

ORACLE LIFE SCIENCES DATA HUB



- Integrate clinical data from multiple sources:
 - Electronic data capture
 - Clinical data management systems
 - PK/PD modeling
 - Laboratory
 - ePRO
 - Safety
 - Contract research
 - Drug supplies
 - Trials management
 - Legacy
- 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 SAS and other analytics/visualization tools
- Workflow standardization for analysis and reporting
- Support for emerging standards such as CDISC ODM and SDTM, JANUS, and HL7
- Out-of-the-box integration with Oracle Clinical

Oracle Life Sciences Data Hub (LSH) is an integrated environment for clinical data that enables life sciences organizations to make better decisions based on more accurate and timely information. It can enhance productivity, aid compliance, and reduce risk across clinical development. LSH supports the mission-critical task of integrating clinical and nonclinical data from multiple sources into a single environment where it can be analyzed, visualized, and reported on by clinical researchers.

Streamline Clinical Development Information Management

Leading life sciences organizations are exploiting advances in genetics, genomics, combinatorial chemistry, and high-throughput screening to discover more lead compounds. The rapid increase in lead compounds inevitably increases the pressure on clinical development to manage the throughput, but also to identify early which compounds are not likely to succeed.

Effective information management across clinical development and the broader enterprise is key to making the right decisions in clinical development and to ensuring that accurate study documentation is submitted as quickly as possible. However, this is difficult to achieve, as the complex array of systems for functions like electronic data capture, clinical data management, metadata management, ePRO, trials management, PK/PD, pharmacovigilance, analysis reporting, and financial reporting have typically created isolated information silos. LSH resolves these issues with a single, compliant infrastructure for data access, transformation, persistence, and distribution.

Reduce Risk

The Oracle Health Sciences Data Hub lets life sciences organizations collate all relevant safety information from multiple systems and deliver that information to the scientist's desktop. As data is fed into LSH, workflow can proactively trigger integration from multiple sources and route reports to the appropriate staff so appropriate action can be taken.

Integration and aggregation of data in LSH 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, LSH provides the infrastructure and tools to support decision making.

Lower Cost of Ownership

LSH can reduce the overall cost of IT systems ownership by replacing multiple analytical systems with a single integration and reporting system for data integration, metadata management, blinding and unblinding, report execution, report storage and retrieval, workflows, and data visualization for the entire clinical development organization. The repositories in LSH 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. All clinical development staff can access the data and business intelligence in a common, secure environment that is independent of the original data sources.

Simplify Clinical Integration

Integrate and extract value from new and existing data sources without the need for complex IT projects.

Flexible and Extensible Architecture

The traditional solution for clinical data integration has been to create one or more large-scale data warehouses. These have typically been rigid in structure and difficult to adapt to new sources or data types. Combined with the variability of clinical trial design, clinical warehousing projects have frequently suffered from high maintenance costs and inflexibility. LSH has been designed to support any data structure and to adapt to changing industry needs.

Open Integration

Life Sciences Data Hub uses adapters to both integrate with source systems and data structures plus load data intelligently. Out of the box, it can integrate data contained in any Oracle database tables and view. Other adapters include SAS datasets and transport files, Oracle Clinical, text, and XML. Additional adapters can be built with the supplied adapter toolkit.

Rapidly Embrace New Standards

LSH has been designed to support numerous and interoperable data models. This enables organizations to adopt emerging standards and to benefit from any tools and methods associated with those standards, with the flexibility to adapt when new versions are released or different standards emerge. Standards like CDISC and HL7 can coexist and interoperate with company-wide standards within LSH.

Controlled Application Development

Components are defined within LSH for data definition, loading, transformation, analysis, and reporting within a flexible hierarchy. These components can be defined, built, and tested by developers under full version control and include:

- Table and column definitions
- Source code for programs and reports
- Parameters for programs and reports
- Report sets – indexed collections of reports

LSH enables existing SAS developers to use SAS's full power within the LSH regulated framework. Transforms can also be developed using PL/SQL, reports developed in Oracle Reports, and ad hoc visualizations created using Oracle Discoverer. Additional tools for loading, transformation, reporting, and visualization can be integrated using the adapter toolkit.

Empower Clinical Researchers to Make Better Decisions

Researchers can focus on extracting scientific knowledge across the entire clinical portfolio, rather than on using multiple applications to compile the necessary data.

Achieve a Single View of Clinical Data

LSH provides researchers with a single view of all clinical and nonclinical data. Data can be accessed in accordance with any hierarchy, such as study, project, compound, therapeutic area, or company. The currency of this data can be defined as required, whether it is real-time, weekly, or static data from legacy systems. Advanced algorithms ensure that data remains blinded as appropriate.

A single view allows the clinical team to speed up and improve processes such as:

- Study progress – for example, a single visualization containing pages late, open discrepancies, enrollment, and lost-to-follow-up with drill-up/down from entire trials to individual patients
- Safety reviews

Improve Productivity with Self-Service Analysis and Reporting

Once transforms, analyses, and reports have been built and tested, they are available for execution by clinical researchers. Execution parameters allow these programs to run in different scenarios to ensure the researcher gets the right view.

Automate Complex Processes and Approval Chains

Workflows can be set up to automate sequences of actions and automatically route information to anyone who needs to review or approve it. For example, a nightly job could be defined to load data from a central laboratory, combine it with demographic data, execute a report for a specific patient subset, and deliver the report to a safety analyst for review and approval the following morning. The simplicity of scheduling complex processes like this empowers clinical teams to discover the hidden value in their data, which historically would not be possible without asking the programming team to extract the desired information.

Work with Regulators to Optimize Approval Process

Forge better relationships with regulators by being more open and responsive.

Ensure full traceability, from source to submission

LSH allows every interaction with the data to be traced, from acquisition to submission. Strict version control and security profiles ensure that only approved team members are allowed to execute tested programs on final data. If a regulator inquires how a particular report was generated, LSH can show the program that defined the report and any associated data. Moreover, a new version of the table can

be generated from the original source dataset if the regulator requests a reanalysis.

Support ongoing regulatory reviews

As regulators adopt more iterative review cycles, the number of interactions between pharma and regulator will increase significantly. LSH has an advanced classification system for indexing and searching programs and outputs to ensure the right report is retrieved each time.

Technical Architecture

LSH is built on the Oracle Applications Framework and is engineered as a centralized, high-performance system that can handle hundreds of gigabytes of data and hundreds of simultaneous users. LSH fully leverages the scalability and reliability of Oracle databases, with built-in failover and load-balancing capabilities, deployed to the user through a true thin-client interface. Users access LSH through a Web browser but can also launch other integrated applications, such as the SAS interactive development environment, as required.

Implementation, Training, and Support

Oracle has partnered with IBM Business Consulting Services (BCS) throughout the development of the Life Sciences Data Hub. IBM BCS consultants bring significant industry, technology, and change management experience to help companies realize rapid benefits from LSH implementations. The joint Oracle/IBM consulting services offering provides a wealth of expertise in project management, data and system integration, and user training.

Contact Us

For more information about Oracle Life Sciences Data Hub, please visit http://www.oracle.com/industries/health_sciences/index.html or call +1.800.ORACLE1 to speak with an Oracle representative.

KEY BENEFITS

LSH provides a complete solution for integrating all of your clinical and operational data. It securely manages the transformation, storage, and access to the data and published output.

RELATED PRODUCTS AND SERVICES

LSH has been built on the Oracle Applications technology stack and utilizes products in the Oracle life sciences suite, including:

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

APPLICATION SERVER

- Solaris, HP/UX PA RISC, or Linux x86
- Oracle Application Server 10g
- Oracle Reports
- Oracle Discoverer
- Oracle Warehouse Builder
- Oracle Workflow

DATABASE SERVER

- Solaris, HP/UX PA RISC, or Linux x86
- Oracle Database 10g

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