



PHASE I-IIa TRIALS

SGS has over 35 years of experience as a life science, global contract service organization, providing integrated services from preclinical activities to Phase I-IV trials, bioanalytical and laboratory services. With more than 1,600 employees, SGS serves the pharmaceutical, biotechnology and medical device industries throughout Europe, North America and Asia. Through years of executing complex clinical trials, SGS began the European early phase trials benchmark CRO to early phase studies.

SGS offers competitive advantages for your clinical development:

- Over 35 years experience in scientific input to build up innovative and customized study design
- Only 2 weeks study initiation timelines in Belgium
- Strong expertise in Combined Protocols offering time savings from FIH to POC
- Comprehensive background in QT/QTc trials: 2-3 per year
- Capabilities to conduct 14C-based ADME studies
- Easy access to patients and special populations
- Large state-of-the-art clinical unit with over 88 beds in total enabling study flexibility
- Full regulatory and medical affairs support

MAKING THE RIGHT DECISION ON TIME

SGS offers complete solutions for early phase development moving products through the pipeline safely and quickly.

CLINICAL SERVICES

FIRST-IN-HUMAN TRIALS

Over the last 6 years SGS performed 500 trials, of which 33% were FIH trials. SGS conducts simple and complex FIH studies such as:

- Single Ascending Dose (SAD) & Multiple Ascending Dose (MAD)
- Combined protocols: SAD/MAD + food + Proof of Concept (POC)

REGULATORY PHASE I TRIALS

SGS provides clinical trials to comply with EMEA and FDA requirements, but also variety of additional information to facilitate your "GO - NO GO" decisions.

■ QT/QTc trials

SGS, as one of the leading early clinical development CRO's with partners specialized in cardiac data reading (ECG/Holter), has developed a strong expertise providing high-quality ECG reading and analysis in QT Prolongation & Safety Pharmacology studies to the Pharmaceutical and Biotech Industries. SGS performs 2-3 QT/QTc studies per year.

■ Pharmacokinetic studies

SGS performs:

- Drug-drug interaction studies including the bioanalysis of the markers of main cytochrome activities involved in metabolic interaction
- Pharmacokinetic studies in special populations (elderly, race, gender, renal insufficiency including CAPD, liver disease)
- 14C-ADME trials in human

SGS

- Bioavailability and bioequivalence studies including transdermal systems

EXPLORATORY CLINICAL TRIALS

Early demonstration of a drug candidate's relevance provides key information on how or whether to move forward in development. Critical time points for collecting this information often lie in the pre-IND stage of development and at the early Proof of Concept stage.

■ Viral Challenge Testing

SGS conducts viral challenge studies in order to efficiently develop and evaluate new-generation vaccines and treatments for – but not limited to – influenza and RSV; approaches aside from large-scale field trials must be considered to provide early evidence of proof-of-principle in humans.

The SGS quarantine facility is in an under pressure system, including individual cells for the infected volunteers and a dedicated laboratory equipped with a flow cabinet, acid cabinet, dedicated work space and specific workflows to handle specific (viral) cultures, using HEPA-filtering and an airlock system.

■ Proof of Mechanism/Concept

Through working many years in the field of early compound development, SGS has gained a unique expertise in clinical trials at low pharmacologically active dose and Early Proof-of-Concept trials, e.g.: Asthma challenges (exercise, metacholin, allergen); Brain receptor occupancy (PET); Cardiac telemetry; Coagulation-thrombolysis tests; CSF sampling.

PRECLINICAL SERVICES

- Bioanalytics for toxicokinetics including method development and validation
- Metabolite profiling: 14C labelled drug
- *In vitro* cell-based testing
- Immune function testing: immunogenicity, flow cytometry, cytokine multiplexed ELISA

THE BEST CONDITIONS TO DELIVER

STATE-OF-THE-ART CLINICAL UNITS

SGS' clinical facility, located in Antwerp, Belgium, is equipped with the latest technologies and allows easy access, and comprehensive flexibility to deliver on time client requirements. This clinical unit has successfully passed inspections by US FDA and local regulatory authorities.

- 88 beds of which 48 intensive monitoring beds
- Safety & quality of data collection: supervised by physicians and medical staff with appropriate levels of training and expertise, 24/7 medical control of trial participants, resuscitation cart at each floor
- Equipment: ECG, BP, SPO2 monitoring and O2 supply at each intensive care bed ECG telemetry for 60 subjects, EEG with spectral analysis, 24h-Holter ECG
- GMP Pharmacy, enabling manufacture of non-sterile products, primary and secondary packaging and labeling, and batch release of imported IMP
- eSource system designed to directly capture study data electronically and streamline the clinical process

HEALTHY SUBJECTS AND PATIENTS RECRUITMENT

The central location of SGS' clinical units give access to a large and diverse population.

SGS has one of the largest subject data base in Europe. It encompasses healthy volunteers, special populations and patients.

A MULTI SOURCE RECRUITMENT APPROACH

- Direct subjects recruitment: data base of over 10,000 subjects
- SMO/recruitment: dedicated recruitment team working with local physicians reporting their patients to us
- Hospital network: collaboration with Antwerp hospitals and external phase I units
- Multicenter solutions managed through SGS' Clinical Trial Management department: Western EU, Eastern EU and Russia

SPECIAL POPULATIONS

In addition of its healthy subject data base, SGS recruits: Elderly subjects; Hepatic/ renal impaired; Slow metabolisers (cyp2D6, cyp2C19); Asthmatic/COPD; Post menopausal women; Overweight/obese; Diabetes type II; Schizophrenics; Penile erectile dysfunction.

CONTACT US

EUROPE

t +32 15 27 32 45

NORTH AMERICA

t +1 877 677 2667

clinicalresearch@sgs.com

WWW.SGS.COM/CRO

 JOIN OUR SCIENTIFIC COMMUNITY
www.sgs.com/LinkedIn-Life

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

WHEN YOU NEED TO BE SURE

SGS