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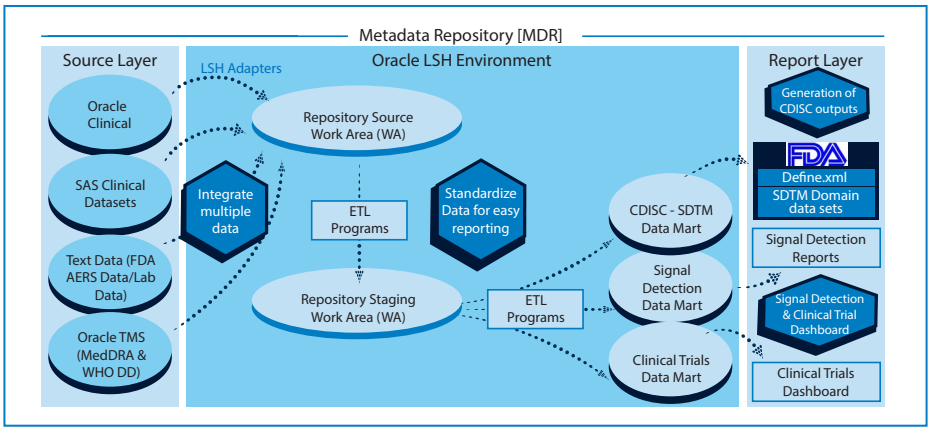
INFOSYS ORACLE PRACTICE: OUR SOLUTIONS ON LIFE SCIENCES DATA HUB (LSH)

Oracle LSH is a data integration environment, created specifically to meet requirements of Life Sciences organisations. It offers a flexible and open system, which can easily integrate data from clinical, operational and financial systems- thereby offering a single source of information to make informed decisions. It facilitates comparison of financial, safety and efficacy profiles of competing projects; as well as in taking critical decisions for adaptive trials. Being a system which supports full traceability as well as transformation of data according to regulatory standards, it simplifies the process of regulatory submission and review.

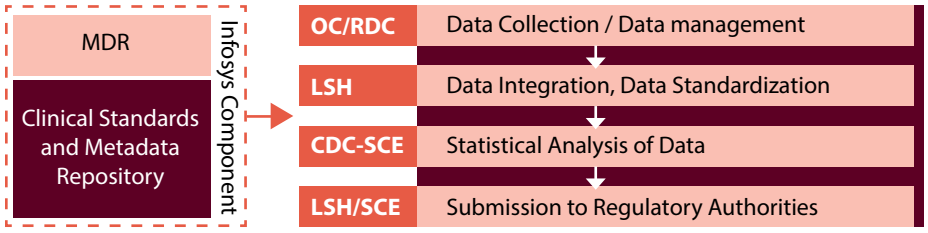
Infosys Solutions in LSH space

Having identified LSH as one of the core applications in the Oracle HSGBU stack, Infosys has developed 3 different solutions which extend LSH's functionality and address some frequent pain points. Backed by a flexible customization framework and an established implementation methodology, these solutions augment LSH's functionality and offer a better RoI. These are also supported by a sound validation framework, which ensures absolute regulatory compliance.

Applications environment in Infosys solutions :



Solution 1: Clinical Meta Data Repository (MDR) based End-to-End Clinical Data Chain Implementation (E2E-CDCI)



Our Solution

To help the pharmaceutical organizations to create a single source of truth (SSOT) for clinical data standards and clinical metadata for end-to-end processing of clinical trial data.

Business Needs

- To simplify the process of clinical data collection and processing, as per various standards.
- To create a centralized repository which holds various standards (CDISC, Company, Study) that ensures that all the standards are accessible and reusable.
- To create a process to reference the metadata across the clinical chain.

Solution Benefits

- Offers metadata repository for storing, retrieving and maintenance of standards - CDISC, industry, therapeutic and project standards and analysis and reporting standards.
- Integrates multiple environments with MDR and APIs to facilitate referencing and accessing metadata across the clinical chain.
- Simplifies and automates the creation of industry standard reporting deliverables (e.g., CDISC and SDTM datasets, DEFINE. XML) across studies and therapeutic areas for easy reporting and timely regulatory submissions.
- Optimize and expedite the clinical development process by automating the entire metadata transformation process.
- Ensure compliance with regulatory practices (21 CFR Part 11) by introducing audit trail and data versioning concepts to achieve higher quality review.

Solution 2: Implementing CDISC-SDTM Standards

Our Solution

Automate the process of clinical data standardization; generation of CDISC compliant define.xml and domain data sets for regulatory submission of pharmaceutical/ biotechnology products.

Business Needs

- Existing process for converting clinical study data into CDISC–SDTM standards are complex, slow and require significant manual intervention
- Simplify integration of disparate clinical sources across the enterprise using a robust and proven tool/package
- Quickly generate required documents for regulatory submission, while retaining full traceability from source to submission

Solution Benefits

- Offers automated generation of study datasets in CDISC-SDTM compliant format
- Workflow based system & automation using APIs reduce the time spent in CDISC-SDTM conversion. Being reusable, it allows standardization of data conversion across enterprise
- Reduces cost significantly in terms of effort and time spent on clinical data standardization
- Provides effective analytical reporting, clinical dashboard system for decision making.

Solution 3: Risk Analysis and Signal Detection Reporting

Our Solution

To leverage existing LSH environment for generation of risk analysis and signal detection reports. These can be used for tracking safety profile during pre/post regulatory approval Phases. It Involves data acquisition from multiple sources into LSH and generation of signal detection reports using custom dashboards. Some of the data sources include: **Proprietary AE Data, Public AERS Data from FDA Surveillance website, Publicly Available adverse event data.**

Business Needs

- To identify and report high quality Adverse Event (AE) information in a timely and efficient manner ensuring an accurate and integral safety profile of drugs.
- To improve the current processes for signal detection which is generally time consuming and involve extensive computations

Solution Benefits

- Provides ability to extract data from various sources (proprietary/public) and multiple studies. Simplifies signal generation process, thereby helping in swift identification of those safety problems that might have been overlooked due to data complexity.
- Supports data transformation and enrichment using various bio-statistical formulae like Proportional Reporting ratio (PRR), Relative Risk (RR), Chi Square and etc.
- Customizable dashboards provide domain wise risk analysis reports using OBIEE

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For more information, contact askus@infosys.com

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