APCER LIFE SCIENCES
Together for better health

BROCHURE

Let's work Together

Post-Marketing Safety Services

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 treatments possible.

Building blocks of flexible, scalable solutions

Solutions	Clinical Safety	Post-Marketing Safety	Medical Information	Medical/ Clinical Affairs	Regulatory Affairs
Customized Support Teams			Executive Steering	Quality, Compliance & Training	Project Management
Centers of Expertise		Pharmaco-Vigilance Center	Integrated Response Center	Medical Writing Center	Regulatory Intelligence Center
Solution Enablers		Safety Systems	MedInfo Systems	Literature Systems	Submissions Systems

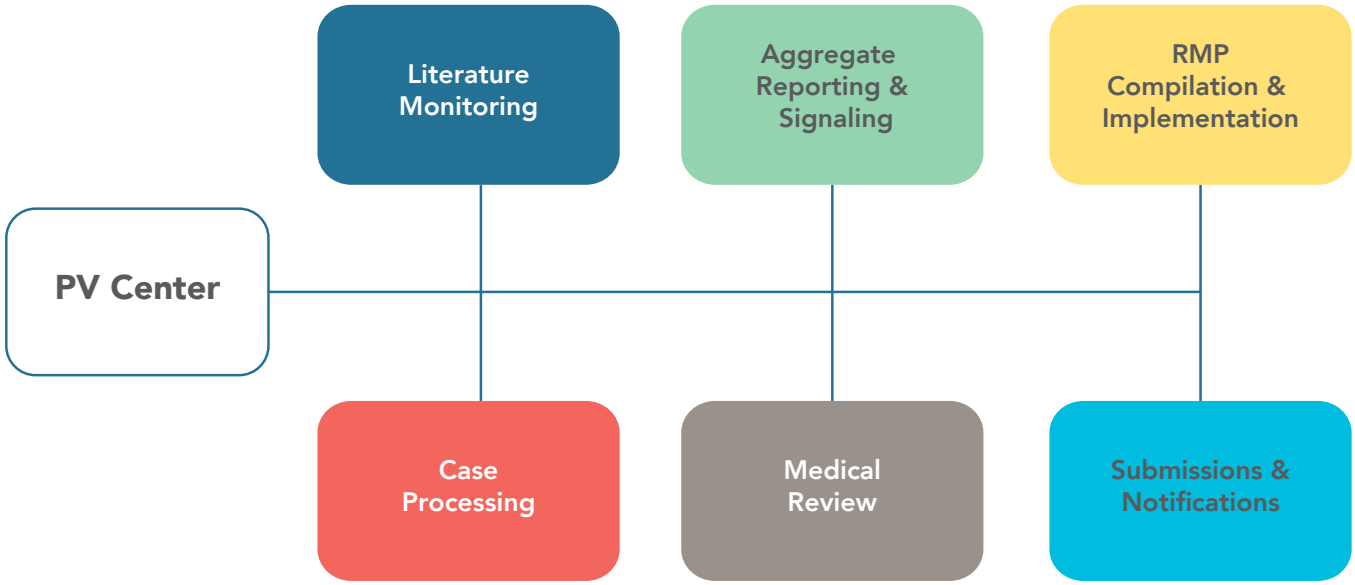
Together for safer therapies

Since 2007, biopharmaceutical and medical device companies of all sizes have trusted APCER Life Sciences to monitor the safety of their products, during development and post approval, cost-efficiently. We help you:

- Keep in compliance with ever- expanding global regulations.
- Keep pace with ever-increasing volumes of adverse event cases.

Together to minimize risks

Minimizing risks to patients requires building the safety profile early in product development and putting each case in context as exposure grows through each phase. APCER Life Sciences is a company of healthcare professionals and safety scientists, with one of the highest ratios of physicians in the industry. Our specialized model has proven to deliver a deeper, more consistent level of medical assessment, critical to signal detection and benefit/risk evaluation, compared to large CROs.



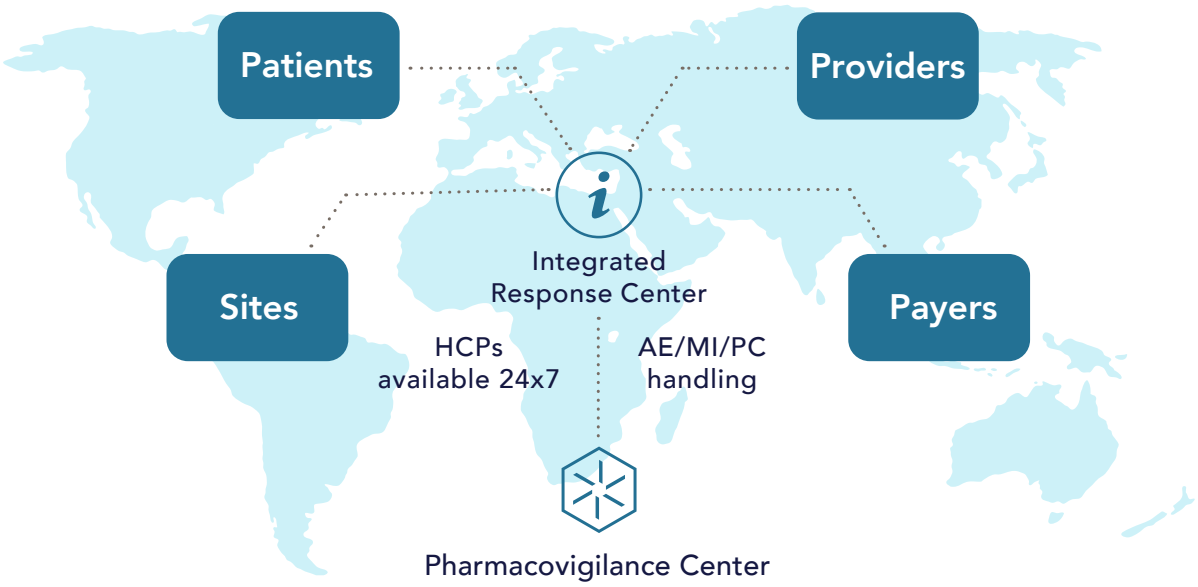
Together for informed decisions

Patients, providers, and payers need a reliable source of information about the products they take, prescribe, or cover. When you partner with APCER Life Sciences, you'll have highly trained healthcare professionals available 24x7 to handle adverse event reports, medical inquiries, product complaints, and patient support/assistance programs.

Together to communicate information

Developing and marketing medical products requires a constant flow of high quality scientific writing. APCER Life Sciences has an experienced team of writers with clinical, medical, and regulatory expertise to help companies gain approval, demonstrate value, and stay in compliance world wide throughout the product lifecycle. All content is written by or under the close supervision of a physician.

A responsive, professional, integrated model for safety and medical affairs



Medical

- Manuscripts and Abstracts
- Conference Slide Kits and Posters
- Review Articles
- Drug Monographs
- Sales Force Training Manuals
- CME Slide Kits
- Standard Response Letters & FAQs
- Reimbursement Dossiers
- Medication Guides and Questionnaires for REMS
- Patient Information Leaflets

Clinical

- Investigator Brochures
- Clinical Study Reports
- Informed Consent Documents
- Patient Safety Narratives
- Synopses for Public Websites (ClinicalTrials.gov, EU Clinical Trials Register, Company specific)

Regulatory

- Common Technical Documents
- Standalone Clinical and Non-Clinical Overviews
- SPC
- Clinical Expert Statements
- Briefing Document
- IND/NDAs
- Annual Updates
- Aggregate Report Writing
- Risk Management Plans
- REMS and Safety Updates
- Labeling and Core Data Sheets

Together to unleash potential

APCER Life Sciences is a company of experts who take ownership of the problems you face. We work together with our clients to find solutions and meet deadlines, providing the resources needed to unleash the potential of your innovations. We are always willing to start small to demonstrate the quality of our work and gain your trust; yet we stand ready to deliver a complete outsourced solution, across multiple continents, under the tightest of timeframes.

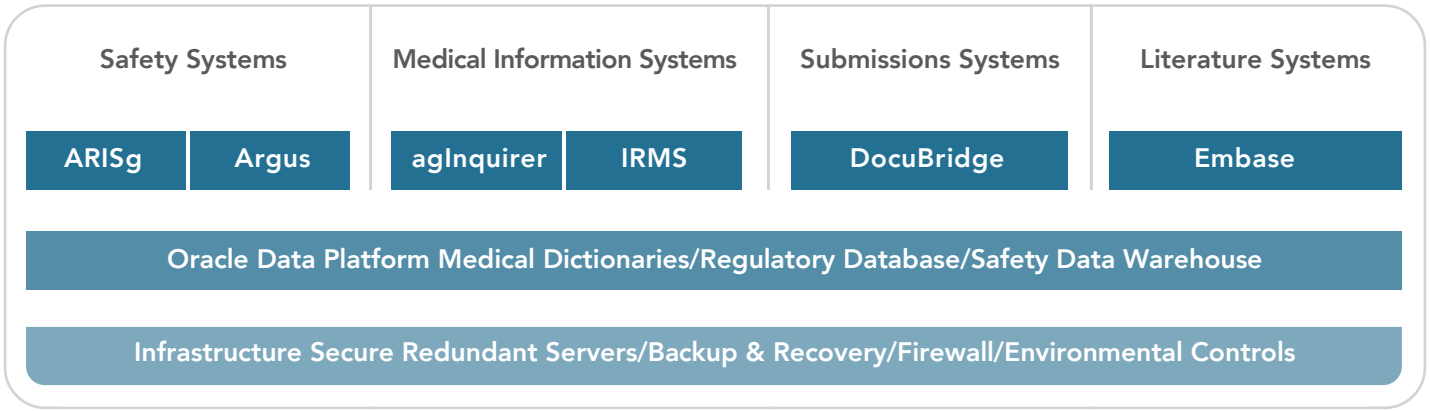
Local knowledge, global compliance

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



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