

ORACLE HEALTH SCIENCES CLINICAL DEVELOPMENT CENTER

KEY BENEFITS

DATA MANAGEMENT BENEFITS

- Provides a single system for storing, integrating, preparing and analyzing clinical information
- Simplifies workflow complexities among collaborators and partners
- Provides a single location for discrepancy management across sources
- Automates system setup and data delivery
- Provides out-of-the-box integration with Oracle Health Sciences InForm GTM
- Streamlines validation, reconciliation, review, and transformation of data sets
- Manages information flow more efficiently
- Consolidates overall data integrations
- Streamlines standards support and regulatory compliance

STATISTICAL BENEFITS

- Provides a single system for analyzing all clinical information
- Optimizes statistical analysis by leveraging end-to-end traceability and control
- Facilitates understanding of all upstream and downstream dependencies
- Allows executives to make decisions based on the latest information
- Reduces the time it takes to collect, rerun or replicate analyses
- Streamlines the submission readiness process
- Optimizes the process workflow for storing, integrating, and analyzing data

Oracle Health Sciences Clinical Development Center provides a centralized environment for storing and integrating all clinical data as well as a controlled solution for automating and managing analysis, reporting, and submission.

One System to Integrate, Manage, and Analyze Clinical Information

The amount of electronic information generated to bring a new drug or device to market continues to grow, and as a result, the processes for storing, integrating, preparing, and analyzing information from multiple collaborators and partners have become increasingly complex. It is difficult to maintain complete traceability between the continual flow of new information and analysis results. The companies able to optimize and harmonize these process workflows in a controlled, traceable environment will be able to see their operational efficiency improve and their regulatory requirements more effectively met.

- **Oracle Health Sciences Clinical Development Center, Data Management Environment.**
A secure and managed environment for receiving, integrating, transforming, and storing clinical data, information, and standards.
- **Oracle Health Sciences Clinical Development Center, Statistical Control Environment.**
A controlled solution to automate and track the statistical analysis process, providing end-to-end traceability of data, analysis, and reports.

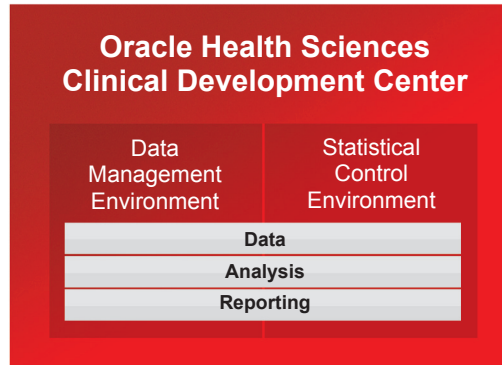


Figure 1. Oracle Health Sciences Clinical Development Center includes two components: a data management environment and a statistical control environment.

Data Management Environment

As the volume of scientific data continues to grow, integrating electronic data capture (EDC), electronic patient reported outcomes (ePRO), labs, trial supply information, images, and other data sources into a single centralized system can help reduce the time and effort involved in delivering analysis-ready data. When linked to a statistical control environment, it can smooth the hand-off to biostats, enabling in-stream safety monitoring and rapid mid-study decisions.

DATA INTEGRATION AND VERSION CONTROL

Key data integration and version control features include:

- Out-of-the-box integration with Oracle Health Sciences InForm GTM for data handling
- Automated data load and execution triggers for hands-off data refresh
- Status flag recording for review progress tracking
- Project metrics and management dashboard
- Supports studies in any language

Data Integration and Version Control

The Data Management Environment is designed to handle data, files, programs, and documents for all trials within one central environment. The system provides data model libraries to enforce standards and accelerate study setup. In addition, the Data Management Environment provides out-of-the-box integration with Oracle Health Sciences InForm GTM, which helps automate system setup and data delivery (including queries and CRF status information) and provide direct links to data sources. Other third-party integrations are supported through automated schema setup and data load conformance checking.

The Data Management Environment also helps automate the data import process and provides complete traceability between related objects managed by the system. Objects and relational datasets are versioned, and snapshot capabilities ensure full traceability.

Simplify and Automate Tasks with a Metadata-Driven System

As a metadata-driven system, the Data Management Environment helps simplify database setup, provides end-to-end traceability, and assists with the automation of repetitive tasks. Capturing every data handoff, data change, and data point association, the Data Management Environment provides automated data loading, intelligent cumulative file handling, plus triggered and scheduled job execution so organizations can effectively track the continual flow of new information and improve overall data quality and integrity.

Validate, Review, and Transform Imported Data Sets

Clinical data can be derived from a wide variety of sources and formats (including SAS, ASCII, and XML data sets). The Data Management Environment allows organizations to validate, reconcile, review, update, transform, organize, and track information in a single centralized environment. The system enables users to manage and reconcile source data by raising discrepancies, and flagging review progress. Data sets can be easily reviewed using the built-in drag-and-drop data browser. In addition, plug-ins are included for applications such as SAS, Excel, Spotfire, I-Review, and J-Review so that the entire process—including cleaning and reviewing—can be supported from within one environment. Data can also be converted to and from SAS data sets to Oracle data structures on a scheduled basis. This includes generating standard views such as CDISC's SDTM standard.

Multi-Stakeholder Access and Collaboration

The security model employed by the Data Management Environment allows controlled access to objects stored within the data repository. This facilitates and safeguards the sharing of sensitive information among various groups such as partners and collaborators, including data management, biostats, and CROs. The information stored in the data repository tables can be accessed based on relevant business needs.

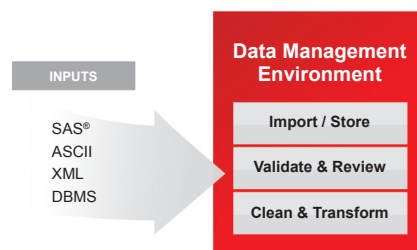


Figure 2. The data repository allows controlled access to objects stored within it.

KEY FEATURES

CLINICAL DATA REPOSITORY

A centralized and secure, repository for storing, transforming, managing, and integrating clinical data, under full traceability, and, control. Organizations, across all sources, can:

- Query and review data, manage, and reconcile discrepancies
- Receive data blinding support
- Transform data to any corporate or industry standard
- Benefit from an open environment for working with SAS and S+

STATISTICAL CONTROL ENVIRONMENT

Automation, management, and control of statistical analysis and reporting. Key features include:

- Configurable development and output quality control steps
- Output staleness detection
- Program library support and multiple parameter passing options
- Pooled program execution servers

Statistical Control Environment

Today’s regulatory reviewers want to verify results and assess the robustness and validity of collected data. To effectively scale, biostats groups must efficiently develop and reuse statistical analysis routines in an environment that ensures full accountability and traceability

By leveraging program and macro libraries that have progressed through a formal development and quality control process, new study teams can reduce setup time using validated corporate standards. Once in place, statisticians need to confirm that all outputs are generated on the latest data and correct program versions, while also meeting regulatory requirements more efficiently.

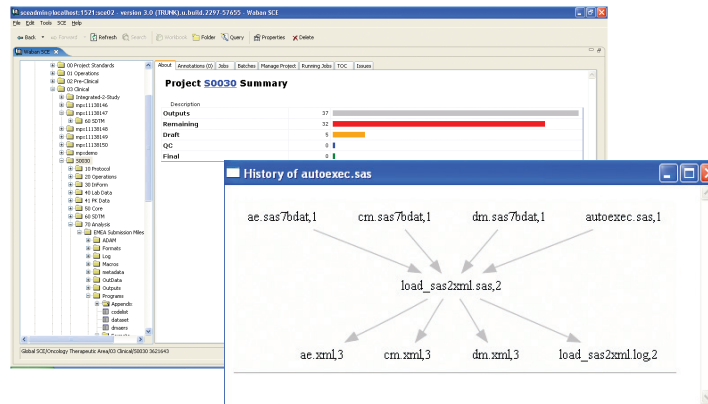


Figure 3. By selecting a task in Oracle Health Sciences Central Designer, users directly access the area to be worked on.

Enjoy End-to-End Traceability and Control

Oracle Health Sciences Clinical Development Center, Statistical Control Environment delivers complete system control and end-to-end traceability in a single environment. In addition to providing full user access control with complete versioning and auditing capabilities, the environment automatically tracks all data, Statistical Analysis Plan (SAP) specifications, programs, macros, and outputs to provide detailed dependency relationship links that users can view graphically. These dependency relationships can also be generated in reports so they can be deposited into a document management system—making it easy for bio-statistical groups to manage, check, and document their work.

Because Oracle Health Sciences Clinical Development Center, Data Management Environment can create a snapshot of the clinical data repository at any given point in time, users can reproduce results based on earlier data. This allows users to include data that was available at the time the conclusion was drawn and submitted to regulatory authorities. The “as-of” processing gives organizations the ability to quickly and easily respond to regulatory requests during the critical period of regulatory review.

Reduce the Time It Takes to Collect, Rerun, or Replicate Analyses

Oracle Health Sciences Clinical Development Center, Statistical Control Environment includes the ability to define the outputs for any planned or ad hoc study reporting event. Statisticians can define the required tables, listings, and graphs and then track the status of the supporting programs being developed. The Statistical Control Environment automatically flags when outputs are stale based on input or program version changes, so the statistician knows to rerun the program.

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 that can scale to 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 for additional flexibility.

RELATED PRODUCTS

Related Oracle Health Sciences products include the following:

- Oracle Health Sciences InForm GTM
- Oracle Health Sciences OutcomeLogix On Demand
- Oracle Health Sciences Safety Solutions

Access the Most Up-to-Date Information

Providing real-time status updates for data and information contained within the environment, Oracle Health Sciences Clinical Development Center, Statistical Control Environment lets users know if study components such as tables, listings, and figures are “up-to-date” or “stale.” And because the system tracks and manages the dependencies between related elements in a study and takes snapshots over time, users have constant access to both current and historical information. As a result, decision makers are able to act on the latest information.

Streamline Submissions

Any organization submitting a new drug application has to produce analysis and supporting data for its regulatory submissions. Typically, this is the last step in the analysis and submissions process—and it’s performed manually, representing a significant manpower and time investment near the submissions deadline.

Not surprisingly, incomplete or inaccurate documentation accompanying such a submission can result in delays as regulatory authorities seek clarifications and supplemental submissions. Companies can greatly streamline this process by using automation and technology to ensure that timely and accurate documentation accompany the submission. To this end, Oracle Health Sciences Clinical Development Center, Statistical Control Environment can create Define.pdf and Define.xml; it also enables the publication of objects such as PDF reports to Documentum, LiveLink, and other electronic document management systems.

Streamlined Implementation

To successfully deploy a clinical data repository and statistical development environment, companies need to adopt new processes and technologies across multiple groups within their organizations. Unlike solutions from other providers—which can take many months to deploy and employ multiple baseline technology components in “custom” solutions created primarily from scratch by costly consultants—Oracle Health Sciences Clinical Development Center can be installed in as little as a day. And because the system can be set up using pre-existing templates, organizations can begin interacting with it immediately and configuring it to meet their process needs.

Contact Us

For more information about Oracle Health Sciences Clinical Development Center, visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.

 | Oracle is committed to developing practices and products that help protect the environment

Copyright © 2011, Oracle and/or its affiliates. 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 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 and Java are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

AMD, Opteron, the AMD logo, and the AMD Opteron logo are trademarks or registered trademarks of Advanced Micro Devices. Intel and Intel Xeon are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. UNIX is a registered trademark licensed through X/Open Company, Ltd. 0211

Hardware and Software, Engineered to Work Together