

ORACLE LIFE SCIENCES DATA HUB

KEY FEATURES

- Provides clinical and operational data reporting
- Helps to ensure analyses and reports comply with regulatory requirements
- Enables comprehensive auditing of all programs, data, and reports
- Built to work with various analytics/visualization tools
- Offers workflow standardization for analysis and reporting
- Supports various standards such as SDTM and JANUS
- Provides out-of-the-box integration with Oracle Clinical

KEY BENEFITS

- Better regulatory compliance with comprehensive security, an audit trail, and traceability
- More-informed decision-making through pooling and analysis of clinical and nonclinical data
- Improved R&D efficiency by enabling the use of standards

INTEGRATED DATA FROM MULTIPLE SOURCES IN A SINGLE ENVIRONMENT

- Electronic data capture
- Clinical data management
- PK/PD modeling
- E-PRO
- Laboratory
- Safety/pharmacovigilance
- Contract research
- Drug supplies
- Trials management
- Legacy systems

Oracle Life Sciences Data Hub is an integrated, controlled environment for clinical data that enables life sciences organizations to make informed decisions based on more-accurate and timely information. It enables pooling of clinical and nonclinical data from multiple sources into a single environment where it can be holistically analyzed and reported to support informed decision-making and regulatory submissions. Oracle Life Sciences Data Hub promotes the use of standards to facilitate increased R&D efficiency, while ensuring regulatory compliance with comprehensive security, an audit trail, and traceability. Oracle Life Sciences Data Hub provides a robust, extensible platform with public APIs and development tools that can be used as a strong foundation upon which to build a clinical data warehousing strategy across the wider enterprise.

Enable Global Regulatory Compliance

Life sciences organizations must ensure they are compliant with global regulations as well as open and responsive to regulatory requests. As regulators adopt more-iterative review cycles, the number of inquires continues to increase. Companies depend on Oracle Life Sciences Data Hub to help manage compliance requirements in a timely and proactive manner.

Oracle Life Sciences Data Hub is a validated and secure repository for safety, clinical, and nonclinical data. Strict version control and security profiles in this controlled environment provide full traceability for data and programs, allowing every interaction with the data to be traced from source to submission, with a fully maintained audit trail. Utilizing features such as snapshots, “as of” time stamps for data, and program versions, the exact environment that existed at some desired point in the past may be re-created. To help support ongoing regulatory reviews, Oracle Life Sciences Data Hub has an advanced classification system for indexing and searching programs and outputs to ensure the right report is retrieved each time.

With Oracle Life Sciences Data Hub, organizations can reliably react to regulatory inquiries with confidence in not only the speed of the response, but also in the data standards that ensure high-quality responses.

Gain Better Insight Into Data for Informed Decision-Making

A complex array of systems and technologies for functions including research, development, surveillance, analysis reporting, and financial reporting create isolated information silos. Oracle Life Sciences Data Hub moves beyond the silos to deliver holistic views of internal and partner data for better decision-making. This single source of truth supports the acquisition and management of data from multiple studies and data sources into a single, compliant infrastructure for data access, transformation, persistence, and distribution.

Importantly, Oracle Life Sciences Data Hub supports structured business processes for integrating clinical, preclinical, and safety data. It has an open architecture to interface with commonly used transactional systems and technologies to facilitate data acquisition as well as an open API to build additional integrations as needed. Using advanced workflow (including notifications and approvals) and API features, companies can build appropriate automation to support their specific business processes and needs.

In addition, Oracle Life Sciences Data Hub enables organizations to adopt existing and emerging data standards and benefit from tools and methods associated with those standards. Data in multiple standards (such as CDISC CDASH, CDISC SDTM, JANUS, etc.) can coexist and interoperate with companywide and therapeutic area standards. Data can be transformed to a common standard and pooled to enable standardized reporting and analysis.

Oracle Life Sciences Data Hub uses Oracle's technology architecture making it very reliable and highly scalable. It supports multiple technologies (including Informatica, SAS, and R) to enable data integration and analysis. Several data visualization tools widely used in the industry (I-Review/JReview, Spotfire, and Oracle Business Intelligence Enterprise Edition) are also supported. Using APIs and an open architecture, these capabilities can be extended to other tools as needed.

The integration and aggregation of data can be used to provide clear business intelligence to drive portfolio decisions and reduce the risks inherent in conducting a clinical research program. Whether making decisions for adaptive clinical trials based on predetermined milestones or comparing financial, safety, efficacy, and progress information on a clinical program with comparator and outcomes data, Oracle Life Sciences Data Hub provides the infrastructure and tools to support decision-making.

Improve R&D Efficiency

Oracle Life Sciences Data Hub can help improve R&D efficiency by streamlining business processes around the acquisition, analysis, and reporting of data via workflow capabilities including:

- Business process simplification
- Automated business processes
- Business process coverage

Oracle Life Sciences Data Hub also reduces the overall cost of IT systems ownership by replacing multiple analytical systems with a single integration and reporting system for the entire clinical development organization. The consolidation of data enables the retirement of legacy systems, freeing IT to focus and support more-critical systems.

In addition, the repositories are designed and maintained by business users, such as clinical programmers and statistical programmers, without the need for IT specialists to build, validate, and generate data repositories and reports. Simplified clinical integration means that organizations can integrate and extract value from new data sources without the need for complex IT projects.

ORACLE LIFE SCIENCES DATA HUB TECHNICAL SPECIFICATIONS

APPLICATION SERVER

- Oracle Solaris, AIX, HP-UX PA RISC, or Linux x86
- Oracle Application Server 11g Release 2
- Oracle Reports
- Oracle Business Intelligence Enterprise Edition
- Oracle Workflow

DATABASE SERVER

- Oracle Solaris, AIX, HP-UX PA RISC, or Linux x86

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 healthcare and life sciences solutions. Oracle's consultants complement the 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 consultants have many years of experience implementing Oracle's healthcare and life sciences solutions. The team is composed of global 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 and CDISC), and embrace a partner-friendly strategy all while backed by the power of Oracle's global consulting organization. Oracle Health Sciences consultants are uniquely positioned to ensure project success.

Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences provides you with the industry's most comprehensive set of software solutions addressing every aspect of the health value chain from discovery to care delivery. With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization's goals today and in the future.

Contact Us

For more information about Oracle Life Sciences Data Hub, visit oracle.com/healthsciences, e-mail healthsciences_ww_grp@oracle.com, or call +1.800.633.0643 to speak to an Oracle representative.



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Hardware and Software, Engineered to Work Together