

ORACLE LIFE SCIENCES DATA HUB

OVERVIEW

- Integrate clinical data from multiple sources:
 - EDC
 - CDMS
 - PK/PD
 - 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 analytic/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 is an integrated environment for clinical data, which lets life sciences organizations make better decisions based on more accurate and timely information. It can enhance productivity, aid compliance, and reduce risk across clinical development. Oracle Life Sciences Data Hub 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 companies 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 silos of information.

Oracle Life Sciences Data Hub (LSH) resolves these issues with a single, compliant infrastructure for data access, transformation, persistence and distribution.

Reduce Risk

LSH allows life sciences companies to 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 that 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.

Reduce 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 to 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 the changing needs of the industry.

Open Integration

LSH uses adapters to integrate with source systems and data structures, and to load data intelligently. Out of the box, it can integrate data contained in any Oracle Database tables and views. Other adapters include:

- SAS Datasets and Transport Files
- Oracle Clinical
- Text
- 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 that standard, 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 Oracle LSH.

Controlled Application Development

Components are defined within LSH for data definition, loading, transformation, analysis and reporting of data 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 the full power of SAS 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 non-clinical 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 the clinical team 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

KEY BENEFITS

Oracle 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

Oracle LSH has been built on the Oracle Applications technology stack. It was built to utilize products in the Oracle Pharmaceutical Applications suite, which includes:

- Oracle Clinical (OC) and Remote Data Capture (RDC)
- Oracle Adverse Event Reporting System (AERS)
- Oracle Thesaurus Management System (TMS)
- Oracle Clinical Siteminder and Trialminder

Oracle and IBM jointly offer LSH implementation consulting services. This provides a wealth of expertise in project management, data and system integration, and user training.

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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 enquires 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 re-analysis.

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 Database, 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.

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

Implementation, Training, and Support

Oracle has partnered with IBM Business Consulting Services (BCS) throughout the development of LSH. IBM BCS consultants bring a wealth of industry, technology and change management expertise to help companies realize rapid benefits from LSH implementations. The offerings are listing in the sidebar. Contact your Oracle or IBM representative today to learn more about LSH.

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