Drug safety and pharmacovigilance

Health Inspired,
Quality Driven.

SGS

About SGS Clinical Research

With over 40 years of experience as a mid-sized full service CRO, SGS provides expert support for every stage of your clinical development, including oversight on drug and patient safety.

Patient safety is paramount throughout a product's lifecycle—from first-in-human trials to post-approval. SGS Clinical Research is a trusted partner in drug safety and pharmacovigilance. We offer regulatory-compliant, high-quality safety services tailored to the needs of biotech and pharmaceutical companies worldwide.

Our extensive global presence and decades of experience make us a preferred choice for ensuring patient safety and regulatory success.

When you need to be sure, choose SGS.

"Safety is more than a requirement—it's the foundation of every successful trial. At SGS, we bring expertise, precision and reliability to every client project."

RAFAËL SMETS,
HEAD MEDICAL SAFETY & REGULATORY, SGS

End-to-end services

We provide end-to-end pharmacovigilance services and expert consultancy, ensuring compliance and proactive risk management at every stage of drug development. With a quality-first approach and flexible solutions, we actively safeguard drug safety, helping you meet global regulatory standards. From early clinical trials to post-marketing surveillance, we anticipate and address safety risks before they become critical, reducting delays and regulatory setbacks.

Rules change, but we stay ahead

With up-to-date knowledge of country-specific safety reporting requirements, we guarantee timely and compliant submissions to health authorities, ethics committees and key stakeholders.

One source of truth

Scattered safety data creates risk. We bring all the safety data of your compound into one single, unified database, giving you full oversight and ensuring smooth regulatory submissions. Need support to migrate systems into one centrailzed safety database? We make it hassle-free.

Flexibility without compromise

You need a partner that adapts to your reality. Our solutions fit your needs, balancing cost, quality and compliance—without cutting corners.

We specialize in

- Safety database setup and management (Oracle Argus or client system)
- ICSR management
- Regulatory reporting (DSUR, PSUR/PBRER, PADER/PAER, periodic listings)
- Literature surveillance and ICSR detection
- Safety data analysis and signal detection
- Benefit-risk assessment and risk management
- Clinical safety summaries and overviews
- Medical evaluation and assessment
- EudraVigilance support
- Client system audits
- In-/out-licensed product management

Long-term partnerships

At SGS, we go beyond providing services—we build longstanding partnerships. One of our longest-standing partnerships has been active for nearly 20 years, demonstrating the trust and consistency we bring to your entire product safety lifecycle.

We support clients from first-in-human studies through post-marketing, ensuring seamless pharmacovigilance management at every stage.

Our tailored, fit-for-purpose solutions are designed to align with each client's unique needs, providing flexibility without compromising on quality.

Through long-term collaborations, we ensure consistency, stability and a deep understanding of our clients' evolving challenges, helping them navigate regulatory complexities with confidence.

Whether responding to urgent regulatory requests or adapting to evolving compliance requirements, our team ensures proactive risk management and continuous patient safety and enduring partnership value.

> “We don’t just deliver services; we integrate seamlessly with our clients, ensuring that pharmacovigilance is not just a requirement, but a strategic advantage.”

RAFAËL SMETS
HEAD MEDICAL SAFETY & REGULATORY, SGS

Why SGS?

When it comes to medical safety, experience and reliability matter. At SGS, we combine a highly skilled team with proven processes to deliver compliant, high-quality safety reporting - on time, every time.

Expert safety team

Large, highly skilled team ensuring seamless, top-quality case processing.

Unmatched reporting quality

Regulatory-compliant, audit-proof reports with strong KPIs and proven reliability.

Expedited case handling

Fast unblinded ICSR reporting while maintaining study integrity.

Proactive risk management

Continuous safety monitoring, signal detection and literature reviews.

Regulatory intelligence

Up-to-date insights on country-specific regulatory requirements.

Seamless safety database migration

Expertise in ensuring smooth, secure transitions.

“For patient safety, every detail matters. Our commitment to quality and compliance ensures your safety data is in the best hands.”

PATRYCJA KOLODZIEJCZYK
MANAGER DRUG SAFETY PHYSICIANS, SGS

Our safety experts

At SGS, we believe that expertise makes the difference. Our large, multilingual team is composed of highly qualified MDs, PhDs and pharmaceutical scientists with broad therapeutic expertise, ensuring that every project benefits from deep scientific and regulatory knowledge.

Our experts ensure seamless safety operations, business continuity and on-time safety reporting, allowing you to focus on advancing your drug development programs with confidence.

Meet Catherine De Clercq

MEDICAL SAFETY MANAGER, SGS

Every client benefits from the insights and dedication of experienced professionals like Catherine De Clercq, ensuring seamless safety operations and business continuity.

She played a pivotal role in developing safety strategies for complex clinical trials, ensuring regulatory compliance, and driving innovative risk management solutions.

Pharma

Health Inspired, Quality Driven.

Contact us

clinicalresearch@sgs.com

sgs.com/pharma

sgs.com/linkedinpharma

SGS

When you need to be sure