



Building and maintaining a clinical data warehouse - challenges and opportunities for pharmaceutical programmers

PhUSE 2009 – Annual Conference

Basel, 19.10.2009

- ADVANCE Program
- Data Warehouse

What will we deliver for Novartis?

A new Electronic Data Capture (EDC) system

- Study cycle time savings
- Increase operational efficiency
- User-friendly interface for investigators

A state of the art Clinical Data Warehouse with a submission and reporting platform

- Proactively detect safety signals
- Implement new FDA compliant data standards
- Increased automation based on new submission standards

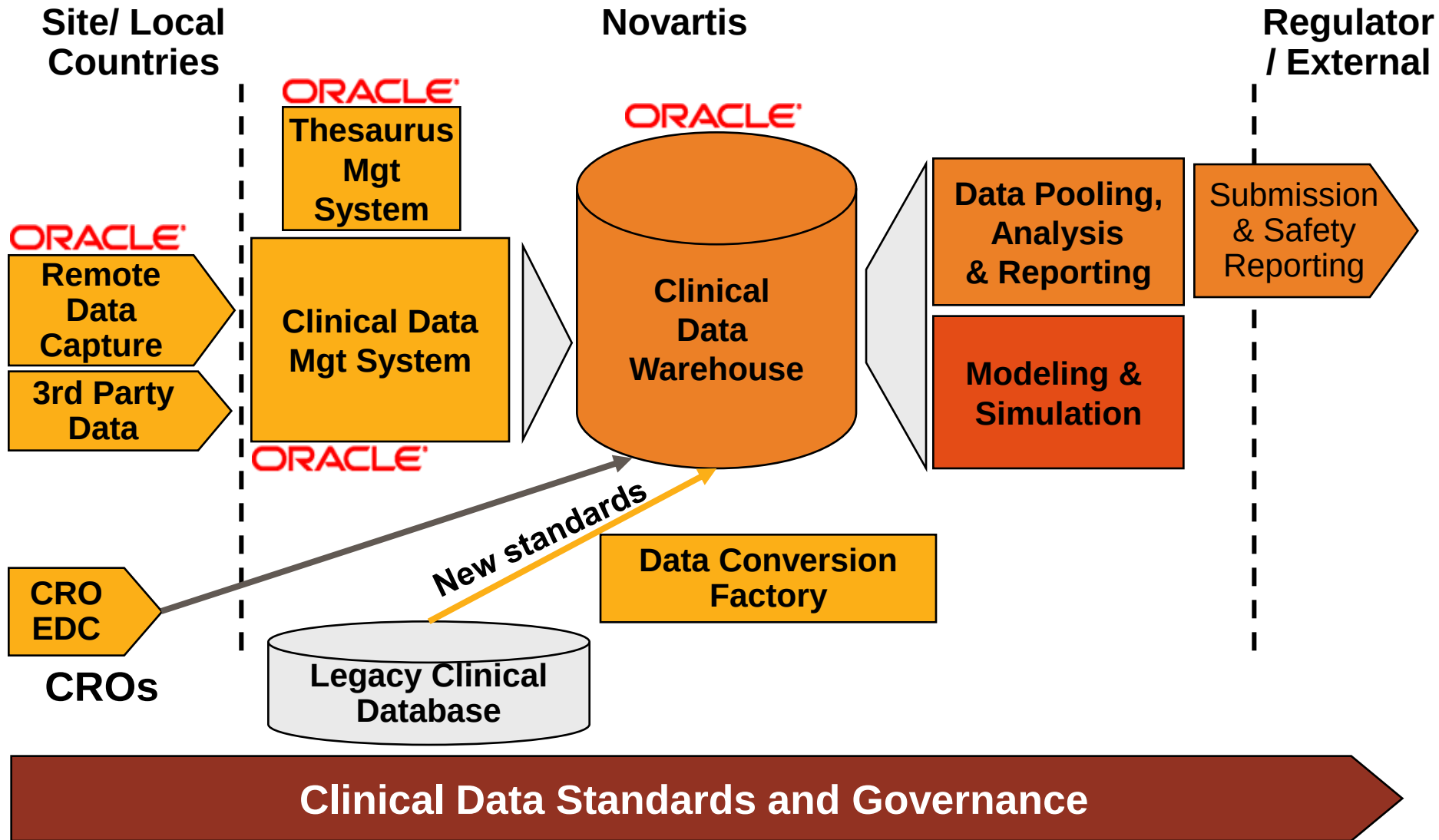
A state of the art Modeling & Simulation environment

- High-performance computing power platform
- Reporting and visualization Tools

New FDA compliant clinical data standards

Application Landscape - *ADVANCE*

An integrated solution for clinical trial data
from collection through submission



ADVANCE Case for Change

New capabilities needed to manage increasing workload and complexity



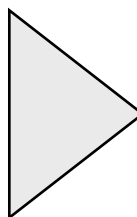
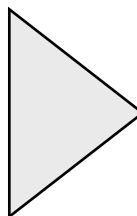
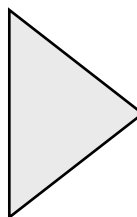
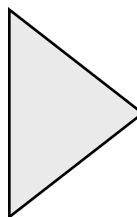
Challenges:

Increasing workload to capitalize on rich Development product pipeline

Increasing volume and complexity of requests from regulatory authorities

High effort for generation of regulatory compliant data

Increasing maintenance and support costs for customized solutions



Answers:

New Capabilities to manage clinical data flow more efficiently

Seamless data access for rapid, comprehensive responses to authorities

All data in FDA compliant format and automated submission with new standards

Industry-leading out-of-the-box solutions

- ADVANCE Program
- Data Warehouse

Objectives of Data Warehouse within ADVANCE ADVANCE

The Data Warehouse will be the key element for loading and processing clinical data from several sources in new standard

The new Data warehouse is an integral part of ADVANCE as it will...

- provide additional data access and use capabilities, based on new external Industry standards (CDISC)
- significantly increase automation for statistical reporting
 - improved re-usability of programs
 - use of new standards to accelerate submission
- Provide an initial conversion of legacy data into CDISC standards

Data Warehouse Vision

The Data Warehouse will become a one stop shop for reliable clinical data over the the next few years

Step 1: *Facilitates innovation and excellence in execution*

- Facilitates secondary analyses and reporting at study and program level
- Faciliates Safety reporting, esp., signal detection and validation
- Expedites access to broader range of data for Modeling and Simulation



Step 2: *Integrated processes from data to information*

- Facilitates generation of knowledge to substantiate decisions
- Enables application of advanced Modeling & Simulation methods



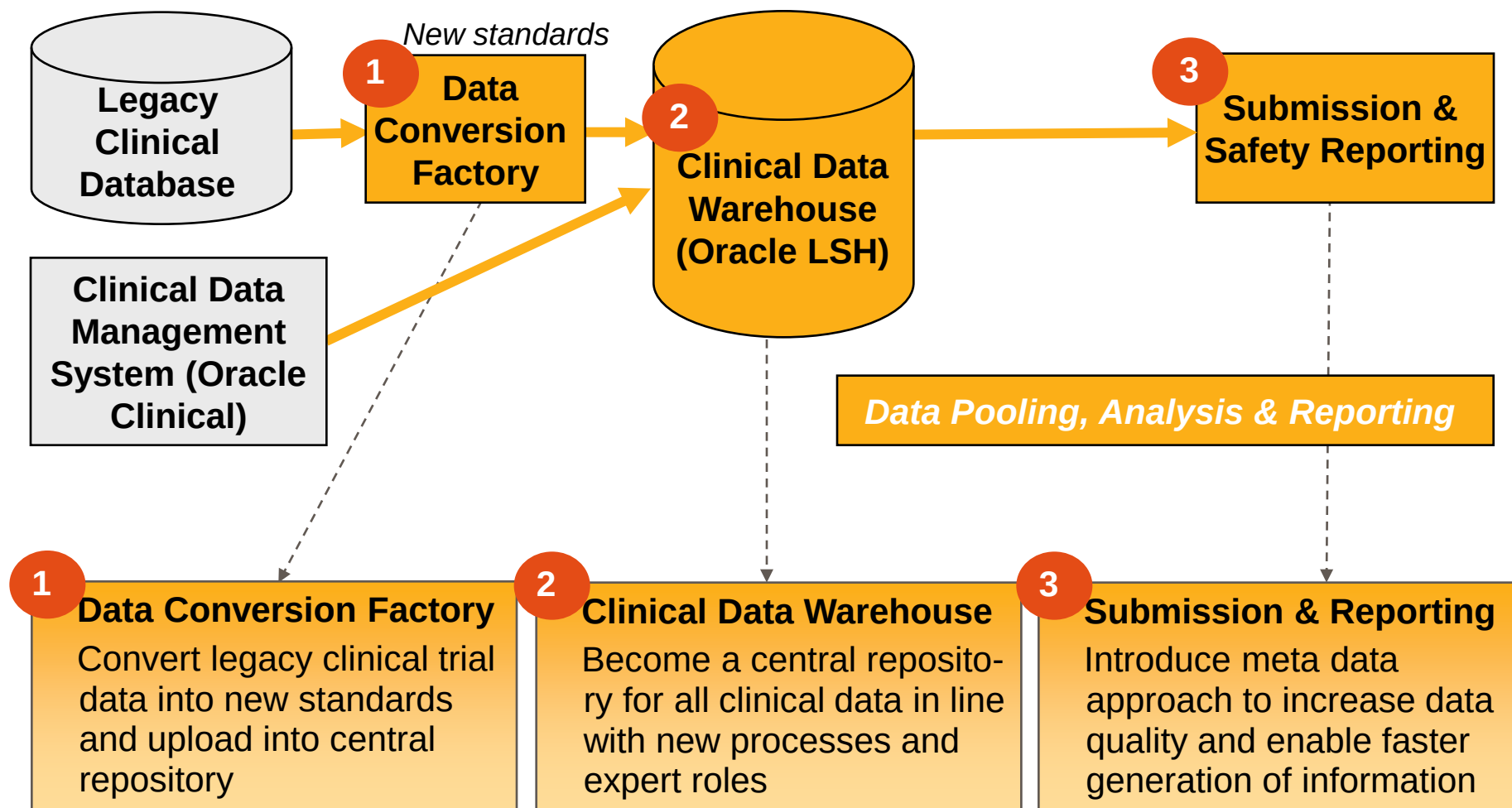
Step 3: *One stop shop for reliable clinical data*

- Loads and stores all (global) clinical data in a central repository
- Additionally makes available data assets from legacy trials

Data Warehouse Approach

The Data Warehouse will be initially implemented and gradually populated with new and legacy clinical data during 2009/10

Simplified for illustrative purposes only

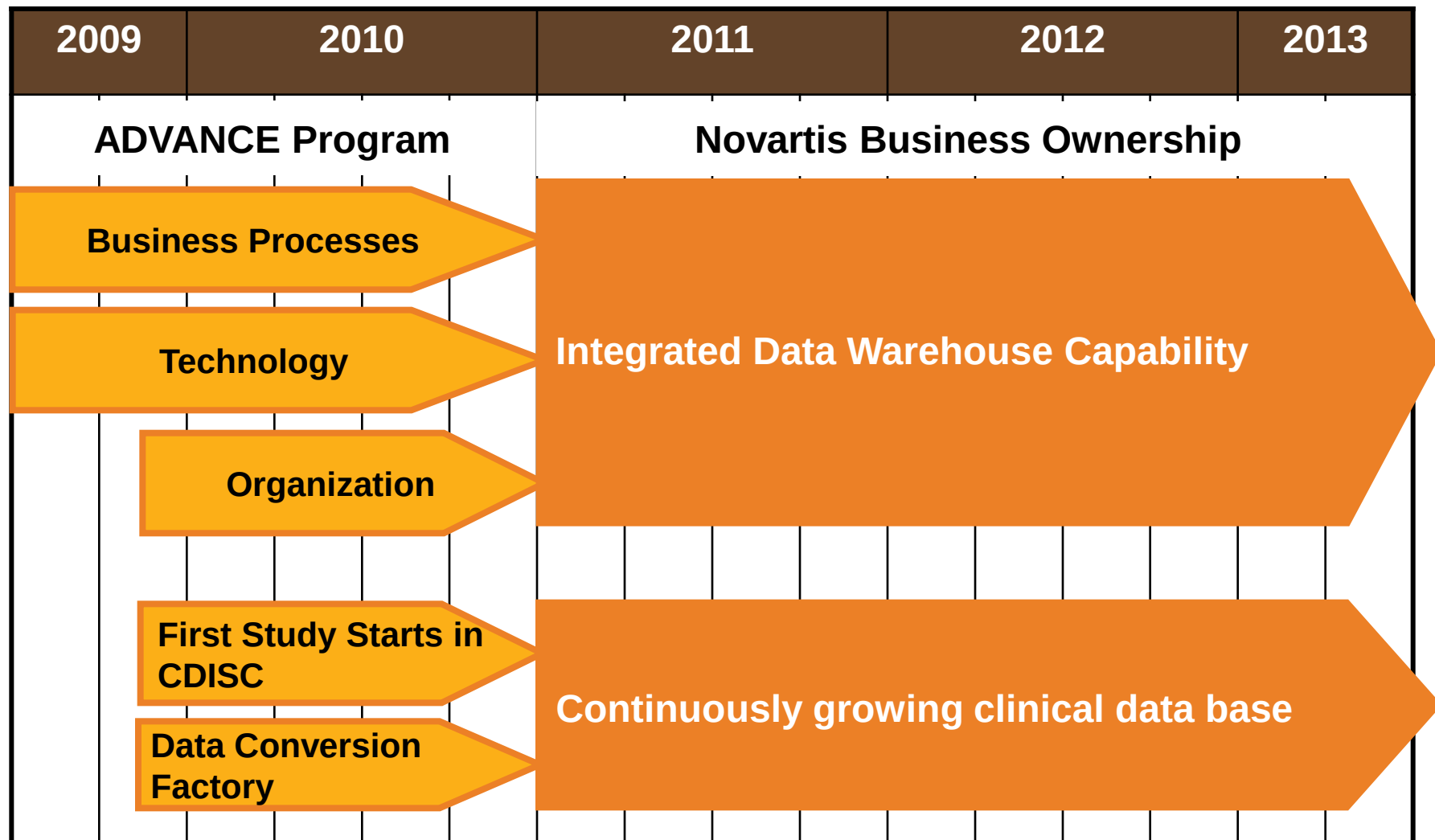


Data Warehouse Implementation Timeline



In late 2010, the integrated Data Warehouse Capability with new processes, technology and organization will be handed over to Novartis.

Simplified for illustrative purposes only



Data Warehouse Benefits



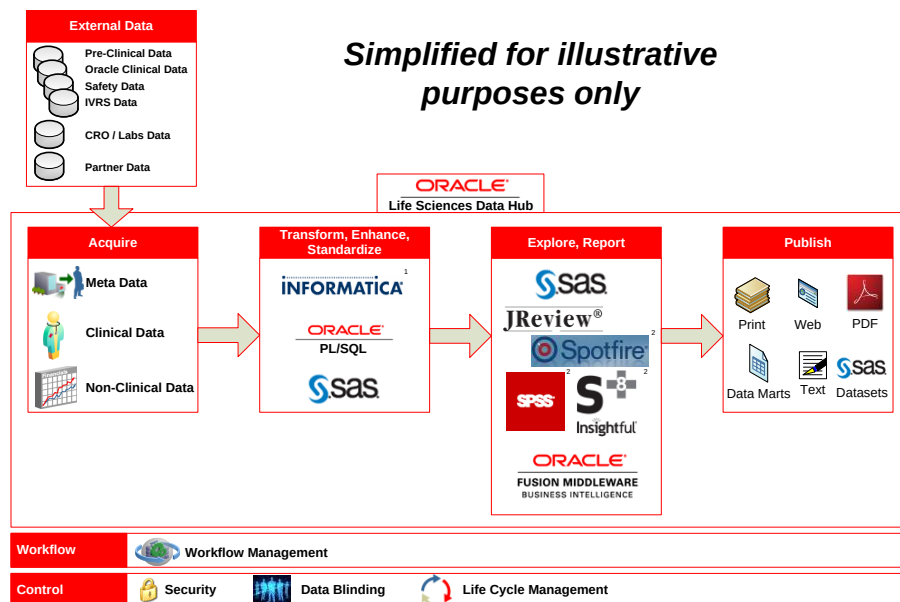
The new Data Warehouse will enable Novartis to focus on innovation and creation of added value by automating routine processing

The new Data Warehouse will support Novartis in achieving:

- Increased quality of submissions through adherence to new CDISC compliant standards and dry-runs to detect deviations early
- Greater efficiency via increased automation of statistical reporting & submission processes
- Increased flexibility to adjust to new requirements by easily enhancing standards library
- Faster, easier secondary analysis across clinical projects and trials through metadata-driven data selection
- Easier data pooling due to further automation and data compatibility
- Faster, more complete responses to HA questions, increasing the quality and decreasing the risk of submission

Data Warehouse Technology

The new Data Warehouse will be based upon the state of the Art Oracle Life Sciences Hub (LSH) technology



LSH clinical data flow:

- Acquisition of data from various sources
- Transformation of data into a common standard
- Availability of data for
 - Meta-data based search
 - Reporting in visualization tools
 - Submission and publication

LSH State of the art technology features

- CRF part 11 compliance enables validation within one environment
- Complete audit trail for statistical data and code
- Extendable solution, including Service Oriented Architecture (SOA)

Data Warehouse Organization

Besides technology capabilities, Novartis will build up organizational capabilities to operate and continuously improve the Data Warehouse

Data Warehouse Organization

LSH Governance Organization

LSH Business Process Owners

- Responsible for driving the Strategy and Vision and implementing domain specific processes

LSH Operations Organization

LSH Experts

- Responsible for data transfer, conformance and storage of assigned trials in LSH
- Responsible for meeting data consumer needs

LSH Data Consumer Community

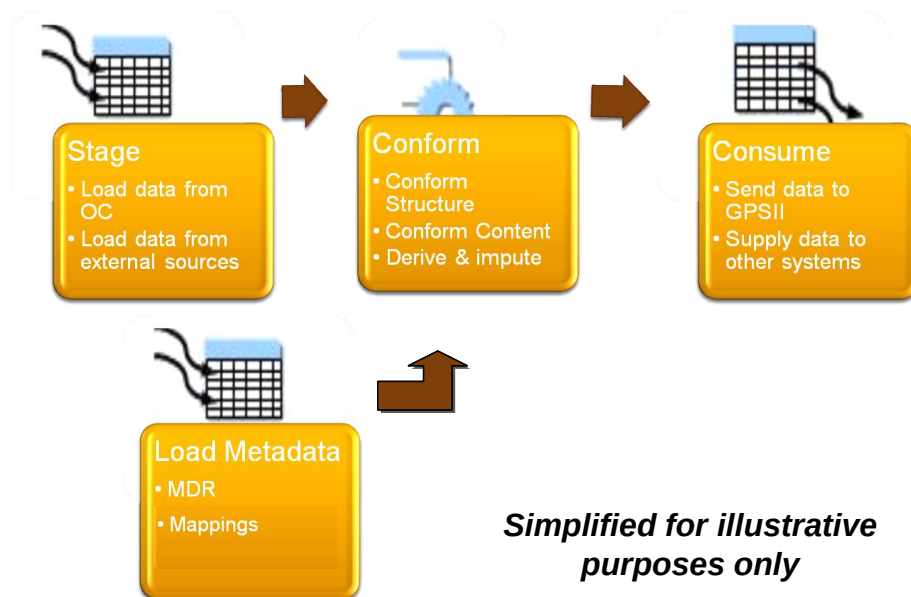
LSH Clinical/Randomization Data Consumers

- Responsible for placing requests
- Responsible for browsing data and extracting data sets for reporting in visualization tools

Data Warehouse Processes

The designed business processes for the Data Warehouse will foster a changing mindset within the Programmers Community

Data Warehouse Processes



End to End Process from

1. Loading data from external sources over
2. Conforming data and preparing it for ongoing data transfer to
3. Making data available for consumption, i.e. reporting, submission, data pooling and secondary Analysis

Changing mindset

- Easier access to clinical data for a broader audience
- Revised data search through meta data (category) driven search
- Variations in data output due to consolidated reports and new standards

Thank you for your attention.
What questions do you have?