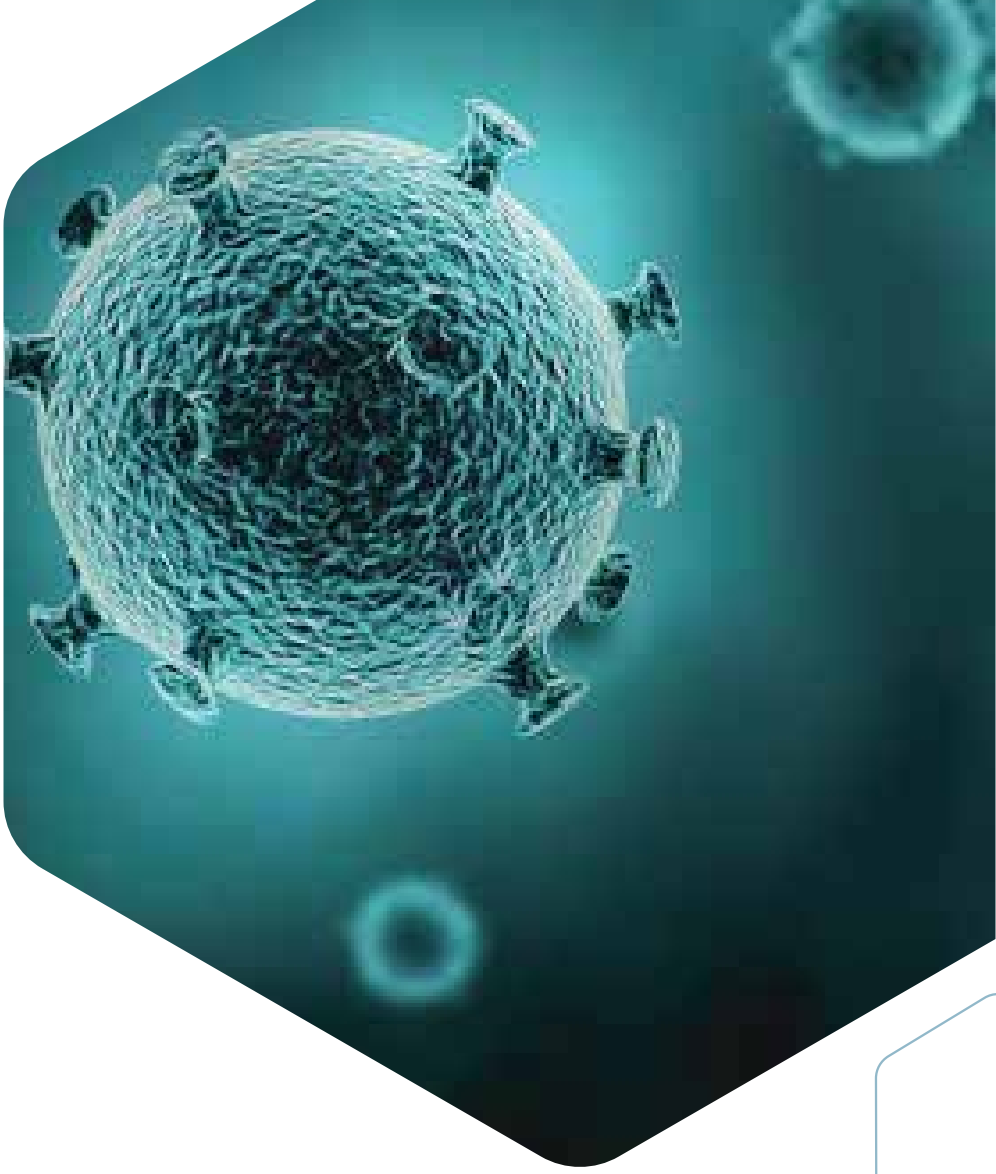
APCER LIFE SCIENCES
Together for better health



BROCHURE

Together for Safer Therapies

A Model for Clinical Safety

Efficacy is only half of the equation

With profit margins and public trust declining across the life sciences sector, both the funding and the patients needed for clinical studies are becoming precious resources. Companies must gain insights from every data point obtained in every trial – and efficacy is only half of the equation for measuring health outcomes and potential returns.

Safety needs equal attention

Safety is now a significant factor in determining the value of potential new therapies. Whether in a large company running hundreds of trials around the globe or an early-stage virtual company looking to out-license its most promising candidates, you're competing for the funds needed to bring new treatments to market. Documenting the safety profile needs equal attention to proving effectiveness.

Questions in the CRO model

To access the right patients, most companies work with more than one contract research organization (CRO), even for a single investiga- tional new drug (IND). Serious adverse event (SAE) cases begin to scatter into multiple CRO systems as clinical development programs expand.

- If an unexpected SAE occurs in this model, how quickly will you be able to locate, compile, and analyze all the safety cases involving that IND?
- Will you be able to gain the insights needed if cases were processed, coded, and assessed by varying SOPs and skillsets?

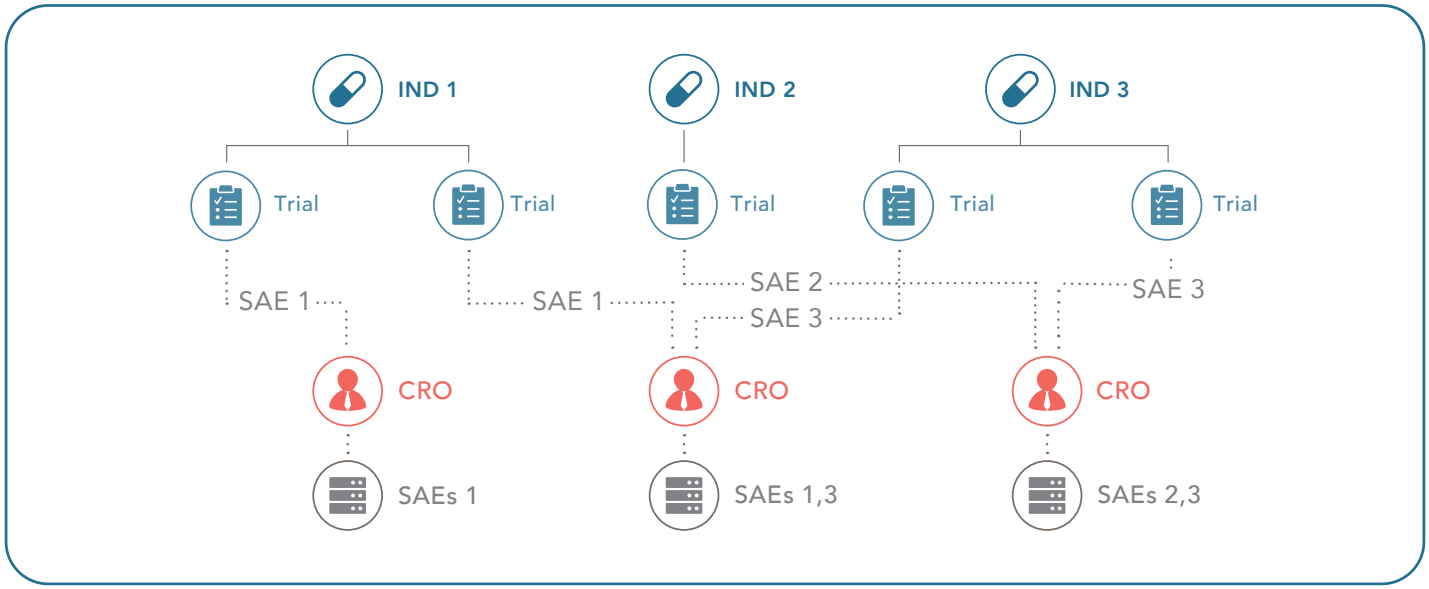
When regulators or watchdogs are the first to describe an emerging safety signal to patients, their families, the press, and your investors, your company risks losing the confidence of all stakeholders.

Clinical safety program management with APCER Life Sciences

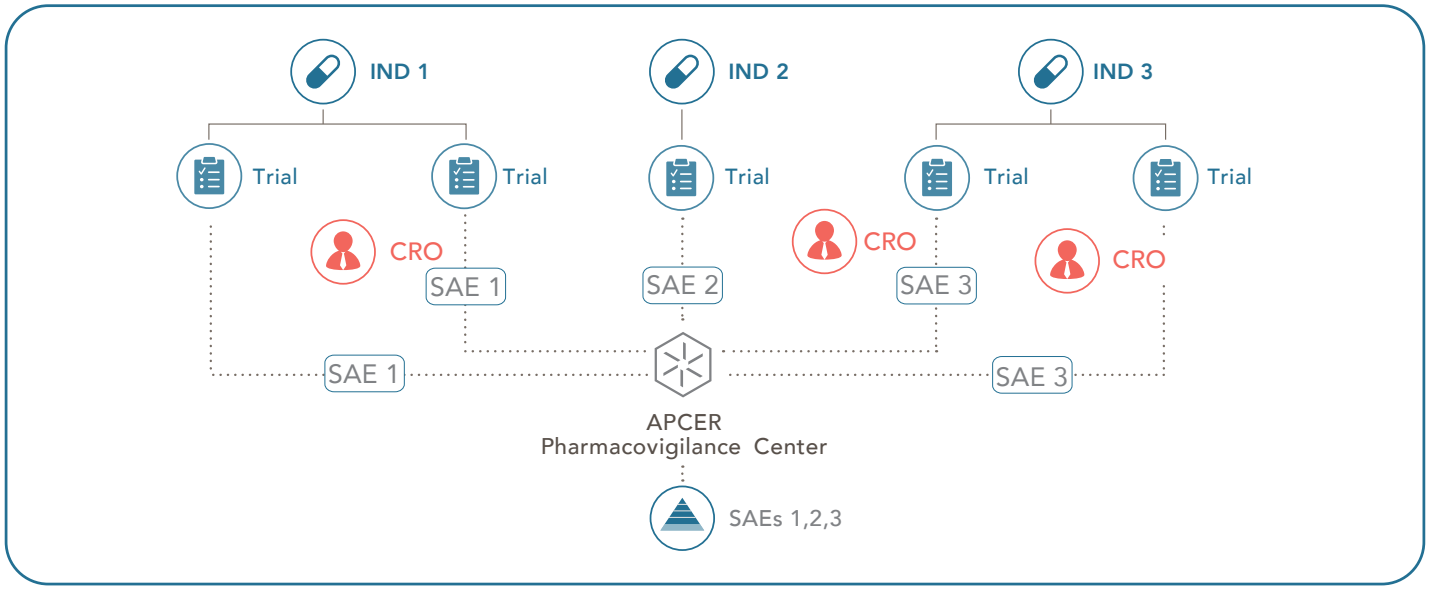
APCER Life Sciences works together with your team and your partners to create a centralized safety program that captures and reports on SAE information across all studies, geographies, and phases in the lifecycle of a product – accurately, completely, and consistently.

Because signal detection requires a uniform data set that illuminates outliers, we provide a core team skilled in case processing, narrative writing, and query management, operating under a single set of global SOPs and supervised by physicians with therapeutic area expertise.

SAE cases scatter as the CRO model expands



Centralized SAE reporting builds consistent safety profiles



Together for safer therapies

APCER Life Sciences provides all the disciplines of a global clinical safety program. Our 24x7, multilingual Pharmacovigilance Center is staffed exclusively with clinically trained safety scientists and one of the highest ratios of physicians in the industry. We provide knowledge and insights while meeting strict regulatory requirements and timelines.

Clinical Safety Disciplines

Foundational activities

- Safety management plan
- Centralized safety system
- Legacy data migration
- EDC integration
- SOP's and working practices

Time-sensitive SAE/SUSAR response

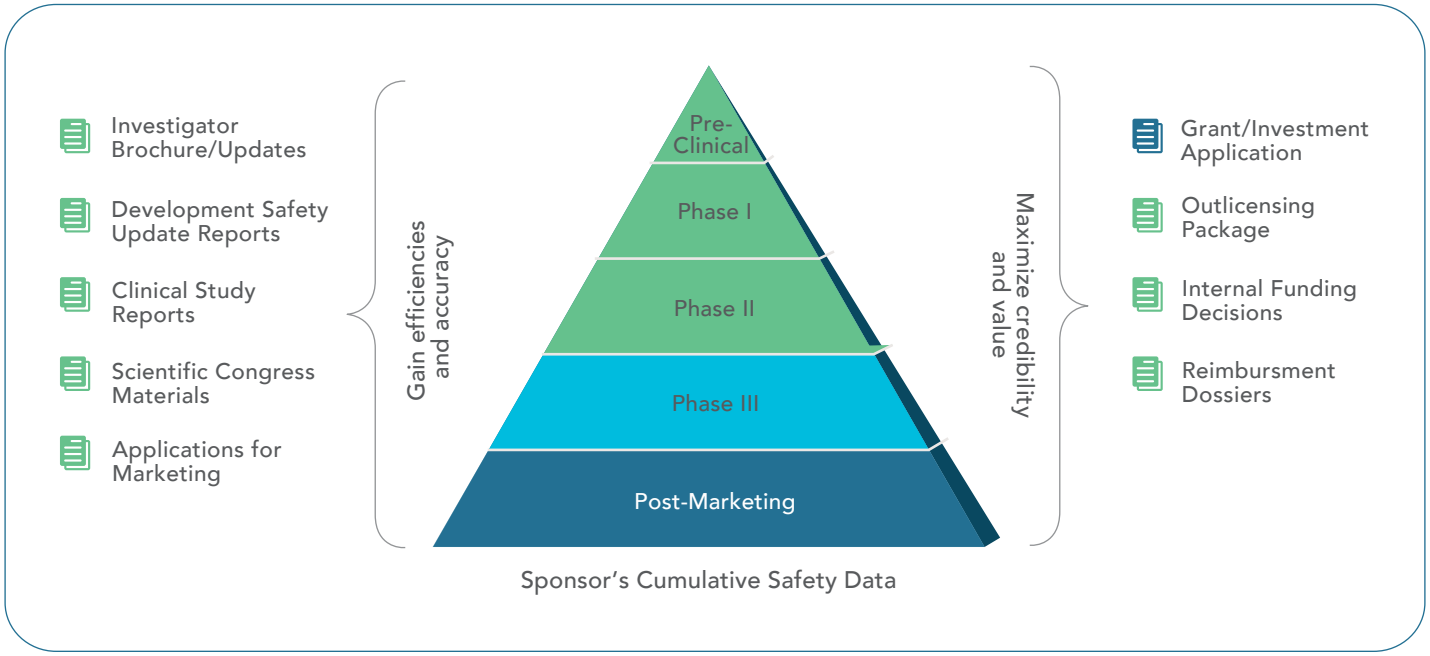
- Case receipt/entry
- Query management
- Coding
- Narrative writing
- Medical review
- Proactive communication with sponsor, CRO, site
- Reporting to regulators
- Notifications to ethics commitees, IRBs, investigators
- Expedited case unblinding

Continuous analysis of safety

- Safety data reconciliation
- Development Safety Update Reports
- Integrated Summary of Safety
- Investigator Brochure updates
- Medical monitoring
- Signal detection and analysis
- End-of-study unblinding

Clinical safety program management benefits companies in every stage

It's never too early or too late to start building a safety profile that becomes a tangible asset. You'll have quicker access to more accurate information while reducing overhead and feeseach time you prepare scientific communications, regulatory reports, and applications for marketing. You'll also demonstrate the integrity of your development programs and the credibility of your company to investigators, investors, and out-licensing partners.

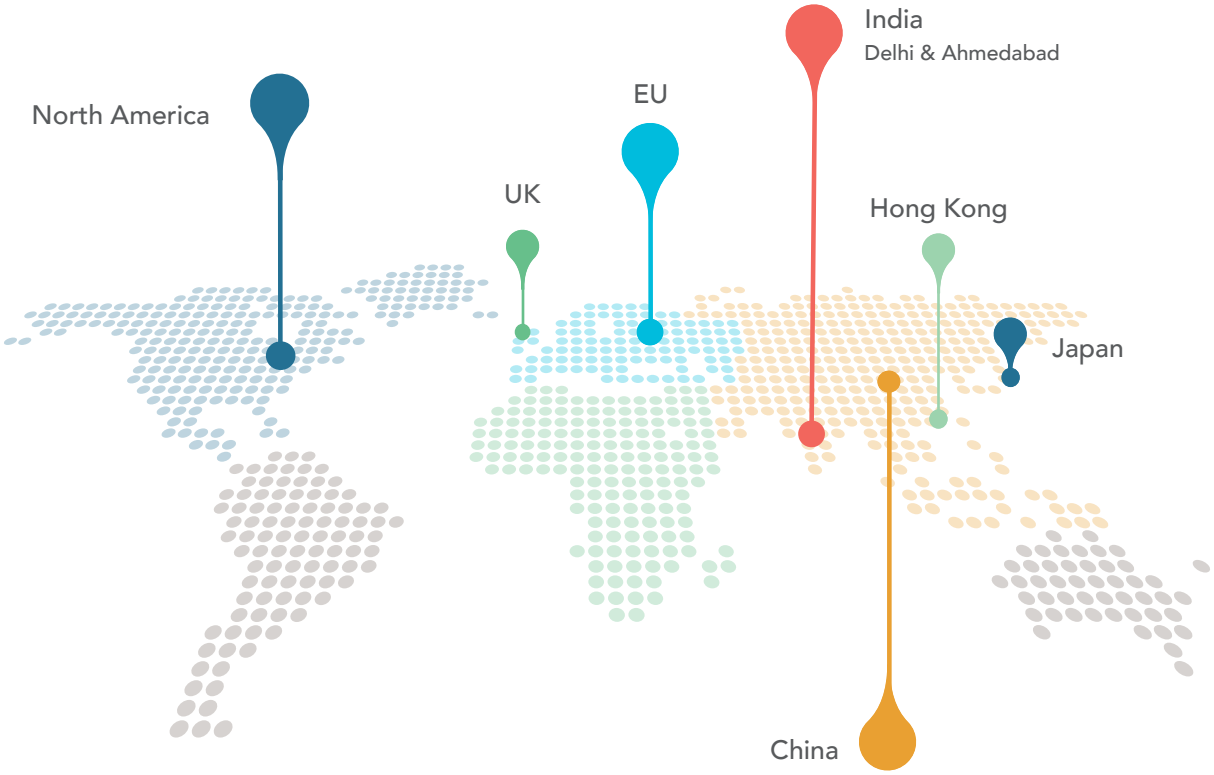


Technology hosting

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.

Best of all worlds

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.



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

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