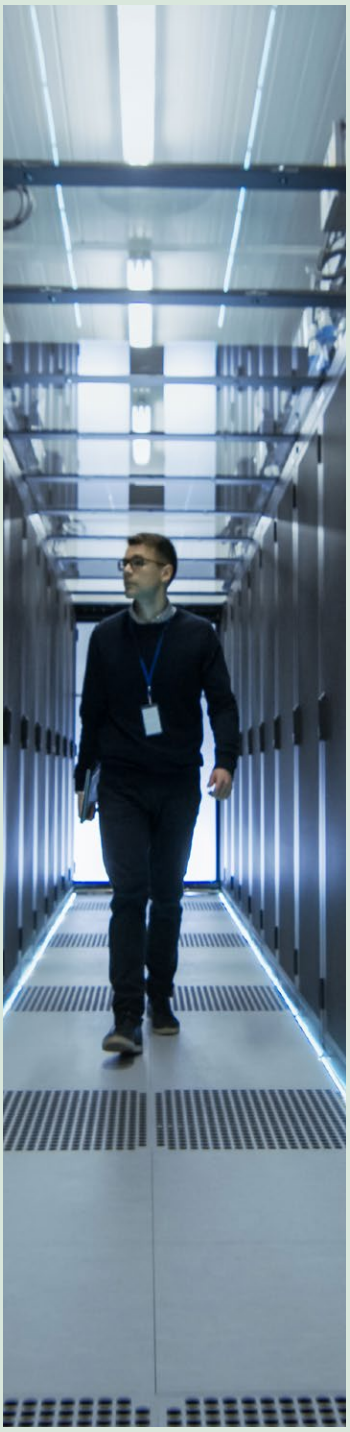
WHITE PAPER



AGILE DATA MIGRATION IN PATIENT SAFETY SERVICES

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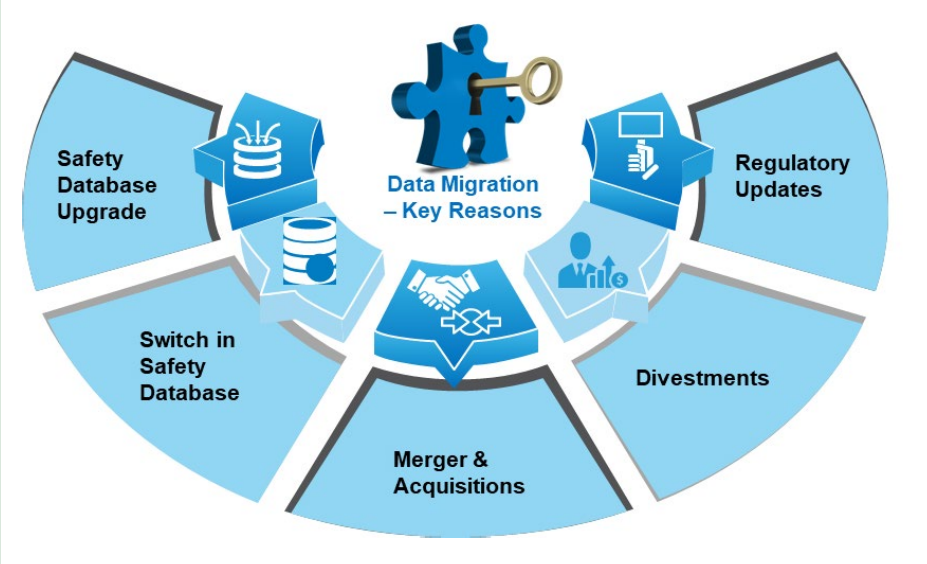
Data Migration in Pharmacovigilance

Pharmaceutical organizations as part of regulatory obligations must have a PV system/database to monitor adverse events/reactions (ICSRs - Individual Case Safety Reports)

of their products which is a GxP validated system serving as a central repository for ICSRs. There are several contexts when pharmaceutical organizations need to migrate the safety data (ICSRs).

The reasons that require data migration are isted in this diagram



We can anticipate that safety data migration is inevitable and unavoidable but also bears a risk of data loss, data integrity breach, and regulatory impact depending on the size, type, and approach of data migration. For small to medium organizations (ICSRs volume >30K), the migration can be easily managed, however for larger data migrations it becomes challenging as several key aspects like database compatibility, quality of data, various internal PV conventions of case processing need to be considered to avoid suboptimal migration.

To overcome these challenges, pharmaceutical companies should adopt newer approaches by applying agile methodologies where such big data migrations are broken down into incremental iterations. However, organizations are reluctant in adopting agile methodologies due to a highly regulated environment that requires documentation of each step performed.

The accurate and complete migration of safety data helps the organization in performing aggregate analysis of the safety data while drafting periodic reports, clinical study reports, and during signal management activities. From a compliance point of view, safety data migration becomes a critical aspect as this information is typically updated in the Pharmacovigilance System Master File (PSMF).

Causes for Safety Data Migration Failures

Safety Agile Data Migration:

The Scrum technique/process of agile methodology can be used for safety data migration. The whole safety data migration can be divided into multiple sprints/iterations.

Infosys recommends Scrum technique to best suit safety data migration as:

- User stories can be well-defined
- Certain requirements are completed only after they are deemed correct in each sprint/iteration
- The additional changes of requirements/user stories/backlog items as requested by the business can be incorporated and can be implemented in further sprints/ iterations
- The migration can be completed in quick time with good quality

Key Benefits of This Approach

- **Leadership Oversight -** The leadership teams of the pharmaceutical organizations are appraised on a regular/periodic basis about the progress of the safety database migration, and they shall have complete oversight of the project and their suggestions/feedback can be incorporated into the migration.
- **Templatized Migration Process -** A migration platform that applies the principles of agile methodology for scalability.
- **Fail Early Process -** We will follow fail early process by performing continuous iterative testing and will learn about the discrepancies/issues/ bugs so that they can be fixed in the early stages, which will help in reducing the overall cost and risk to the migration.
- **Incremental Release -** Early and regular incremental releases of requirements/user stories/backlogs lead to higher customer satisfaction.
- **Quality of the Data Migration -** High quality of the safety data migration is possible without missing any safety data after each sprint/iteration.
- **Transparency, Flexibility, Short-Term Predictability,** and **Long-Term Vision.**

High-performance Project Execution

- **Design Workshop:** Initiate workshops to understand and plan the business objective, requirements, configurations (types of configurations drug/vaccine/ combination products, product licenses, reporting configurations etc.), storage of data (on-premise/ cloud), data migration plan, volume of cases, versions of E2B (R2 to R3), and migration between same database (upgrade) or migration between different databases.
- **Key Deliverables:** Based on the workshop, prioritize configurations and design user stories as per business needs for immediate value generation using the Value-Realization Framework (VRM).
- **Project Planning:** Draft project plan, define backlog (user stories), sprint and duration (2 to 4 weeks). Once all the above have been discussed and agreed upon, then the core project team (Product Owner [PO], Scrum Master [SM], and Development Team [DT]), will prioritize the backlog and will discuss the key deliverables for the 1st sprint.

Infosys – Agile Safety Data Migration Partner:

Infosys possess techno-functional experts who can draft the safety data migration plan, create a project plan along with project charter, workflow process documents and User guides.

With our expertise we can handle all kinds of risks, uncertainties, and challenges of safety data migration by using the scrum methodology. Some of the examples are listed below:

People	• Infosys possess PV Subject Matter Experts (SME's) with agile/scrum experience. • Infosys also possess techno-functional experts to handle all kinds of associated risks, uncertainties and challenges associated with safety data migration by using agile methodology.
Technology	• **Data Loss:** We shall create mapping documents and strictly adhere to these documents at each sprint/iteration step to control the data loss. We can also automate some of the reconciliation process to verify if all the safety data is transferred or not. • **Input and Output logic:** We shall introduce input and output logic for each field from safety databases/products prior to data migration. • **Data Transfer/File Transfer Vs Cost:** Availability of data in HTML or XML Vs Size of the data. If XML files, then handling of non-E2B tags Vs custom E2B tags. • **Data Storage:** On-premises data migration Vs cloud based data migration.
Process	• **Compatibility check:** We shall evaluate the compatibility for database upgrades and for inter database migration (E.g.: ARGUS to ARISg databases). • Value Creation (time and cost)
Governance	• **Data Security:** Data Security assurance (AWS Cloud platform Vs Enhanced security). • Timely transition and execution of safety data migration.
Knowledge Management	• **Knowledge Transition:** We shall create mapping documents to enable the end-user's knowledge on the data flow from existing to new safety databases. • Trainings
Data Quality, Risk & Compliance	• **Data Validation:** After data migration, results are subjected to data verification to determine whether complete data has been accurately migrated into the new system. • **Automated Scripts:** We shall create automated scripts and execute the scripts to verify the migrated data. • **Automated Templates:** We shall use rapid automated templates to transfer the data related to libraries (products, study protocols and company units [sender & receiver] etc.). • **Compliance with Data Privacy:** We also possess the expertise to handle the migration of cases with data encryptions for meeting the data privacy rules (E.g.: EU-GDPR rules and US-HIPPA rules).

About the Authors

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Dr. Hari has 12 years of experience in CRO & Pharma client engagements as a Lifesciences domain consultant. He is a Certified Scrum Product Owner (CSPO®) and experienced professional in Pharmacovigilance - Program Management, Aggregate Reports, Medical Writing, Product Management, ARISg Safety Database Implementations, Admin Configurations, Integrations, Database Upgrades and ARGUS to ARISg Database Migrations.

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Dr Srinivasa has 12+ years of experience with end-to-end Pharmacovigilance (PV) activities. He has worked in varied capacities as Program Lead, Project Manager, Business Analyst providing leadership, oversight and direction to PV projects including clinical & post-marketing along with life science projects.

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