

CLINICAL RESEARCH

FULL-SERVICE, ON TIME, ON BUDGET

SGS has over 35 years of experience as a life science, global contract service organization, providing integrated services organization providing integrated solutions from preclinical activities to Phase I-IV trials, Bioanalytical and Quality Control testing. With over 1,600 employees and 2,000 trials performed, SGS serves the pharmaceutical, biotechnology and medical device industries.

SGS' state-of-the-art facilities include a Phase I unit with a total of 88 beds, two bioanalytical labs, and seven Clinical Trial Management offices across Europe (incl. CEE), North America for global Phase I-IV trials coordination. With broad clinical pharmacology experience, innovative study designs, top quality facilities, tailored biometrics services and strong regulatory intelligence, SGS can significantly **improve clients' drug development timelines and decision-making processes.**

CLINICAL RESEARCH SERVICES

EARLY DEVELOPMENT

As one of the largest European Early Development CRO, SGS offers a complete range of services encompassing:

Clinical Pharmacology

Through years of executing complex trials SGS has a wealth of expertise in:

- First In Human trials: Single Ascending Dose (SAD) & Multiple Ascending Dose (MAD), combined protocols: SAD/MAD + food + POC
- Regulatory Phase I trials: Drug-drug interactions, Pivotal TQTc prolongation trials, PK and PD studies, BA/BE studies
- Exploratory Early phase trials: Early POC studies in patients, ¹⁴C radiolabelled ADME studies, Biomarkers for clinical trials, Viral Challenge testing

The SGS clinical unit in Antwerp, Belgium has successfully passed several US FDA inspections during recent years. Clients benefit from the favorable regulatory environment in Belgium with very short phase I trial approval times of two weeks, as well as a large database of over 10,000 volunteers and special population subjects.

Pre-clinical and bioanalytical

With its GLP certified and FDA inspected bioanalytical laboratory network, SGS has an international reputation for assay of drugs in biological fluids as well as for complex method development and validation. SGS offers:

- Drug sample bioanalysis (31 LC-MS/MS)
- Animal metabolite profiling and balance studies (14C labelled drug)
- Toxicokinetic analyses and In-vitro cell-assays
- Immune function testing: immunogenicity, flow cytometry, cytokine multiplexed ELISA
- Biopharmaceuticals - cell characterization

For continuous increases in efficiency, benefiting clients, SGS consistently adopts the latest technologies in all critical aspects of laboratory science including: latest generation of LC-MS/MS, Turboflow, Qtrap, multiplexing, Watson LIMS.

LATE DEVELOPMENT

SGS is organized as a full CRO provider to deliver on Time and on Budget Phase II-IV clinical research services. Whether you request a one-stop-shop service package or are interested in individual selected services, SGS is set up to accommodate your needs.

Phase II-IV trial management

Employing a team of 100 individuals, highly trained in the latest International guidelines and company SOPs, SGS has conducted over 800 projects including trials with patients in Western, Eastern and Central Europe, Russia, and North America. SGS' monitoring and management offices are located in France, Spain, Czech Republic, Poland, Romania, USA and Singapore.

For high quality clinical trial execution, clients can count on SGS:

- Proven therapeutic expertise with a focus in Infectious, Cardiac and Neurological diseases
- Centralized Project Management with multilingual senior Project Managers
- Efficient Project Management tools such as CTMS, IVRS, central ECG reading, EDC
- Large database of investigators and key opinion leaders
- Site Management Organization (SMO) managing a network of clinical sites and hospitals for many disease areas

Data management/statistics and medical writing

As one of the largest independent data management teams in Europe, SGS supports all in-house and external project needs for clients' clinical trials, powered with Clinitrial®, Oracle Clinical® and SAS®. Clients benefit from a knowledgeable, proactive staff with broad experience working with various EDC systems and e-CRF templates. SGS is fully CDISC compliant and successfully experienced in full electronic FDA submissions.

CLINICAL SUPPORT SERVICES

Regulatory & medical affairs

- Regulatory Affairs department offers consulting in both European and U.S. registration of Biotech and, Prescription drugs, veterinary products and medical devices with comprehensive EMEA and FDA authorities expertise. SGS has established strategic submission plans using extensive country specific regulatory intelligence covering 76 countries.
- Medical Affairs department provides full Phase I-IV pharmacovigilance services including Serious Adverse Event (SAE) handling, ADR reports, medical review and narrative medical writing, electronic reporting in Europe to Eu-dravigilance and Health Authorities.

LABORATORY SERVICES

To complete its portfolio, SGS also offers laboratory testing services. These services include analytical chemistry, microbiology, stability studies, method development, protein characterization and bioanalysis. Operating 29 facilities in 14 countries, SGS represents the largest global network of contract analytical laboratories.

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WHEN YOU NEED TO BE SURE

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