George Clinical's Safety & Pharmacovigilance Services

With our immense experience in clinical trial and post-marketing surveillance, we provide the latest safety and pharmacovigilance services, keeping abreast of global safety regulations.

Pharmacovigilance Partner of Choice

Being a scientific research-oriented organization, our established process and capabilities managing medicinal product safety expands from the developmental stage to swiftly continue throughout the post-marketing stage.

With our tailor-made business model encompassing robust processes and global presence including a strong local legacy throughout the Asia-Pacific region, clients can better manage costs by outsourcing clinical trial safety and pharmacovigilance to a trusted partner such as George Clinical who understands the safety profile, costs and qualities of your product.

Since our engagements are metrics-driven, clients can expect an ongoing focus on quality and efficiency as required throughout a product lifecycle. Pharma and biotech companies look to George Clinical when launching products into regulated markets or performing safety surveillance for products in markets across the world. Our collaborative approach establishes clear objectives for safety profile management addressing how those objectives will evolve over time.

Our Advantages

- Global presence and strong local presence throughout Asia-Pacific region
- More than 20 years of experience in safety management
- Proven track record of service delivery with quality and compliance
- Well versed in local and global safety guidelines and regulations
- Flexible, cost-effective solutions

Our Services

George Clinical's safety and pharmacovigilance experts ensure a patient's well-being is paramount. Striking the right balance between benefit and risk, we can provide safety surveillance strategies for the sustenance of the medicinal product throughout the product lifecycle.

Clinical Study Safety Services

- Clinical Trial Safety Monitoring
- Clinical Trial Safety Processing
- DSUR Preparation
- Safety Regulatory Reporting

Post-Marketing Safety Services

- ICSR Management
- Global Literature Surveillance
- Signal Management
- Risk Management
- Pharmacovigilance System Master File (PSMF)
- Aggregate Report Preparation—PSUR, PBRER, PADER
- Medical Information Management

Medical Device Safety Services

- Device Vigilance—US FDA MDR, EU IVDR and EU MDR Compliance
- Post-marketing Surveillance
- Technical Document Preparation

Safety Surveillance

George Clinical offers end-to-end oversight of all key safety aspects of product lifecycle.

We emphasize automation through technology and streamline safety and pharmacovigilance processes from pre-marketing all the way through post-marketing ensuring a smooth transition in a product's lifecycle as well as cost-effective management. By evaluating risk assessments based on each study phase, we help clients monitor a product safety profile that not only ensures patient safety but also enables ongoing evaluations and risk mitigation continuing through post-marketing stage.

"George Clinical offers a complete package in safety surveillance from product development to post-marketing monitoring to help our clients move from one phase to another smoothly, efficiently and cost-effectively while keeping patient safety top of mind." said Maria Ali, Chief Medical Officer for George Clinical.

Key Benefits

- Safety and pharmacovigilance experts deliver cost-effective, quality services with compliance.
- Presence of local safety representatives with regional regulatory knowledge across Asia-Pacific, USA and Europe.
- Team of medical safety experts represent a diverse range of therapeutic backgrounds.
- Rigorous quality oversight implemented across all pharmacovigilance activities.
- 24-hour help desk access through mobile and email.
- Global coverage with a thorough understanding of clinical trial safety and pharmacovigilance reporting requirements.
- Phase I-IV commercial and academic research experience through our scientific leaders
- Cost-efficient, yet comprehensive, safety management system through Oracle Argus Safety and other technology solutions.

Safety Data Management

Pharmacovigilance data challenges organizations due to its significant volume, inherent complexity and longitudinal nature. The George Clinical PV team leverages Oracle Argus, a comprehensive, highly scalable safety database for case management and reporting activities. This advanced platform not only consolidates a client's clinical trial safety data into a single system, it eases integration with other toolsets your organization already relies upon. Such data too often resides insides silos which prevent teams being able to make rapid yet thorough insights.

Machine learning and rules-based process automation greatly improve the speed of data processing, lower monitoring costs and reduce manual input and the risk of poor data integrity. Teams freed up to focus on intelligence gleaned from PV data vs. the laborious management of such data further improve the economic and risk profile of your marketed products.

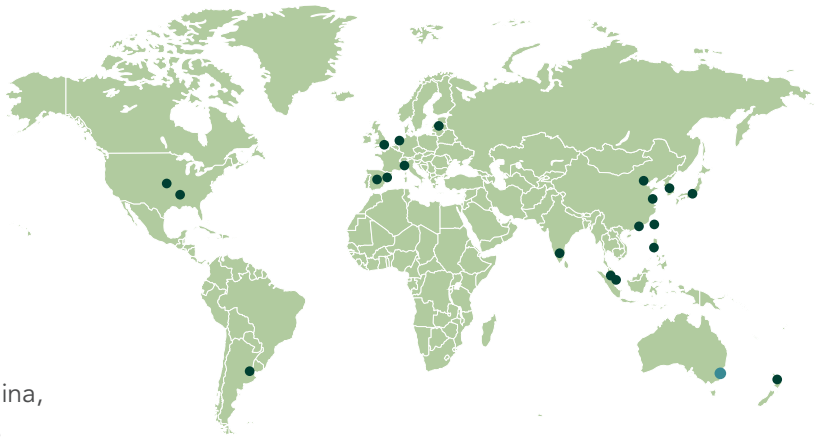
- 21 CFR Part 11 compliant
- E2B (R3) compatible
- Adheres to GxP and ICH standards
- Compliant with global data privacy regulations

Local PV Regulations & Qualified Persons

As many developing nations are actively upgrading and implementing more stringent regulation for local safety monitoring, George Clinical helps clients to meet the mandatory requirement of a local presence via a qualified person with regional language proficiency by reducing operation cost with a balanced centralized and decentralized model. Our PV team includes local experts in China, Malaysia, Taiwan, Hong Kong, Indonesia, Philippines, India, South Korea, Australia, Singapore and elsewhere.

Global Reach

George Clinical has grown rapidly and continues to develop and enhance operations around the globe. Headquartered in Sydney, Australia, George Clinical is located across Asia Pacific (Australia, New Zealand, China, Hong Kong, Taiwan, South Korea, Malaysia, Singapore, Philippines and India), Europe (UK, the Netherlands, Spain, Italy and Latvia) and the United States of America. We also provide services in Japan, Indonesia, Sri Lanka, Thailand, Central Eastern Europe and Latin America.



George Clinical

Science. Service. Solutions.

20+ years

Contact our business development team to explore how George Clinical can support your medical products across the globe through optimized safety surveillance solution.

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