

## INFOSYS ORACLE PRACTICE: SOLUTION IN ARGUS SPACE

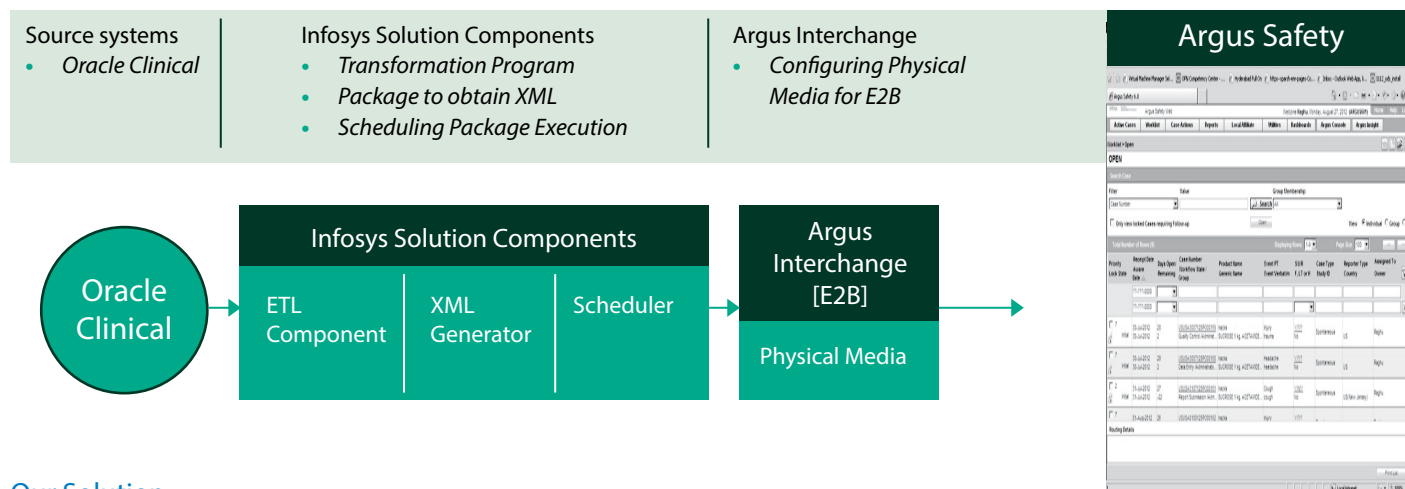
In the Life Sciences industry, enterprises in the clinical development space face challenges in the collection, monitoring and analysis of diverse data across clinical development and safety processes. Linkage between clinical data management system and drug safety systems is of great importance from a compliance as well as business perspective. Infosys has defined a structured and planned approach for safety data migration and integration of SAE data between safety and clinical data management systems. It consists of predefined mappings between certain source systems; custom ETL routines for automating data transformation & migration, backed by comprehensive validation resources.

### Infosys Solutions in Argus Space

Considering the importance of safety data and Oracle Argus safety in the life cycle of pharmaceutical products, Infosys has developed two different solutions, which help in

- Updating and maintaining the safety data of a pharmaceutical product dynamically and contemporarily across various systems and
- Reducing the overall maintenance cost of this data.

### Solution 1 - E2B interfacing between Oracle Clinical (OC) and Argus Interchange



### Our Solution

To create an interface between Oracle Clinical (OC) and Argus safety to make Argus as a single source of truth (SSOT) for all drug safety information and avoid duplicity and tedious process of manual data entry.

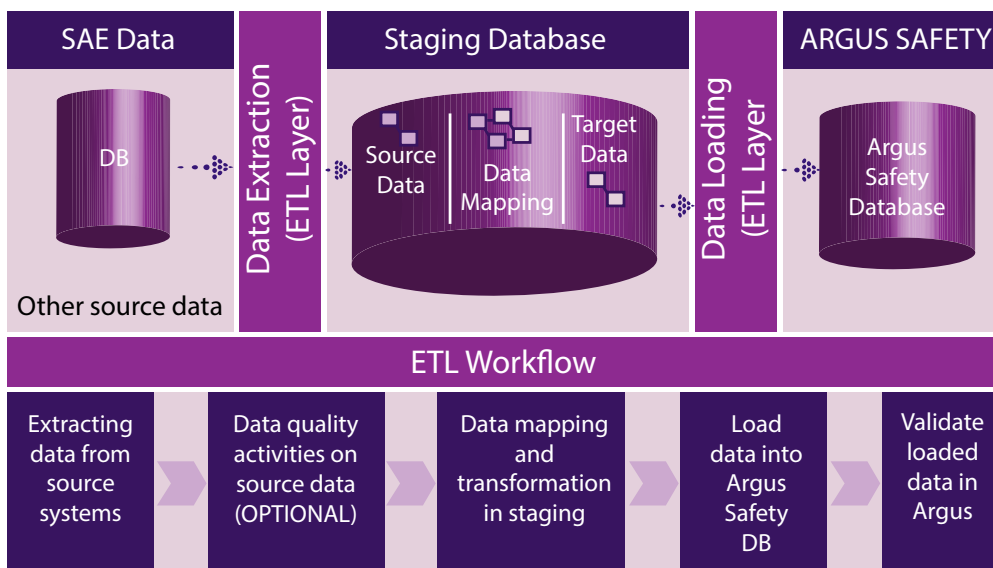
#### Business Needs

- To have a simple interface between Oracle clinical and Argus safety without any additional infrastructure (without gateway server)
- To remove tedious process of manual data entry from Oracle clinical to Argus safety and to reduce manual reconciliation efforts.
- To reduce time to market

#### Solution Benefits

- Removes dependency on other applications for all adverse events related information as Argus becomes single source of truth for all the drug safety information
- Creates simple interface between OC and Argus with minimum or no additional infrastructure cost
  - Includes ETL to extract and process case data from Oracle clinical
  - Offers XML generator helps to create cases in required XML format which is readily accepted by Argus interchange
  - Uses scheduler for running the batch jobs at required intervals of time

## Solution 2 - SAE data migration from legacy system to Oracle Argus



High level solution framework for SAE data migration

### Our Solution

To establish a framework for SAE data migration from legacy system to Argus in a timely, high quality and cost effective manner with complete validation.

#### Business Needs

- To develop a process for migrating the SAE data without any errors
- To provide tested and streamlined process for data migration from legacy system to Argus system
- To check and obliterate the redundant and invalid values which is not easy to identify in manual migration

#### Solution Benefits

- Provides well defined process and methodology for data migration from legacy to Argus safety following 21 CFR part 11 compliance rules
- Provides tested and streamlined process for data migration from legacy system to Argus
- Enables data quality and transformation in staging database and loading the data into Argus safety system



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