



Data Warehousing for the Reporting and Management of Clinical Data

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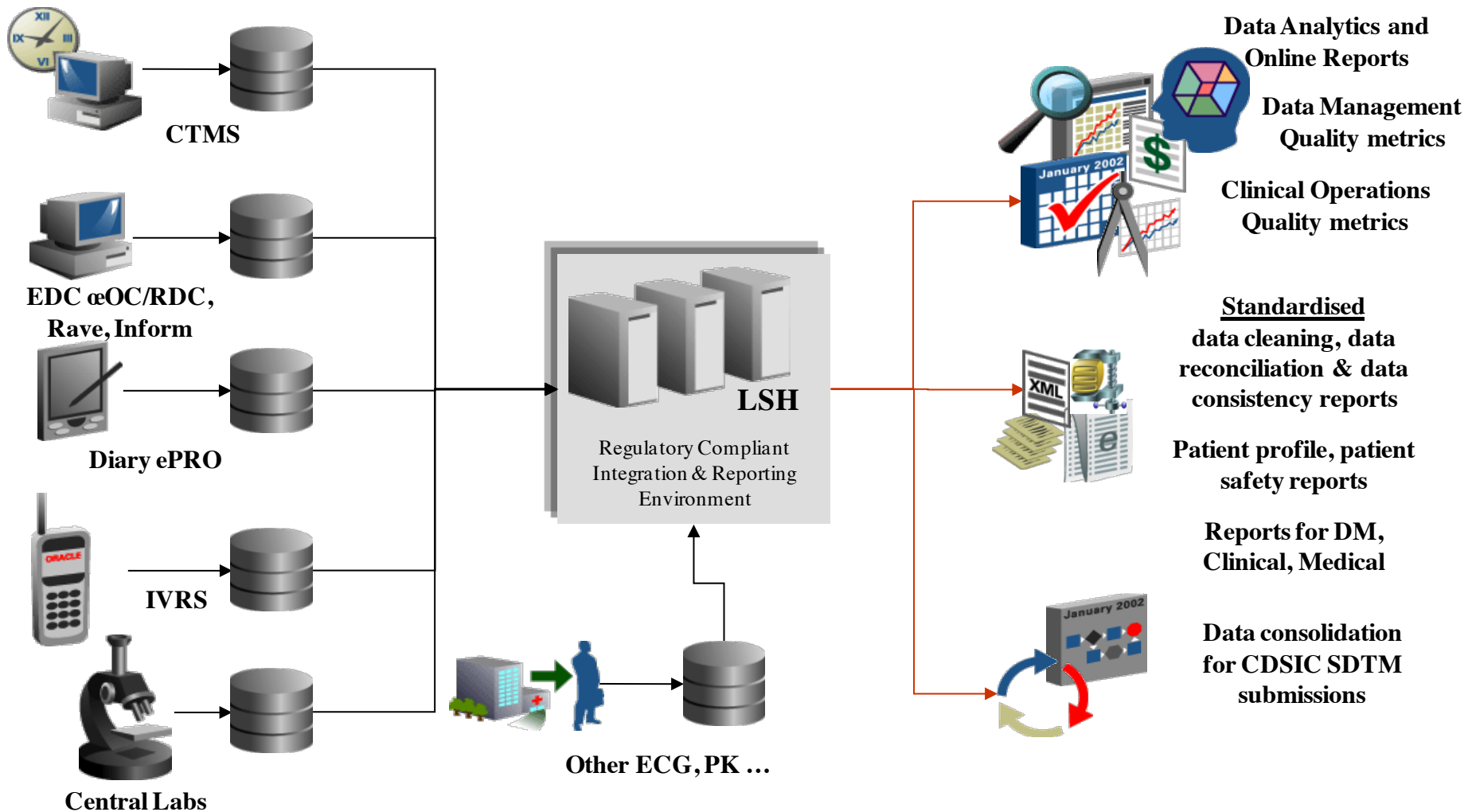
Why Use a Single Central Data Repository?

The primary driver behind ICON's decision to invest time in implementing the Oracle Life Sciences Hub is to

Enhance the analysis and delivery of clinical trial data:

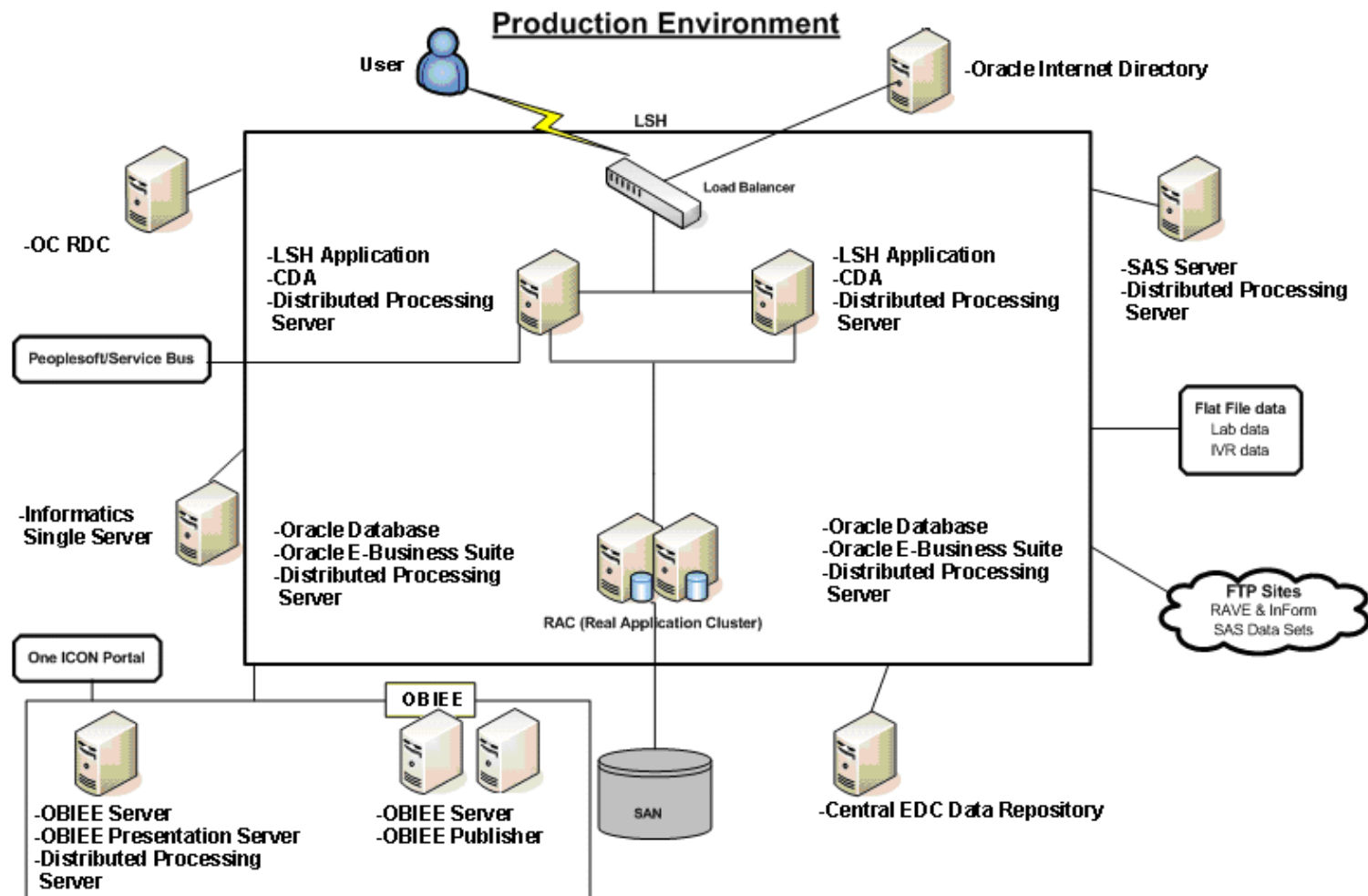
- Increase trial efficiencies
- Data simplification
- Produce standardised operational and management reporting assets
- Standardise Regional operations
- Manage trials across data centres
- Ability to Scale People, Processes and Technology
- Empirical knowledge of trial performance

Implementation of a Data Warehouse



Implementation of a Data Warehouse

Hardware & Software Considerations

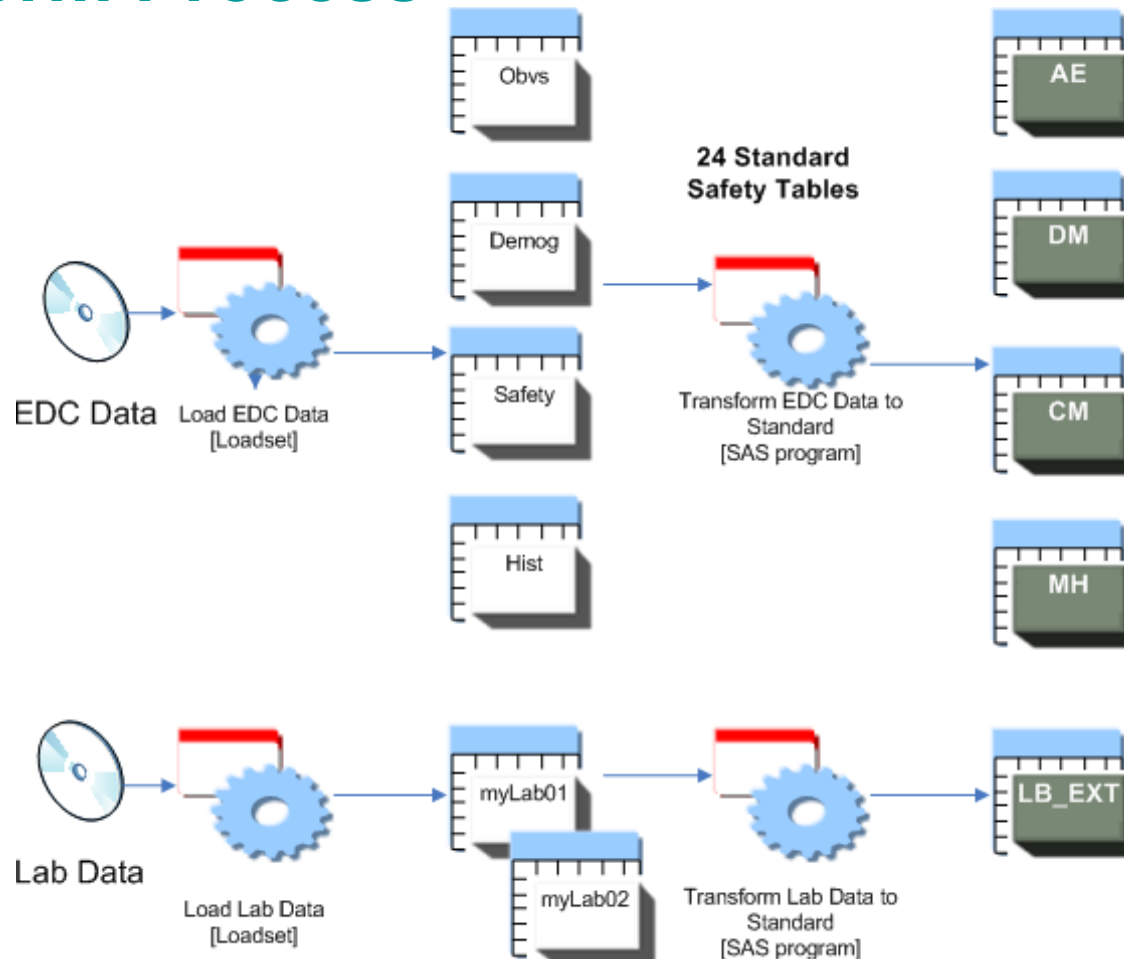


Processes

The primary consideration from a Data Management operational perspective was how to deal with the different data sources that we needed to load into the LSH environment.

Implementation of a Data Warehouse

Transform Process



Procedures

- Setup study structure, users & security in LSH
- Setup study data sources (CDMS, Lab, IVRS, ECG, PK, Diary)
- Setup study SAS programs (Transform, Data Cleaning, Data Reconciliation)
- Promote study to production (Data & Programs)
- Load study data (automatically load on agreed schedule)
- Execute SAS transform programs to transform raw study data to ICON standard patient safety transform tables
- Execute SAS data cleaning & reconciliation programs to generate listings
- Notify study team members that outputs are available
- Study team members self serve and collect their own outputs
- Other department users self serve and collect their own outputs

Handling Data from Multiple Sources

- The need to standardize data across multiple systems and data structures has been the single biggest challenge in centralizing the clinical data.
- Working for multiple sponsors and receiving data in from multiple sources means that often data cannot be standardised at source.
- The process to standardise data has to be study/program/sponsor specific at the data transformation level.

CRO Specific Challenges

AE_SEV
AE_SEVER
AEGRADE
AESER
AESEV
AESEV_
AESEV1
AESEVC
AESEVCD
AESEVER
AESEVN
AESEVQ
AESEVR
.....



“Severity”

Measuring Efficiencies

- A lot of consideration was given to the amount of time required to standardize the data at a study level in comparison to the time saved by removing the need for study specific procedures/ programs
- Case studies were carried out to assess the efficiencies of using standardized data structures
- From these studies it became apparent that we would realize real benefits over a measurable period of time

CRO Specific Challenges

Diminishing Development/Validation Effort for Clinical Report Programming



Future Developments

Phase I of this initiative went live on 30th July 2010. Data Management's programming and study team staff are now able to simultaneously access clinical trial data from anywhere in the world and provide a more globally integrated data management solution to meet sponsor needs.

- Future phases will focus on extending the user base across the larger internal organisation and out to sponsors to ensure consistent and cohesive management of clinical data.
- Discrepancy Manager for DM
 - Single solution to manage EDC and other vendor discrepancies
- LSH automations
 - Automate critical LSH tasks
- Extend LSH for Clinical Reporting

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