An Overview of Adapter Development for LSH

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Assumptions/Scope/Disclaimer

- Assumption: Audience has a basic understanding of integration concepts and OLS applications.
- Scope: LSH 2.1.1.4.
- Disclaimer: This is only a general guideline for LSH Adapter configuration and development.

Life Sciences Data Hub (LSH)

Introduction

Oracle LSH (2.1.1.4) gathers data from various other systems like clinical data management systems (4.5.1), clinical trial management systems, adverse event reporting systems, even financial (11.5.10.2) or other nonclinical systems. It loads the data in one data repository where collaborated data can be analyzed.

Need for LSH

- Life Sciences companies need to gain rapid insights into the safety and effectiveness of compounds.
- Labor-Intensive processes such as structural analysis and regulatory reporting of patient data.
- Limited presence of consolidated data leading to absence of reusable components i.e. metadata.
- Data present on secure file systems and generally inaccessible due to security restrictions.

Life Sciences Data Hub (LSH) (2)

Features of LSH

- Ability to pull together all the available correlated patient data from multiple technologies via adapters.
 - Provides integration, data loading, analyzing, viewing and reporting on clinical and non-clinical data
 - It helps to take better and quick decisions with accurate and timely information.
- Data loaded onto LSH can be easily converted standard formats and can be managed by business users.
- Design to promote and assist with regulatory compliance.
- Open APIs (Application Programming Interface) enable standardization of data transformations and manipulations.
- Libraries and version control promote reusability and traceability.



- Flexible Architecture Allows Connectivity to Almost any other Product/Tool which Stores Data.
- Life Sciences Hub provides an incredibly flexible architecture which allows connectivity to almost any other product or tool which can store data.

Adapters Center to the Strategy

Adapter Toolkit

- LSH is built on state-of-the-art Oracle Fusion Middleware and Oracle Database. [Courtesy of Oracle Corporation]
- Enables LSH to fit within an enterprise's architecture for integration with clinical data.
- LSH comes with an adapter toolkit which can be used to adapt to additional technologies and applications.

Adapter Structure

- Adapters serve as the interface between Oracle LSH and each external system.
- Each adapter can be customized for external system.
- Adapters to different types of external systems are:
 - Source Data Systems To load data into Oracle LSH from an external system.
 - Visualization It is required to create:
 - Oracle Discoverer (10.1.2).
 - Oracle Business Intelligence Enterprise Edition (OBIEE) (10.1.3.4).
 - Data Export To transport Oracle LSH data to a different system through an object Data Mart. Two types of Data Marts:
 - Text data load from Oracle SQL*Loader, and
 - Oracle Export.
 - Oracle Clinical It includes different Adapter Areas, one for each type of Oracle Clinical Load Set.
 - Oracle Family Required to create Load Sets of type Oracle Tables and Views.
 - **SAS** It is required to create SAS Load Sets.

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Development Cycle and High-Level Steps to Create Adapters for LSH (FROM LSH INSTALL DOC/REL NOTES)

- 1. Install and configure the predefined adapters:
 - a. Log On to Oracle Applications.
 - b. Click **Submit a New Request**. The Submit a New Request window opens.
 - c. Select **Single Request** and click **OK**. The Submit Request window opens.
 - d. Click the gray LOV button on the right of the **Name** field. The Reports List of Values opens.
 - e. Select LSH LOB Loader Concurrent Program and click OK.
 - f. Click **Submit**. A window pops up with the job ID and asks if you want to submit another request.
 - g. Click No.
- 2. Grant security privileges:
 - a. Make sure that no LSH session is up and running.
 - b. Log in to SQL*Plus as apps.
 - c. Run \$CDR_TOP/patch/115/sql/cdradaptergrants.sql
- 3. No manual steps required to install the notification sub processes.
- 4. Each external system to integrate with Oracle LSH requires installation.
- 5. Assign user groups.

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Development Cycle and High-Level Steps to
Create Adapters for LSH
(FROM LSH INSTALL DOC/REL NOTES)

- Creating a new adapter requires the use of the same definitional object structure as used within predefined adapters.
- The API for adapter creation can be used.
- Once the adapter is created it appears within the LSH user interface.
- Adapter security can be set-up by assigning user groups to adapters and creating roles for required adapter operation.

Testing and Validation Considerations for Building Adapters

- LSH can help to certify that data is handled in a valid manner.
- All defined objects are under version control.
- Generates a report containing validation status of every single defined object including tables, programs and load sets.
- Predefined validation statuses are used to represent different stages in an object's life cycle:
 - Development: LSH gives each object a new object version
 - Quality Control: LSH provides the ability to develop standards for the use of the QC validation status.
 - Production: LSH validation status to show that objects have been tested and certified and are ready for use with production.
 - Retired: LSH validation status for objects that are no longer in use.

Evels of Integration

- LSH supports integration with other systems as sources of data and as means of visualizing and reporting.
- It handles integration with custom adapters made for each external system.
- Set of adapters are custom-designed for the purpose of loading data and meta-data (reusable data) from Oracle Clinical into Oracle LSH.
- Oracle LSH is designed for close integration with SAS (9.2) at several levels.

Examination of the Existing Adapters for Oracle Clinical or SAS as Guidance

- On-Line review from an existing installation of LSH
- SQL Developer customizations and IDE enhancements are now available according to Oracle EC overview of LSH 2.1.1 RUP B

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Summary/Conclusions

- LSH provides a flexible and robust platform for integration of disparate data sources with the Oracle Health Sciences applications
- Uptake of adapter development will increase over time. With Oracle and external partners developing LSH adapters, both market demand as well as the growing increase of the LSH install base will increase the number of adapters on market.
- Once the general framework is understood for LSH adapter development, and given new support from SQL Developer/IDE, there should be a gradual reduction of learning curves to develop LSH adapters, similar to the TMS dictionary loading script historical learning curve.

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