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Single Day Event

Automated Validation of Clinical Data Standard Reports: Enhancing Accuracy and Efficiency in data review

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Agenda

- Overview of Clinical Data Standard Reports
- Data Validation strategy optimization team
- Reporting Tools
- Standard Report Programming and Validation
- Automated Validation of Clinical Data Standard Reports
- Tool Overview
- Validation Algorithms
- Validation Results and Reporting
- Summary and Conclusion

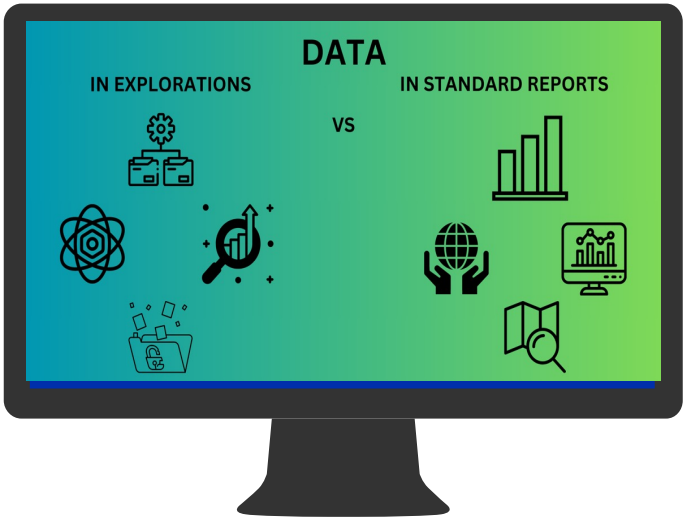
Overview of Clinical Data Standard Reports

Reports are generated to present comprehensive and standardized summaries of clinical trial

Types –
Clinical Study Reports (CSRs)
Adverse Event Reports
Safety Reports
Data Quality Reports
Interim Analysis Reports

Standardization plays a pivotal role in ensuring consistency, interoperability, operational efficiencies in data management and analysis as well as higher quality data through clinical review, which leads to better understanding of the compound's safety and efficacy.

Standardized Report formats for presenting information, making it easier for different stakeholders to understand and interpret the data.

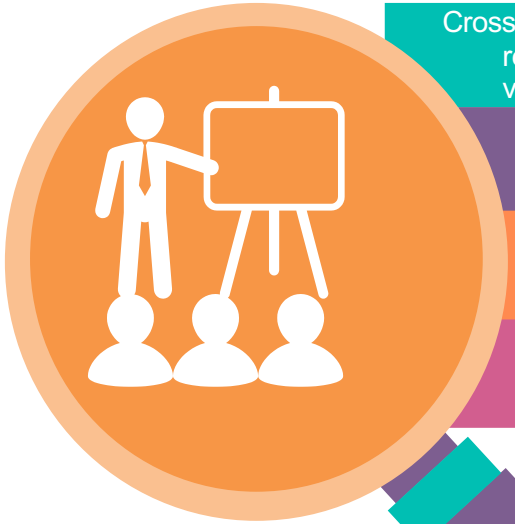


Data Validation and optimization

Team is made up of cross-functional and cross-TA members including:

Clinicians, Study Management, Data Management, Study Build, Data Management Reporting Analysts, Biostatistics, Data Review Team, Standards Management, Risk-Based Monitoring, etc.

Oncology, Vaccines, Inflammation, Pain, Rare Disease, Clinical Pharmacology, Non-Interventional, Neurology, Dermatology, Infectious Disease, etc.



Cross functional team that acts like a Standards Board and is responsible for maintaining the library for all edit checks, validation checks, and data reports.

Central group that will be leveraged to ensure that data validations strategy

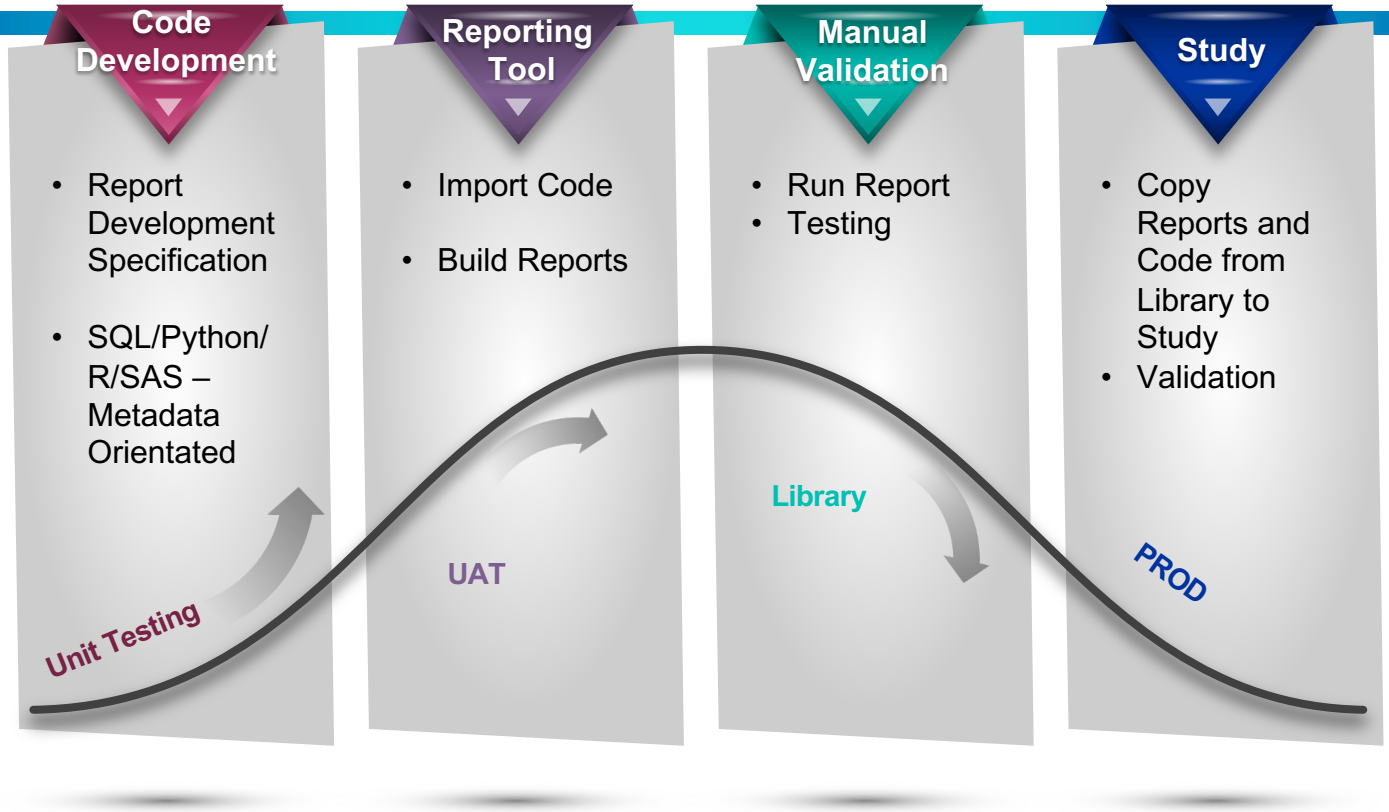
Typically focuses on refining and improving the processes related to data.

Ensuring the accuracy, completeness, and reliability of data.

Standard report programming and reusing reports helps to achieve first time quality and increase efficiency.

Reporting Tools

Standard Report Programming and Validation

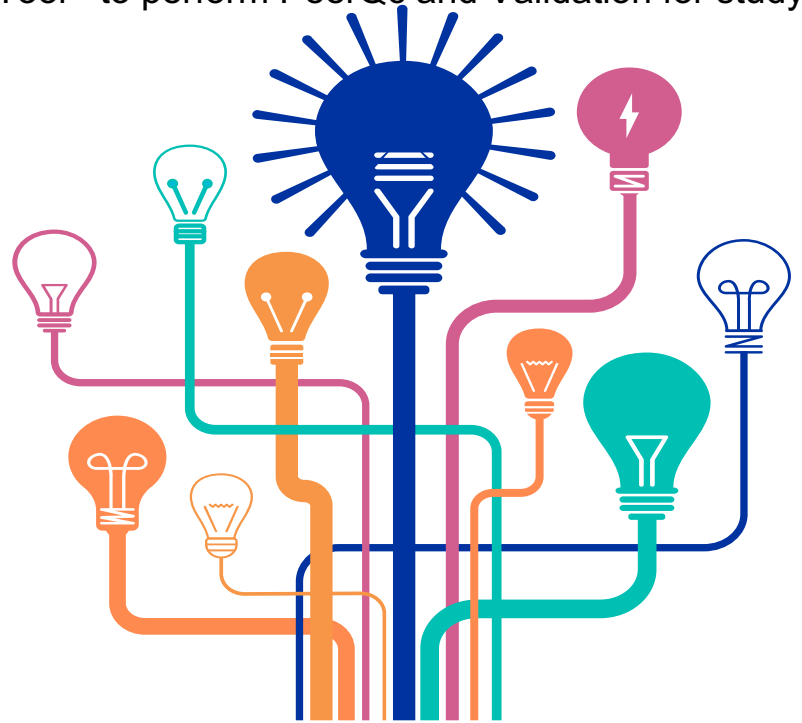


Automated Validation of Clinical Data Standard Reports

Standard Report Validation Tool - to perform PeerQc and Validation for study level reports copied from DVSOT reports

Standard report programming and reusing reports helps to achieve first time quality and increase efficiency.

Standard Report Tool enables risk-based testing for Listings UAT to increase Efficiency and Quality of Reports Build and UAT



Standard report programmed in Reporting tool, copies and use across studies.

SAS based Custom Tool

Validated tool following Computer System Validation - SDLC principles

Tool Overview

- Reporting Validation Tool enables identification of difference between standard library of reports with study level reports.
- It compare Standard reports with Study level and highlight the differences.
- Performs tasks with precision and consistency
- Early error detection
- Performs unit testing to ensure first time quality
- Ensures timely deployment of reports

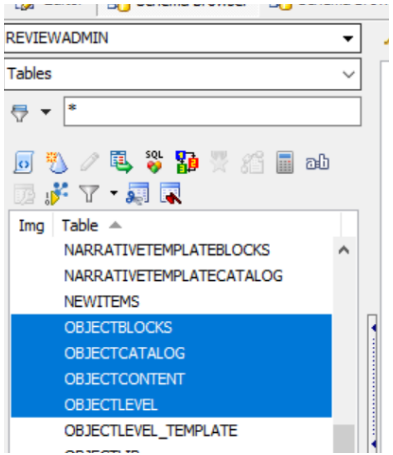
Validation Algorithms

1
SAS

SAS based tool, connected with series of Macros.

2
REVIEWADMIN

Object oriented tables referred from Backend storage Schema



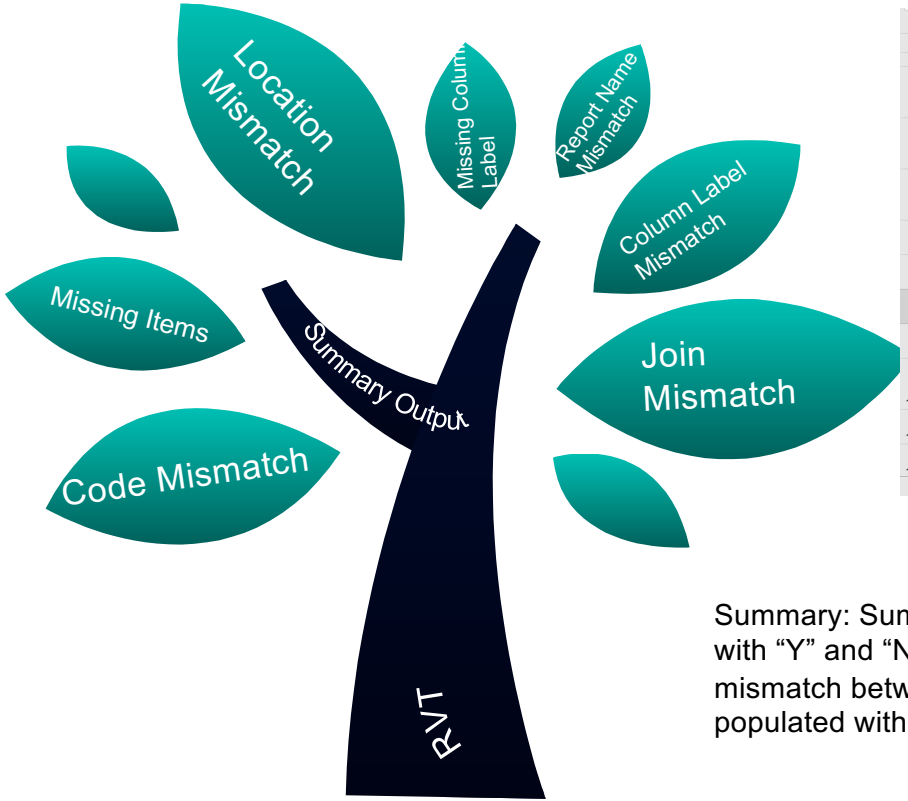
3
Excel

Excel input doc with Standard reports object description

4
Output

Summary Excel Report with defined output

Validation Results and Reporting



Summary

Report ID	SQL Mismatch	Report Location Mismatch	Report Name Mismatch	Missing Column Lab	Missing Items	Column Label Mismatch	Column Order Mismatch	Sort Order Mismatch
Report ID 1	N	N	N	N	N	N	N	N
Report ID 2	Y	N	N	N	N	N	Y	N
Report ID 3	N	N	N	N	N	N	N	N
Report ID 4	N	N	N	N	N	N	N	N
Report ID 5	N	N	N	N	N	N	N	N
Report ID 6	N	N	N	N	N	N	N	N
Report ID 7	Y	N	N	N	N	N	N	N
Report ID 8	N	N	N	N	N	N	N	Y
Report ID 9		N	N	N	N	N	Y	N

Summary | SQL Mismatch | Missing Items | Column Order Mismatch | Sort Order Mismatch

Summary: Summary of all validation category listed in each column with “Y” and “N” for all Standard DRP Reports used in the study. If mismatch between Standard DRP and Study DRP Reports, then populated with “Y ” else “N”.

Summary and Conclusion

Reduced Manual Workload

Identifying structural and code level differences between study-level reports and the standard library of reports.

Benefits of Automated Validation

Allows for a shorter peer review process and a narrower focus on revisions.

Reduces manual testing of standard reports.

Key Achivement

Standard reports are released within 3 days in PROD.

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