apcra

Quality you can see!

Company Profile

Our Experience in Asia

APCRA (Asia Pacific Clinical Research and Auditing) focuses on the specific therapeutic and operational experience of individuals working within our organization. We have worked on small specialist projects, as well as projects involving multiple sites throughout the Asia-Pacific region, giving us an appropriate balance of experience and skill. In addition to our extensive experience in Hong Kong, China and India, we have historically worked with sponsors from France, South Korea, UK and the US.

Our Advantage

- Uniquely positioned in terms of geography.
- Extensive experience and knowledge gleaned from working with different clinical investigators within the region.
- Efficient and integrated team of highly qualified and experienced clinical researchers with excellent project management, regulatory and site management expertise with good oral and written communication skills (English and other Asian languages).
- Complementary skills and knowledge to provide the full range of writing and consultancy services as per international standards in a wide range of therapeutic areas.
- Adequate size to ensure smooth workflow during peak and trough times and provide on-time delivery and within budget.
- We can provide clients with the knowledge and experience they need to navigate the region's regulatory environment and understand the culture.

Our Mission

APCRA is dedicated to improving the quality of international clinical trials that involve regions in Asia, by providing strategic and operational support to pharmaceutical, biotech, medical device industries and academic institutions.

Clinical Research Services

APCRA offers a comprehensive array of clinical research services to the pharmaceutical, biotech and medical device industries and academic institutions.

- Project Management
- Site Management
- Study Start-up
- Interim Monitoring
- Data Management & Medical Statistics (outsourced)
- Quality Assurance
- Medical Writing
- Training

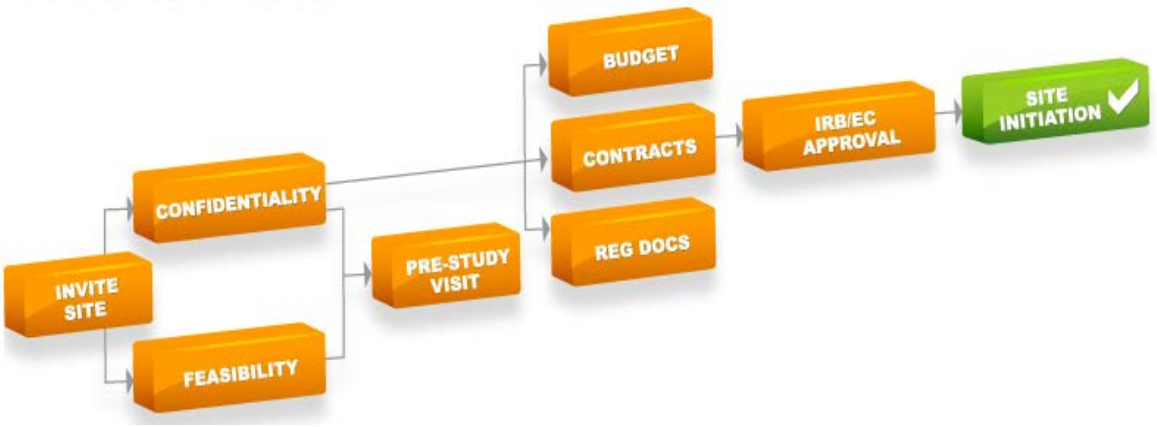
Project Management

Our Project Manager acts as the liaison with the sponsor to ensure that all deliverables are met. They are committed to maintaining flexibility and cost management and supported by innovative clinical tools and systems, which provide a variety of reports with up-to-date study information. These reports enable us to manage and anticipate the next step in the study process and proactively handle potential issues.

Study Start Up

One of the most cumbersome and time consuming activities for anyone starting up a clinical trial is identifying high performing sites.

Recruiting high performing investigators and effective research sites across therapeutic areas is critical for research outcome for a sponsor because this activity directly correlates to quick subject enrolment, attainment of overall goals, high quality data, fewer queries and subject retention for any clinical study.



Once a study site is selected and approved, we continue building the site relationship with your project. Experience has shown that constant communication and training increases the sites' willingness to deliver quality data.

By establishing and maintaining these site relationships, we can work with these sites on sequential studies, which results in significant time savings and cost advantages.

Clinical Trial Monitoring

APCRA's Clinical Research Associates (CRAs) possess therapeutic expertise and clinical research experience. We seek out monitors with the best credentials in these areas because we know they are critical to the success of your trial.

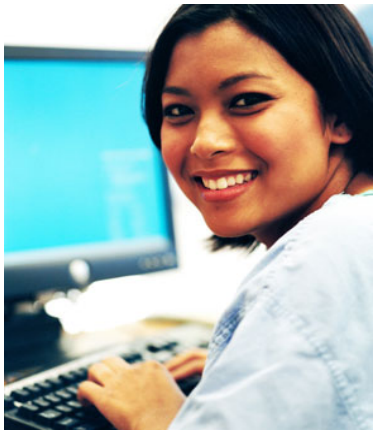
Our CRAs perform clinical monitoring activities to ensure compliance to the protocol and all regulatory requirements. They also maintain strong relationships with our investigative sites to ensure successful study progress.

APCRA's Clinical Trial Monitors:

- Speak English, Chinese and other Asian languages
- Can be outsourced in some cases, to work locally or in other countries in the Asia-Pacific region

Monitoring Locations

- Australia
- Hong Kong
- India
- Korea
- Mainland China
- Malaysia
- Singapore
- Taiwan
- Thailand

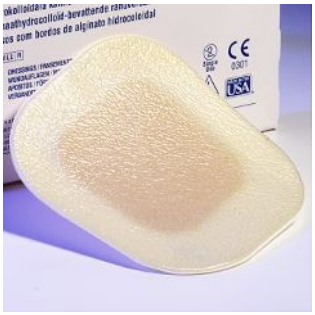


Medical Product Registration in Asia

Product registration in Asia can be a bit daunting because each Asian country has its own unique product registration requirements. Pharmaceutical drug registration is also getting more regulated throughout Asia. APCRA's regulatory compliance experts can handle the approval process for your pharmaceutical/drugs or medical device products.

Local Representation for Medical Devices and Pharmaceuticals / Drugs in Asia

In addition to our product registration services; for companies who do not have a branch or subsidiary office in Asia, APCRA provides local representation for your medical devices and pharmaceuticals / drugs. We can be your independent in-country agent, holding your medical device or drug registrations in your company's name.



Medical Statistics & Data Management

Whether you just need a brief piece of advice, help designing a clinical trial, a statistical analysis plan, or a complete analysis of the results of a study, APCRA, in collaboration with our partner organization provides a complete range of professional data management and medical statistic services.

Data Management:

- Data Listings
- Tables, Figures, Listing
- Analysis Reports
- CRF design
- Preparation of data management plans
- CRF and data query tracking through an electronic database system
- Data entry and verification
- Computerised edit checks for missing, implausible or inconsistent data in CRFs

Medical Statistics:

- Advice on statistical aspects of study design and sample size issues
- Statistical analysis plan development
- SAS programming
- Special programming of non-standard statistical methods
- Production of tables, figures and listings
- Powerful statistical reports also as an independent service from external databases
- Protocol Input
- Sample Size Calculation
- Patient Randomisation

Quality Assurance

APCRA's clinical quality assurance (CQA) services help our clients ensure the integrity of their clinical trials.

Our clinical quality assurance (CQA) auditor is knowledgeable about local, national and international regulations, standards and guidelines and has conducted quality assurance programs for clinical trials in Asia, Europe and USA.

In addition to a comprehensive internal clinical quality assurance program, we provide clinical quality assurance audit services to our clients as part of a full-service or a standalone project. By means of a thorough assessment and insightful, objective recommendations we help sponsors and sites develop the most effective actions to correct and prevent issues.

Among the clinical quality assurance audits we conduct are:

- Clinical investigator site audits. We provide routine, directed, specialized and pre-inspection audits to help sites prepare for regulatory agency reviews
- Clinical database audits and study report reviews
- Clinical study document reviews
- System audits in which we assess client standard operating procedures Vendor audits in which auditors evaluate a client's vendors to ensure they have sufficient capacity and capability to deliver quality products and services on time and in compliance with regulations

Medical Writing

APCRA's experienced Medical Writers provides technical writing services to meet each client's needs. With a commitment to quality and flexibility, APCRA is able to work with clients' report templates, or with its own.

Regulatory Medical Writing Services:

- Clinical Study Reports and appendices according to the ICH-E3 guideline
- Clinical Trial protocols
- Investigator Brochures
- Paper CRF
- ICF & PIS
- Publications

Training

Any organisation conducting a clinical trial on a medicinal product intended for submission to a regulatory organisation is required to follow good clinical practice guidelines. Standards are enforced by periodic inspection by government officials of the country where the trials are to be carried out. Therefore, good clinical practice (GCP) training is important so your personnel involved can comply with the industry and government good clinical practice guidelines, specifications, and local regulations.

We offer a wide range of training courses covering GCP and clinical trial regulations Our trainer's have more than 15 years experience in clinical research, working within the industry and is familiar with local as well as international guidelines and regulations.

Currently, we offer the following training courses:

- Foundation Course in ICH GCP for aspiring CRAs
- Advanced ICH GCP course
- ICH GCP for Clinical Trial Investigators
- Preparation for Audit and Inspections

Further Information

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