

# LIFE SCIENCES DATA HUB FROM ORACLE HEALTH SCIENCES



Oracle's Life Sciences Data Hub is an integrated environment for all clinical data. Benefits of Life Sciences Data Hub include:

- Better Regulatory Compliance
- More Informed Decision Making
- Improved R&D Efficiency

*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. 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.*

## Enabling Global Regulatory Compliance

Life sciences organizations must ensure that 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 inquiries continues to increase. Companies depend on Life Sciences Data Hub to help manage compliance requirements in a timely and proactive manner.

Life Sciences Data Hub is a validated and secure repository for safety, clinical and non-clinical 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' timestamps for data, and program versions, the exact environment that existed at some desired point in the past may be recreated. To help support ongoing regulatory reviews, 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.

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

## CAPABILITIES

- Report on clinical and operational data
- Ensure analyses and reports comply with regulatory requirements
- Comprehensive auditing of all programs, data, and reports
- Built to work with various analytics/visualization tools
- Workflow standardization for analysis and reporting
- Support for various standards such as SDTM and JANUS
- Out-of-the-box integration with Oracle Clinical

## 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. 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, Life Sciences Data Hub supports structured business processes for integrating clinical, pre-clinical, 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

**INTEGRATED DATA FROM MULTIPLE SOURCES IN A SINGLE ENVIRONMENT**

- Electronic Data Capture
- Clinical Data Management
- PK/PD Modeling
- ePRO
- Laboratory
- Safety / Pharmacovigilance
- Contract Research
- Drug Supplies
- Trials Management
- Legacy

appropriate automation to support their specific business processes and needs.

In addition, Life Sciences Data Hub enables organizations to adopt existing and emerging data standards and to 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 company-wide and therapeutic area standards. Data can be transformed to a common standard and pooled to enable standardized reporting and analysis.

Life Sciences Data Hub is built using 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 OBIEE) 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, Life Sciences Data Hub provides the infrastructure and tools to support decision making.

**Improving R&D Efficiency**

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

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.