment. You can also preview the reports on-line before printing.

Elements of the Oracle Solution

Technical support

Oracle offers 24 x 7 technical support from 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.

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 including an adverse event reporting system, thesaurus management system, remote data capture system, and clinical trial management system. 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 CDMS solution that is fully integrated with a front-end EDC 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 in either system and all of the data can be accessed in both OC and RDC.

Enhanced Graphic Layout Editor – build PDF screens

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

Create Annotated CRFs

Oracle Clinical now provides the powerful capability to create annotated CRFs. The CRF Annotation Tool enables you to select from an extensive set of metadata

KEY BENEFITS

Oracle Clinical allows customers to design, implement, and conduct clinical research in a manner that is safe and compliant.

RELATED PRODUCTS

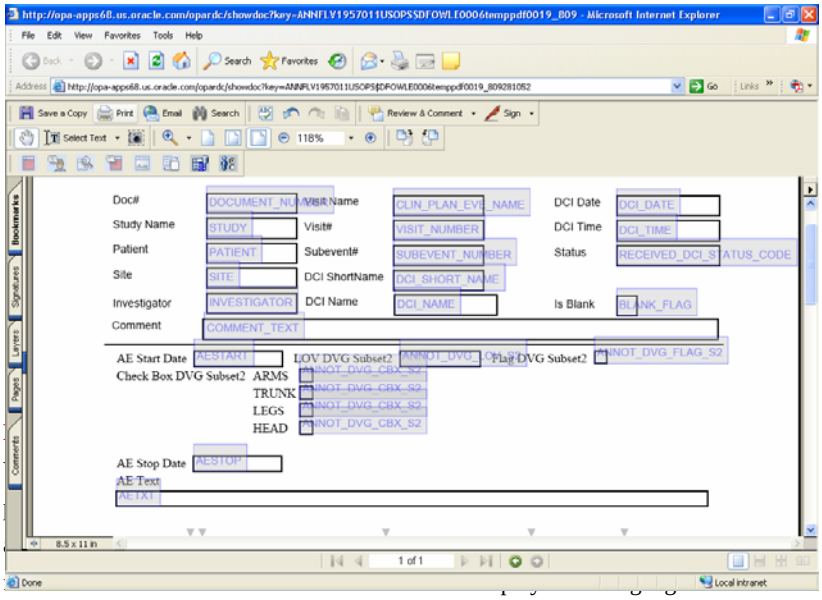
Oracle products that can be used with Oracle Clinical as part of your Clinical Research Application solution:

- Oracle Discoverer
- Oracle AERS
- Oracle TMS
- Oracle RDC
- Oracle SiteMinder
- Oracle TrialMinder

RELATED SERVICES

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

information (Question Name, SAS name, or CRF Name), create successive copies of a CRF with different metadata, and save each as a separate PDF file.



Technical Specification

Database Server	Oracle9*i* (9.2.0.6) Sun Solaris HP-UX PA-RISC Windows 2000 Server Windows 2003 Server
Middle Tier	Oracle9*i* Application Server/Oracle Application Server 10*g* Oracle Portal Windows 2000 Server Windows 2003 Server
Client	Internet Explorer 5.5 or later Windows XP Windows 2000

Copyright 2006 Oracle. All Rights Reserved.

This document is provided for information purposes only, and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor is it subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. We specifically disclaim any liability with respect to this document, and no contractual obligations are formed either directly or indirectly by this document. This document may not be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without our prior written permission.

Oracle, JD Edwards, and PeopleSoft are registered trademarks of Oracle Corporation and/or its affiliates. Other names may be trademarks of their respective owners.