



PHASE I-IIa TRIALS

SGS' Life Science Services, part of the SGS group (53.000 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. 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 30 years experience in scientific input to build up innovative and customized study design
- Only 2-4 weeks study initiation timelines in Belgium & France, respectively
- Strong expertise in Combined Protocols offering time savings from FIH to POC
- Comprehensive background in QT/QTc trials: 6 per year
- Capabilities to conduct C14-based ADME studies
- Easy access to patients and special populations
- Large state-of-the-art clinical units with over 160 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 5-6 QT/QTc studies per year.

SGS

- **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
- 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.

- **Microdosing**

SGS' clinical facilities are fully authorized for 14C to conduct AMS microdosing trials with a GMP pharmacy accreditation. In addition for PET microdosing studies, specialized contracted laboratory facilities have a cyclotron for the production of the radionuclide and are certified for radionuclide labelled drug synthesis.

- **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. A complete list is available on the SGS web site.

PRECLINICAL SERVICES

- Bioanalytics for toxicokinetics including method development and validation
- Metabolite profiling: C14 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 facilities, located in Paris, France and Antwerp, Belgium, are equipped with the latest technologies and allows easy access, and comprehensive flexibility to deliver on time client requirements. These clinical units have successfully passed inspections by US FDA and local regulatory authorities.

- 2 sites: 162 beds of which 74 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

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 14.000 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/obeses; Diabetes type II; Schizophrenics; Penile erectile dysfunction.

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WHEN YOU NEED TO BE SURE

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