CREATION OF ADaM

Define.xml v2.0 validation

OVERVIEW

The customer is a global Biopharmaceutical company and one of the largest pharmaceutical companies by both market capitalization and sales with $40 Billion annual turnovers and global footprints in 140 countries. The company is committed to deliver innovative health solutions.

CHALLENGES

Non-Availability of tools to examine the complete array of checks for validating the contents of Define.xml

Automation Process was not feasible as XML Map software was being used to get all the metadata into SAS datasets in required format

It was a daunting task to accommodate all these measures

Frequent use of services from an external specialist for any Ad-hoc request that emerged when the metadata evolved during the trial

SOLUTION

1. Provided a compact solution using SAS to lay out a validation Process that could serve as an in-house model
2. Extracted key variables, all variable attributes and Code List into SAS datasets using data steps and PRX functions
3. Created a macro to check that the key variables list can identify the unique records in the metadata datasets

OUTCOMES

- Eliminated extra steps used in XML Map and other external software in Define.xml validation process and the manual steps that followed for formatting the metadata dataset
- Process automation was made possible for an end-to-end solution
- Augmented the ability to extract different parts of Define.xml metadata for selective validation needs
- Built an in-house Define.xml validation process which offers more than what other external software can provide, getting rid of the need to depend on the services of a specialist in Define.xml

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