APCER
LIFE SCIENCES
Together for better health

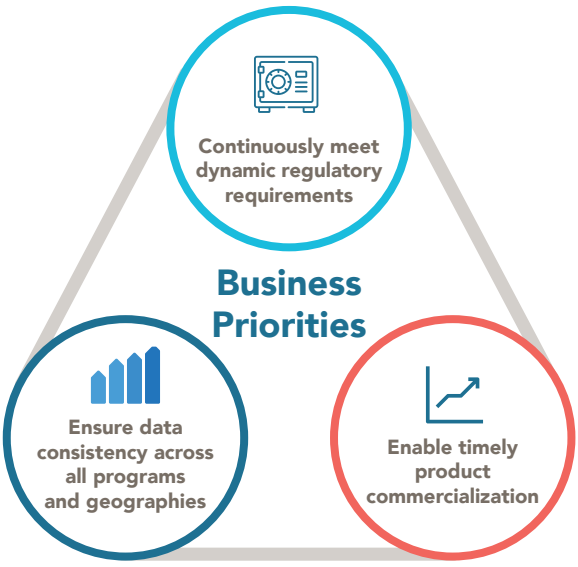
Together for Integrated PV Services

Technology-enabled End-to-End Drug Safety

Pharmacovigilance ensures that biopharmaceutical and medical device companies remain compliant to stringent and evolving regulations while analyzing patient safety risks against product benefits.

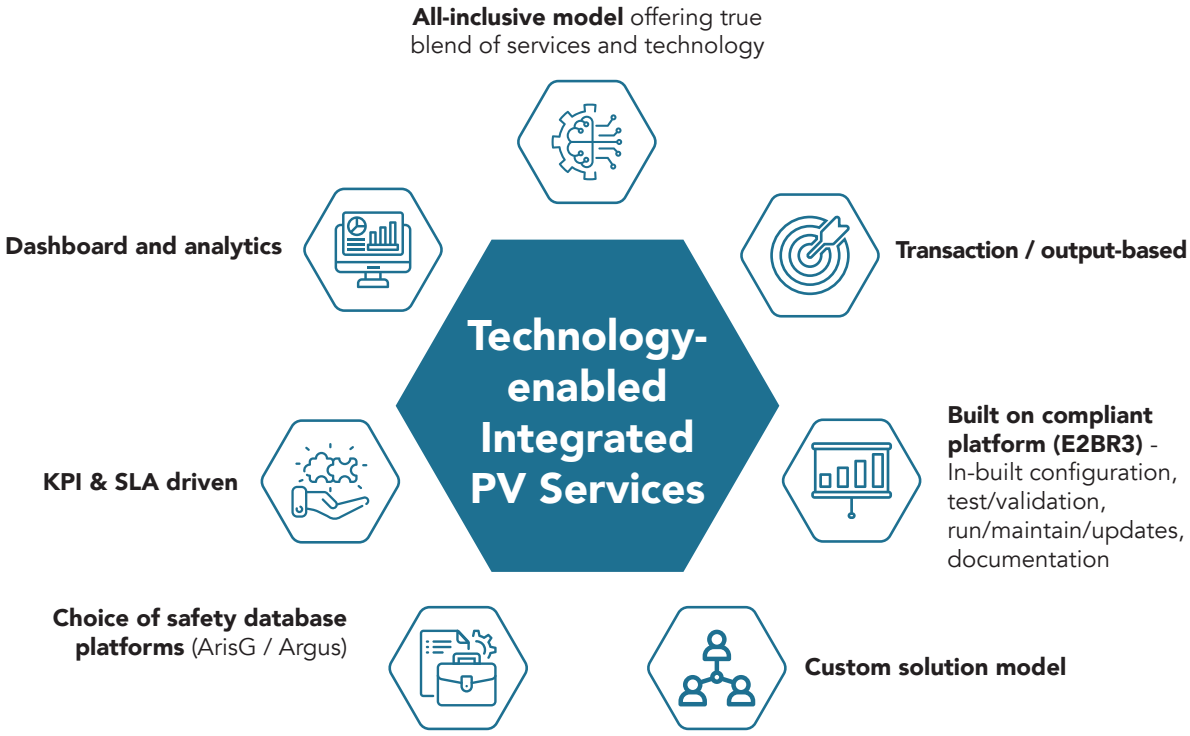
Underlying technology enablers play a significant role for both of these goals. Integrated Pharmacovigilance services offer a true synthesis of drug safety services backed by best-in-class technologies.

Biopharmaceutical companies should consider developing Integrated Pharmacovigilance Services as early in the clinical development as feasible to build their understanding and evidence of the safety profile of their product which will serve them through the submission and into the post-marketing stages of the product life cycle.



Model for Technology-enabled Integrated PV Services

The model ensures a holistic safety approach through seamless information and data flow with well-defined metrics and real-time data analytics.



How will our Integrated Pharmacovigilance Services work for you?

We understand that each company has a unique safety landscape, processes & priorities. As part of our approach, our customers will choose the safety database which integrates best with their preferences.Both the safety platforms that APCER offers are backed by assured infrastructure, certifications, security and quality.

Choice of Safety Platforms

Fully Certified and Compliant, backed by Assured Quality

ISO 27001, ISO 9001 Certified

HIPAA Certified

SOC 2 Compliant

CMMI DEV-3 Certified

Key Automation Elements within the Safety Platforms

AUTO NARRATIVE

Narrative creation within case processing.

Option for manual editing.

Error avoidance to increase the narrative writing efficiency.

Configurable customer-specific templates.

COMMUNICATION MODULE

Generate and track communications related to case data.

Automate and simplify tedious case communications.

Track case-related communications across its lifecycle.

AUTO REPORT SCHEDULING

Easier process of generating various reports in the database.

Configuration of back-end rules in the database to recognize, assess and categorize the overall case assessment and report generation.

AUTO LABELLING

Auto labelling functionality allows for auto-population of adverse events labelling in the database as per their respective labelling documents.

Requires configuration of the labelling terminologies in the database for the system to read and access the event labelling.

APCER Life Sciences - Your Preferred Partner for Integrated Pharmacovigilance Services

A biopharma company with commercialized products may require support to ensure safety for its marketed products.

A biotech company looking to advance its clinical trial program typically needs a specialized pharmacovigilance services partner to manage safety as early as feasible.

Benefits Achieved

Standardized and Integrated Processes

- Leverage APCER's Integrated Services' best practices
- APCER designs and delivers end-to-end services including your safety database, ensuring strong governance (No fragmented ownerships/ integration points /processes)

Agility and Scalability

- Scalability of infrastructure, licenses, etc. are all included in the case transaction fee to eliminate high monthly cost and periodic expenses
- APCER's Information Technology team works directly with each client, configuring their safety database to their preferences and needs

Assured Uptime and Periodic Updates

- MedDRA updates and access to new system releases and upgrades with validated processes which inclues rigorous testing, validation, and documentation, and full notification according to change control processes before going "live"
- Contracted service levels, KPIs to ensure quality and compliance

Optimized Costs

- Financial model of a per case / per transaction fee
- APCER is fully invested for infrastructure / hosting and BCP / DR
- APCER's technology skills and experience provides for infrastructure creation and optimized operations

Together for better health
APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

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