PP21: Automated Quality Control for Safety Aggregate Reporting

Authors

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Introduction

Safety aggregate reporting plays a critical role in pharmacovigilance, ensuring patient safety through periodic reports such as Periodic Benefit-Risk Evaluation Reports (PBRERs), Development Safety Update Reports (DSURs), and Annual Safety Reports (ACOs). Ensuring data integrity and accurate comparisons between consecutive reports is vital for detecting discrepancies and maintaining compliance.

Objective

To streamline quality control in safety aggregate reporting through automation, reducing manual effort while improving accuracy and regulatory compliance.

Methods

Our team developed macros that:

- Automate dataset comparisons
- Implement validation rules
- Detect discrepancies early in the reporting process.

Key Features

- Comprehensive outputs with detailed report on each check
- Excel-based detailed sheets highlighting differences in the numbers of participants between submissions at protocol, treatment, and individual levels
- Standardized quality control framework ensuring scalability and consistency.

Macro results example

ARM Allocation

ARM in current dataset	ARM in previous dataset	In current dataset	In previous dataset	Number of patients
	Therapy 1	No	Yes	1
Therapy 1		Yes	No	2
Therapy 2	Therapy 1	Yes	Yes	1
Therapy 2	Therapy 2	Yes	Yes	2

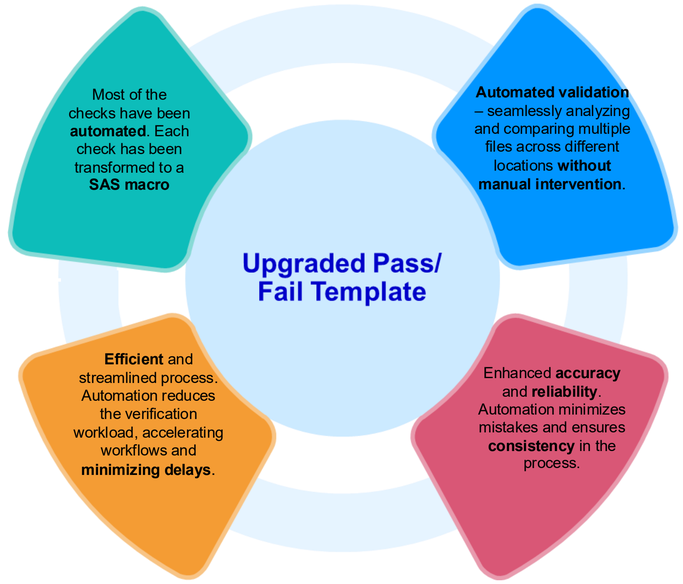
Check how many participants are the same between the two submissions that we are comparing using color code for differences. In this tab the treatment arms are also displayed to check the distribution.
Red meaning: participants do not appear in the current submission, but were present in the previous one.
Yellow meaning: newly added participants.

Protocol Allocation

Protocol number in current dataset	Protocol number in previous dataset	In current dataset	In previous dataset	Number of patients
	Protocol 1	No	Yes	1
Protocol 2		Yes	No	2
Protocol 2	Protocol 2	Yes	Yes	3

Check in more detail using the protocol allocation. This tab follows the same logic as the ARM Allocation tab. Here the protocols are displayed to check the distribution.

Pass/ Fail Template Automations



Results & Impact

- Early detection of discrepancies enhances data integrity
- Automation improves regulatory compliance and optimizes resource utilization
- Reduction in manual effort enhances efficiency in clinical drug development
- Strengthened accuracy and traceability of safety analyses

Conclusions

By integrating automation into safety aggregate reporting, we ensure high data quality, consistency, and efficiency. This innovative approach enhances programming efficiency and reinforces the reliability of pharmacovigilance reporting.