EXPLORATORY DRUG DEVELOPMENT TO PROOF OF CONCEPT

WHERE EXPERIENCE MEETS SPEED

SGS

Helping clients to optimize drug development timelines and decision making processes is our promise. Delivering results is our commitment. 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, quality control testing, biosafety, and biologics characterization (protein/glycoprotein, mAbs) using high end mass spectrometry.

With state-of-the-art clinical pharmacology units and the world's largest network of GMP/GLP compliant laboratories, SGS serves the pharmaceutical, biotechnology and medical device industries across Europe and North America. We have more than 1,600 employees and provide a complete range of services along the pharmaceutical development process.

SGS's global presence and the broad range of services positions the life science services business to become the preferred partner for our pharmaceutical and biotechnology clients.

STREAMLINE YOUR EARLY DRUG DEVELOPMENT PROCESSES WITH SGS SYNERGIES IN PHARMACOLOGY AND LAB SERVICES

FROM LABORATORY ASSAYS TO CLINICAL TRIALS

SGS is the largest European Bioanalytical-Biomarker CRO with three GLP laboratories featuring Mass Spectrometry, Immunoassays and Cell-based Assays.

- Assay development/validation and fast Liquid Chromatography to support exploratory trials within a week
- >700 GLP-validated methods (view the list online: www.sgs.com/ba-methods)
- Robust and high-throughput LC-MS/MS assays with 31 LC-MS/MS instruments; as well as Xevo-TQs, turboflow, Multiprobe robots and Dried Blood Spot Sampling
- Services for small and large molecule testing in TK, PK and PD
- PK assays and calculations closely coordinated with study progress in our clinical pharmacology units
- Discovery biomarkers translated in clinical research (LC-MS/MS and Immunoassays)
- Complete immunogenicity testing solutions
    - o Screening, confirmatory, characterization, neutralizing-antibody assays and ADCC assays:
        - ELISA, RIA, cell-based assays, Flow cytometry (FACs Canto II), Multiplex immunoassays (MSD, Luminex)
- Cell-based assays : cell cultures, cell line banking, cell transfection, activation, proliferation and production, flow cytometry; intra and extracellular staining
- Quantification of biopharmaceuticals and associated biomarkers for TK/PK studies across all phases
- Expertise in biopharmaceutical testing, including: PK, metabolism, impurity analysis, sequencing, to full characterization with particular emphasis on post-translational modifications with appropriate FDA/ICH guidelines compliance (ICH Q6B)
- Metabolite profiling and mass balance studies (^{14}C-labelled drug)

READY TO DOSE:
get your analytical method developed and validated

SAVE TIME:
take your dose escalation decision on-time

GO FURTHER:
identify, profile and quantify your biopharma drug candidate

OPTIMIZED DRUG DEVELOPMENT PLAN:
benefit from our consultancy expertise

INNOVATIVE MODELS
in clinical development

FAST STUDY START
and site activation

FULL SCOPE OF SERVICES:
integrated regulatory, drug safety, biometrics, bioanalytics and modeling & simulation services

FROM HEALTHY SUBJECTS TO PATIENTS

SGS is one of the leading European company in exploratory and clinical pharmacology trials in healthy volunteers and patients with three Phase I units located in Belgium and Hungary.

- Strong study design consulting: scientific input to build innovative and customized drug development plans through a Translational Research approach, including pre clinical pharmacology / PK data analysis and PK/PD modeling & simulation
- Fast study start: 2-3 weeks from submission of the Clinical Trial Application to first subject dosed in SGS full e-Source automation clinical pharmacology unit in Belgium, which encompasses 88 beds, 20 beds biosafety level 2 quarantine facility and a GMP pharmacy
- Significant Phase I trial experience (>400 studies conducted in the last 5 years) with more than 1/3 in First-In-Human (FIH) & safety trials
    - o Single Ascending Dose (SAD)
    - o Multiple Ascending Dose (MAD)
    - o Food / Gender / Age Effect Studies
- Specialist in "Combined Protocols and Adaptive Designs", reducing overall phase I development time by more than 30% by including multiple early phase studies (e.g. SAD + MAD + FE + POC) in a single protocol
  Extensive experience in TQT/QTc prolongation trials with unmatched reading accuracy enabling sample size and cost reduction
  Fast and easy access to healthy volunteers, special populations and patients thanks to a multisource recruitment approach:
    - o Largest in-house European database of over 10,000 subjects
    - o SGS hospital embedded in-patients clinical pharmacology units in Belgium and Hungary for complex early phase patient clinical trials in oncology, infectious diseases and Gastrointestinal including: diabetics, metabolic syndrome, Alzheimer, asthmatic / COPD, and HCV patients
    - o Collaboration with a network of hospitals and specialists across Europe and Americas providing patient referrals
- A large scope of biomarkers and clinical pharmacodynamic models. We are early adopters of new techniques: CSF sampling – Challenge tests (sputum induction, LPS, intravitreal injection, plethysmography, PET, Viral Challenge testing)
- Comprehensive support services:
    - o Expert Data Handling: Data management, statistics and medical writing in full compliance with international guidelines such as 21 CFR Part 11 - FDA/GCP/ICH - CDISC
    - o Full coverage of your Drug Safety Management requirements with fast, tailor-made solutions, from setup to expedited and aggregate reporting
    - o Regulatory pre-registration consulting and support for clinical trial applications

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WHEN YOU NEED TO BE SURE

SGS