APCER LIFE SCIENCES
Together for better health

BROCHURE

Together for Minimizing Risk

The need for vigilance

Safety reports are in demand

Whether marketing innovative new therapies, biosimilars, or generics, your company's adverse event (AE) reports are in demand.

Responding to an expanding matrix of global reporting regulations has been the norm in pharmacovigilance for more than a decade. Even as profit margins shrink, your company must continually submit increasing volumes of AE cases and meet strict timelines to stay in compliance.

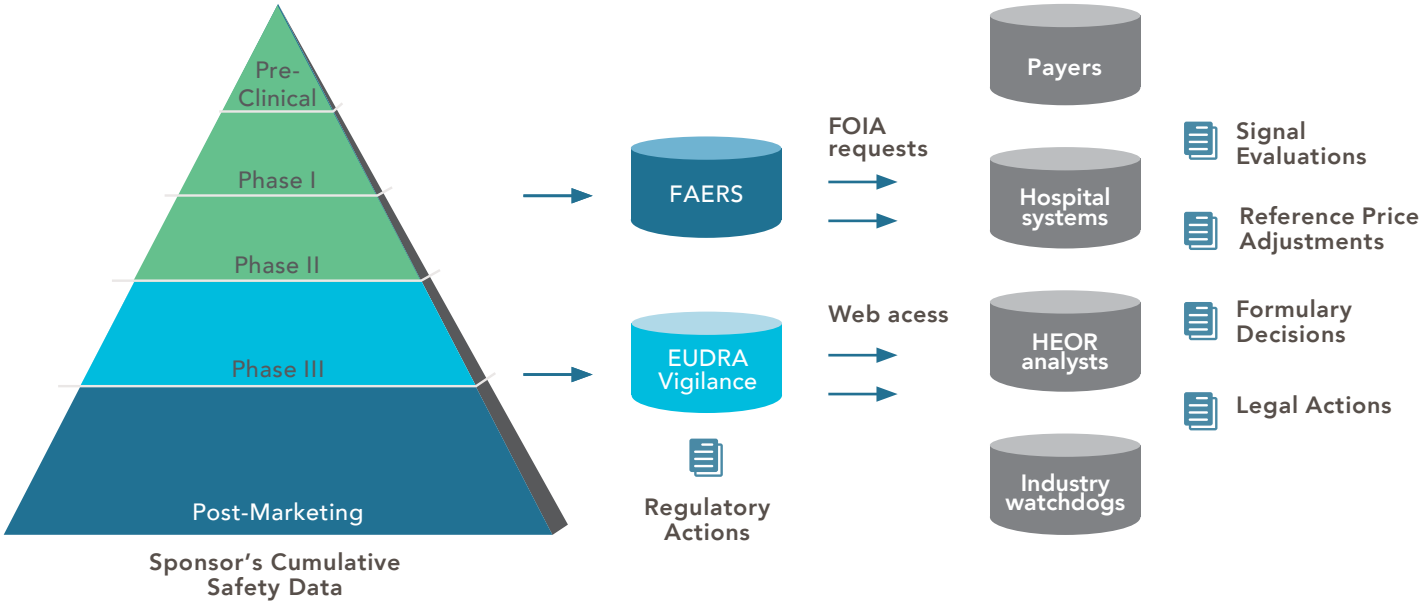
Now, with increased transparency of safety information, regulatory systems are just the first stop for individual case safety reports (ICSRs).

Payers, hospital systems, and other stakeholders are employing healthcare analytics solutions that combine summaries of AE reports from regulatory websites and ICSRs obtained through Freedom of Information Act (FOIA) requests to spot trends.

In this model, payers are now able to detect new safety signals, quantify the impact of adverse events on downstream healthcare costs, and adjust reimbursement rates and formulary decisions accordingly.

The result: Pharmacovigilance practices can have an impact on company compliance, product profitability, and market access.

Regulatory systems are just the first stop for ICSRs



Are your reports as complete as possible?

With this level of transparency and scrutiny, it's more important than ever for companies to build an accurate and complete safety profile for each product. But this may not be happening. For instance, according to the Institute for Safe Medication Practices (ISMP), less than half of serious expedited AE reports submitted to the FDA Adverse Event Reporting System (FAERS) by pharmaceutical companies are considered "reasonably complete."

Incomplete reports make it more difficult for companies to respond with speed and confidence to regulatory agencies and to the variety of interpretations that may arise from other stakeholders with open access to complex information.

Meeting the demand for vigilance

APCER Life Sciences provides the expertise, discipline, and infrastructure needed for global pharmacovigilance. APCER works together with your team and your partners to build a safety program that responds rapidly to serious events, puts each case in context, and monitors benefits and risks.

Post-marketing Safety Disciplines

Foundational activities

- QPPV assignment
- Pharmacovigilance System Master File
- Centralized safety system
- Legacy data migration
- SOPs/working practices
- RMP/REMS development
- Safety data exchange agreements

Time-sensitive SAE/SUSAR response

- Case intake
- Follow-up
- Coding
- Narrative writing
- Medical review
- E2B reporting
- Partner notifications
- Literature search
- Legal case handling
- 24x7 operations

Continuous analysis of safety

- Aggregate report writing and submissions (PSUR, PBRER, PADER, and supplemental components)
- Signal detection
- RMP/REMS updates
- Compliance audits
- Inspection support
- MedDRA maintenance
- Product dictionary uploads

Together to minimize risks

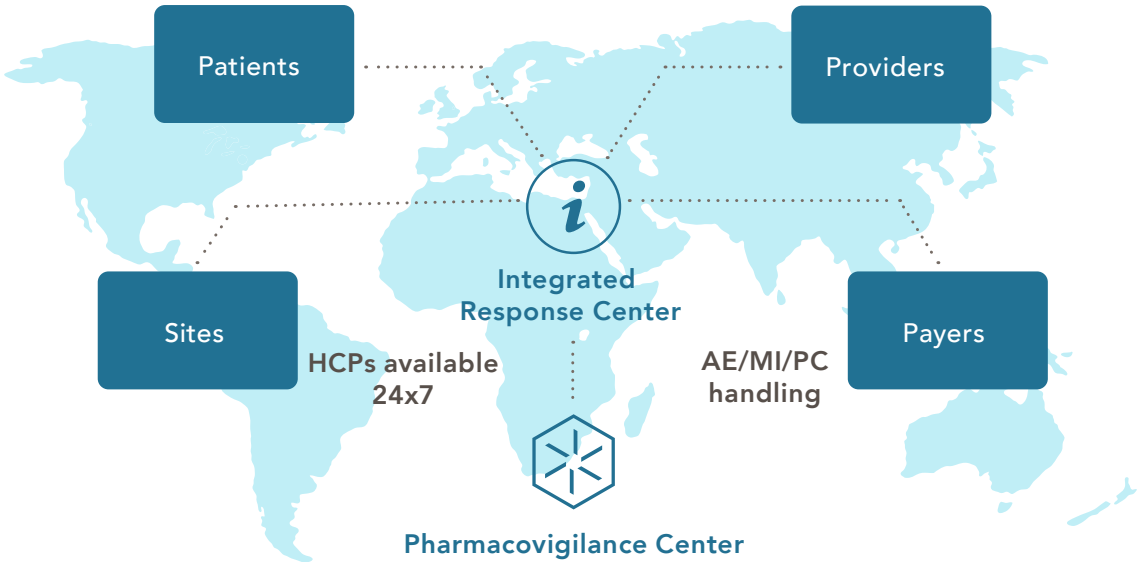
APCER's Pharmacovigilance Center is staffed exclusively with clinically trained safety scientists and one of the highest ratios of physicians in the industry. Our medical focus has demonstrated superior AE case quality compared to full-service CRO capabilities in real-world, large-scale, global post-marketing safety operations. Yet our business model is extremely cost-efficient, giving start-ups and generic companies alike the same opportunity to have an affordable solution that minimizes risks and maximizes patient safety.

Prepared for the spontaneous

APCER's Integrated Response Center (IRC) is available 24x7 to respond to spontaneous AE reports with multilingual support. Experienced healthcare professionals are trained on your products and skilled in the techniques and tenacity necessary to gain as much initial and follow-up information as possible within regulatory timeframes.

The IRC can also handle medical inquiries (MIs) and product complaints (PCs) as a seamless contact center, making APCER the ideal partner for specialty pharmaceutical companies planning their first product launch. With a team of Qualified Persons for Pharmacovigilance (QPPVs) based in our London office, we ensure that you have all the support needed to enter markets throughout Europe.

A responsive, professional, cost-efficient model for pharmacovigilance



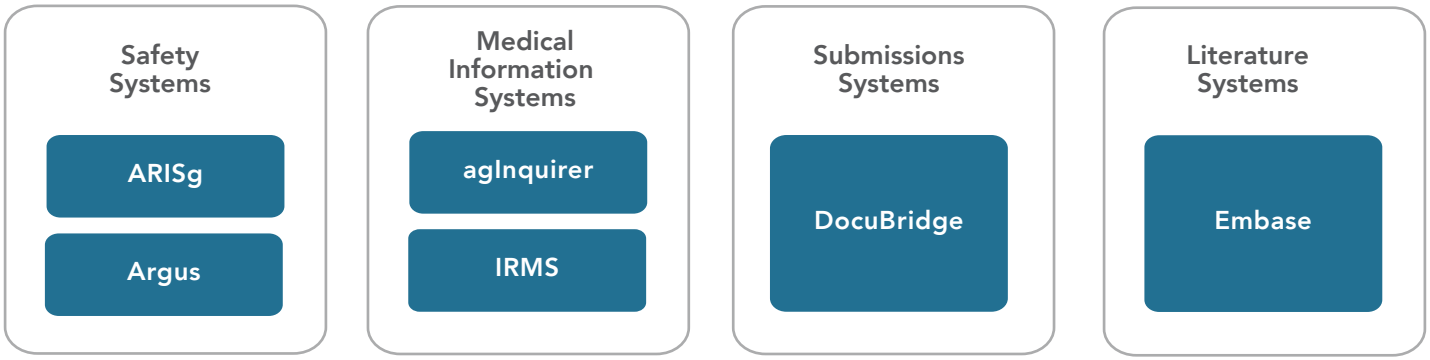
Local knowledge, global compliance

Each of APCER's operational units in North America, Europe, and Asia serves as the regulatory intelligence and delivery center for its respective region. They continually track modifications in standards, guidelines, and regulations, incorporating their knowledge into standard operating procedures, working practices, and training modules that are shared globally.

Technology hosting

APCER provides complete, fully validated technology systems for case management, report generation, signal detection, electronic submissions, and regulatory tracking on a hosted basis, if you prefer to avoid the cost of installing and maintaining these systems in-house.

Solution enablers



Oracle Data Platform Medical Dictionaries/Regulatory Database/Safety Data Warehouse

Infrastructure Secure Redundant Servers/Backup & Recovery/Firewall/Environmental Controls

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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 27001:2013, 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) 11 4650 0802

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