

MEDICAL AFFAIRS

SGS' Life Science Services, part of the SGS group (55,000 employees) has 30 years of experience as a global contract service organization, providing integrated solutions from preclinical activities to Phase I-IV trials, bioanalytical and QC testing. With more than 1,300 employees and 2,000 clinical trials performed, SGS serves the pharmaceutical, biotechnology and medical device industries throughout Europe, North America and Asia.

SGS' Medical Affairs team plays a key role for clients, providing comprehensive solutions for drug safety and risk management during the complete life cycle of a medicinal product.

SGS offers competitive advantages for during and after clinical development:

- Therapeutic expertise, technical and operational excellence
- Global reporting of AE's and SAE's according to country specific requirements
- Tailor-made and cost effective drug safety solutions for small and mid-size pharmaceutical and biotech companies
- Flexible outsourcing of drug safety functions to international organizations
- Quality systems ensuring continuous compliance with international regulatory requirements
- Expedited reporting and database setup when timelines are tight
- 24/7 Availability

COMPLETE SOLUTIONS

SGS provides full service Safety and Pharmacovigilance services for global Phase I-IV clinical trials as well as extensive Post Marketing Services including consultancy and training.

PHASE I-IV CLINICAL TRIAL SAFETY

HANDLING OF SERIOUS ADVERSE EVENTS

- Build and maintain a product's complete Serious Adverse Event Management database
- In-house processing and expedited reporting of Serious Adverse Events (SAE)
- Medical review and assessment of (S)AEs
- Expedited reporting to Authorities
- Electronic reporting in EU through Eudravigilance (third Party Provider)

MEDICAL MONITORING

- 24/7 availability
- Answering patient eligibility and product-related medical questions
- Granting protocol deviations/waivers
- Performing safety analysis
- Input in protocol amendments, clinical development plans
- Performing monitor and investigator training for indication and protocol

MEDICAL REVIEW

- Clinical Trial Protocol
- Clinical Research Form
- Clinical Research Report
- Listings, including adverse events, concomitant therapy, line listings, frequency tables, using MedDRA and WHODRUG, as specified by the client
- Protocol deviations
- Lab/ECG alerts

REPORT WRITING

- Medical writing of (Annual) Safety Reports (ASR)
- Integrated Safety Summary
- Safety section of the Investigator's Brochure (IB)
- Pregnancy reports
- Benefit Risk Assessment

ADDITIONAL SERVICES

- Generating and distribution of IB-amendments
- Maintenance of Pregnancy database

POST MARKETING SAFETY ONGOING SAFETY SURVEILLANCE AND MEDICAL SAFETY ASSESSMENT

- Medical review, assessment and expedited reporting of Adverse Drug Reactions (ADR)
- Expedited (electronic) reporting to Health Authorities worldwide, using Eudravigilance for EMEA and EU Health Authorities
- Literature search and evaluation services, including
 - searches and alerts
 - screening/review of search results
 - processing and expedited reporting of serious literature cases
- Qualified Person for Pharmacovigilance (local or regional/deputy QPPV)

REPORT WRITING

- Periodic Safety Update Reports (PSUR)
- Product-related Clinical Overviews and Expert Reports for European and national registration renewal purpose – Reference Safety Information Revisions (SPC, core label, IB, etc)
- Annual and Ad-hoc Safety Signal Evaluations
- Risk Management Plans

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

MEDICAL STAFF

The department includes MD/Pharmacist/PhD level Medical Affairs Associates and administrative support, all familiar with:

- ICH-GCP
- EMEA/CPMP guidelines
- FDA rules

A multilingual team working closely with Regulatory Agencies worldwide. Temporary staff is available for short-term projects.

SOFTWARE TOOLS

SAFETY DATABASE

SGS's Drug Safety system is Empirica™ Trace, a fully validated, 21 CFR Part 11 compliant, software package. This software helps SGS to collect, code, analyze and report adverse events, as well as meet regulatory reporting deadlines and global requirements.

This software package also allows Medical Affairs Associates to produce a great variety of standard reports such as:

- CIOMS-I & CIOMS-II
- PSUR
- FDA-approved 3500A MedWatch
- Periodic reports (NDA, IND)
- Reports for drugs, vaccines and medical devices

Experience with other software tools for SAE-management: different commercial and sponsor built safety databases, such as ARISg.

EUDRAVIGILANCE

Medical Affairs Associates are fully trained in the EMEA EudraVigilance data-processing network and management system. Through Eudravigilance, the SGS in-house safety database exchanges safety data between the EMEA and National Competent Authorities.

QUALITY SYSTEMS

All activities are based on Relevant Medical Affairs SOPs:

- Processing and Reporting of Individual Serious Adverse Events of Interventional Clinical Trials
- Processing and Reporting of Individual Unsolicited Safety Reports
- Medical Monitoring of Clinical Trials
- Code-break for Serious Adverse Events in Double-Blind Clinical Trials

ADDITIONAL SERVICES

- Writing of client safety related SOPs
- Client System Audits

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WHEN YOU NEED TO BE SURE

SGS