APCER LIFE SCIENCES
Together for better health

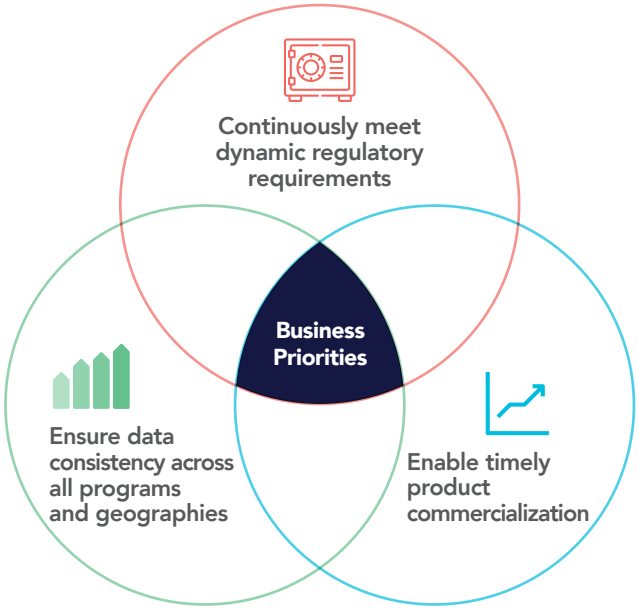
BROCHURE

Together for Integrated PV Services

Technology-enabled End-to-End Drug Safety

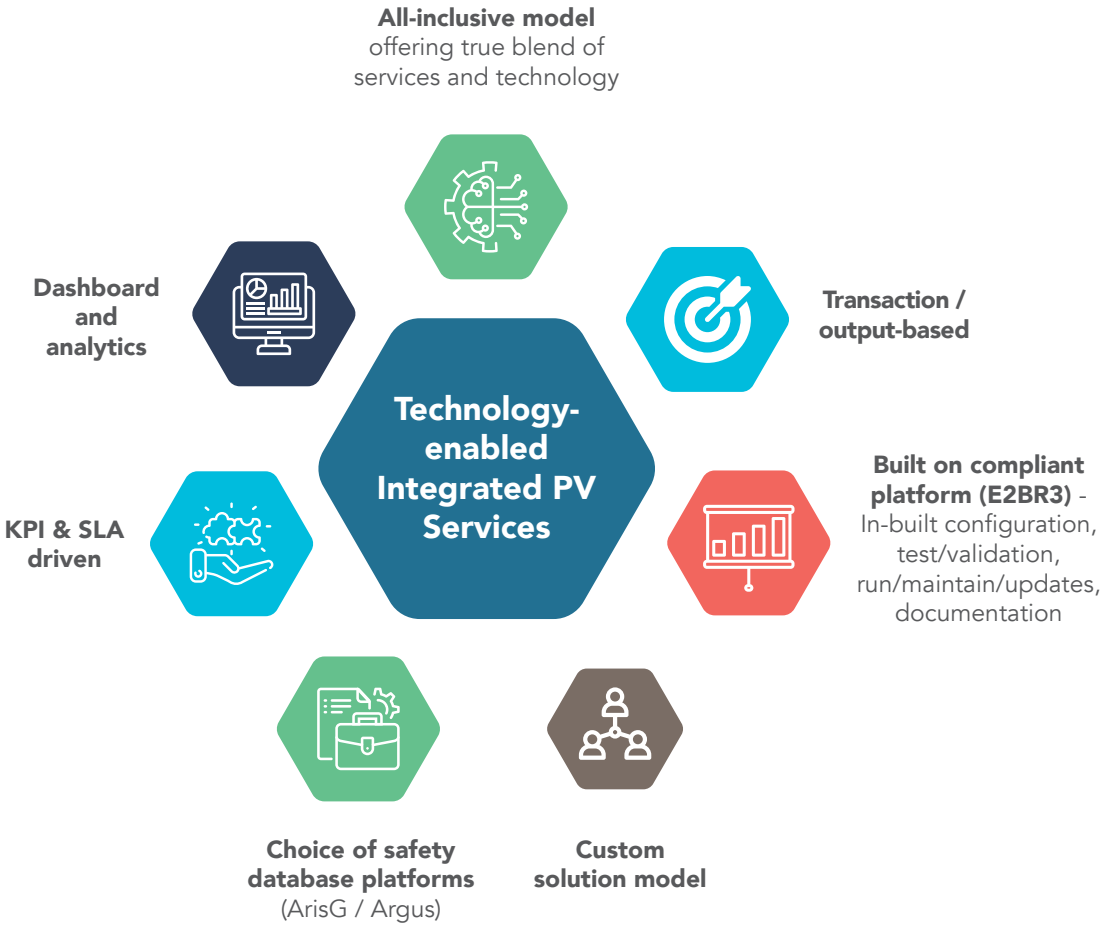
With increasing drug costs and stringent regulatory requirements, the complexity of global, end-to-end Pharmacovigilance systems is increasing. Biopharmaceutical companies are expected to adopt a proactive pharmacovigilance strategy as they seek market approvals for their products in the European Union (EU) and United Kingdom (UK).

The EU and UK regions have stringent Pharmacovigilance and regulatory requirements such as electronic and expedited submissions of ICSRs, electronic submission of PSURs, robust signal management processes, establishment and evaluation of risk management systems and effectiveness of risk minimisation, effective processes to monitor the performance and effectiveness of a pharmacovigilance system and its quality system along with maintenance of pharmacovigilance system master file (PSMF). The companies also need to have an appropriately qualified person responsible for pharmacovigilance (QPPV) who shall reside and operate in the EU on 24-hour basis with back-up procedures in place in case of QPPV's absence.



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 certifications:
ISO 9001:2015,
ISO 27001:2013,
ISO/IEC 27701:2019

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 include 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.

APCER LIFE SCIENCES | Together for better health
Part of APC Group

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.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (91) 79 6677 8600

For Business enquiries, please email at: marketing@apcerls.com
For General enquiries, please email at: info@apcerls.com