SERIOUS **ADVERSE EVENT RECONCILIATION IN** CLINICAL STUDIES

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What is Serious Adverse Event (SAE) Reconciliation and why is it required?

The aim of Good Clinical Practice (GCP) and Good Pharmacovigilance Process (GVP) is to keep patients at the center of drug development efforts and ensure their safety and wellbeing, while at the same time researching more effective, safer cures for diseases. At the juncture of GCP and GVP is the process of SAE Reconciliation, which ensures that the clinical database and pharmacovigilance database are in sync with each other. Completeness and accuracy of data in these two databases is a significant driver in determining outcomes in a clinical trial, affecting clinical reports and safety reports, data management reports, etc. This blog post emphasizes the importance of this critical process in order to achieve better outcomes for clinical trial sponsors and patients alike.

Key Stakeholders in the SAE Reconciliation process

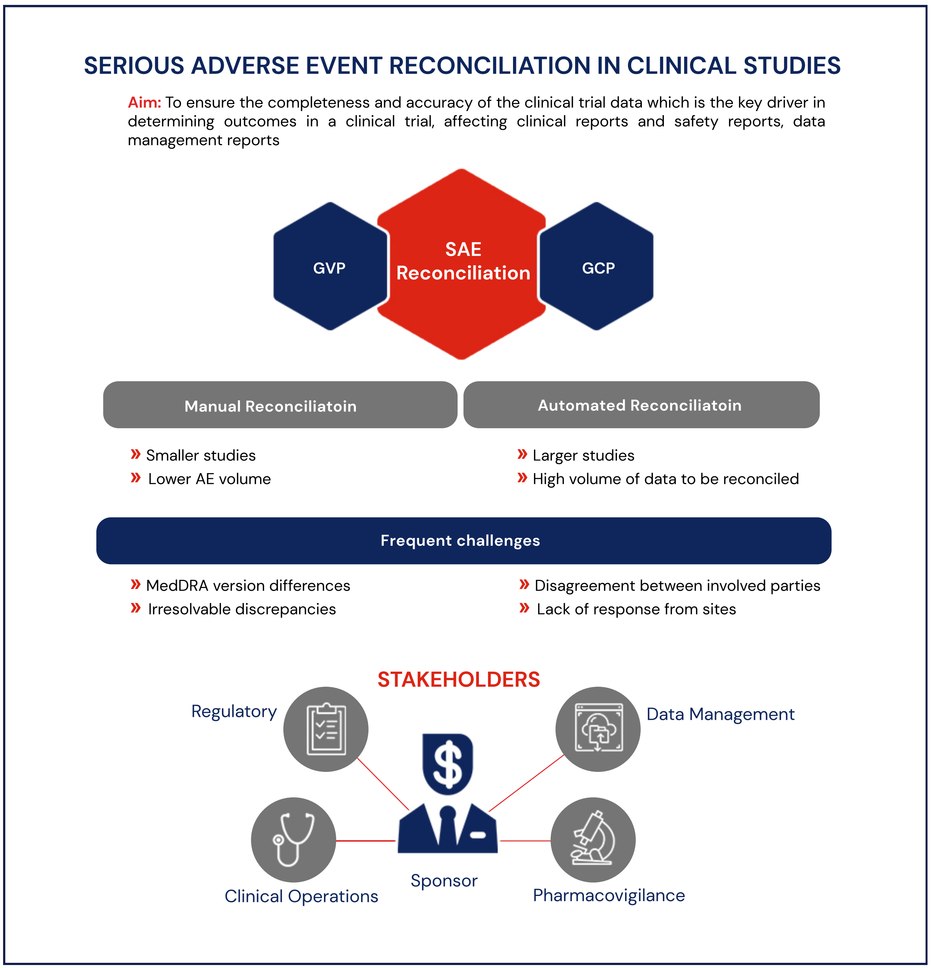
SAE Reconciliation is a group effort by teams that manage the clinical database (i.e., sites, data management), and the safety database (i.e., pharmacovigilance). Support is often required from Clinical Operations in co-ordinating with sites & site personnel in resolving issues that arise, Regulatory in co-ordinating submissions where required, and contract research organizations that may have been contracted by Sponsors in the study.

Manual vs. Automated SAE Reconciliation

SAE Reconciliation may be a manual or automated process, depending on the size of the study population and the volume of adverse event data in a study. Sponsor personnel, along with their Data Management and Pharmacovigilance teams, agree to a list of fields that would be reconciled during the course of a study, and the frequency at which such reconciliation is to be done. Detailed documents, e.g., Data Management Plans may be prepared to document the process, responsibilities & timelines. Regular meetings may be required for parties to clarify any discrepancies that may arise during the SAE reconciliation process.

Frequent challenges faced during SAE reconciliation and their remedial measures

Some frequent challenges include MedDRA version differences, irresolvable discrepancies, disagreement between involved parties, lack of responses from sites, etc. With effective management of the process, and automation tools, where the volumes justify their use, the process efficiency can be maximized, thus bringing about higher accuracy of data across both the databases.



Reference:

1. Bart Cobert. Reconciliations https://lifesciencescare.hcltech.com/blog/reconciliations/

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Tanvi is a pharmacist with over 11 years of experience. She has expertise in pre-approval and post-marketing safety and has managed end-to-end project setup for clients including process development, database setup with data migration and validation, transition of PV and MI services and team onboarding. She has experience across various PV domains like case processing, literature management, regulatory intelligence and pharmacovigilance quality assurance. She is eligible to provide Responsible Person for EudraVigilance (RPEV) services to Sponsors of Clinical Trials in the EEA.

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