LIFE SCIENCES

CLINICAL TRIAL MANAGEMENT

EXPERTISE, QUALITY & FLEXIBILITY

SGS

A GLOBAL CRO WITH 40 YEARS OF EXPERIENCE

SGS has over 40 years experience as a global contract service organization, providing integrated solutions from drug development consultancy to Phase I-IV trials, bioanalytical and quality control testing.

SGS offers effective and high quality end-to-end clinical trial management.

By operating a global network of therapeutic-specific key opinion leaders, subject-matter experts, vendors and pre-qualified investigator trial sites that will ensure the success of your trial - SGS will help you bring new therapies to the market safely and quickly.

With a dedicated team of regulatory affairs experts in place for 70 countries, we provide regulatory guidance and regulatory IND/NDA submission experience in Europe, USA, and Canada. We can also advise you on drug import regulations and procedures for every country in Europe and North America.

- 500+ EMPLOYEES
- OVER 1,000 CLINICAL TRIALS EXECUTED
- SUPPORTING THE TOP 10 PHARMACEUTICAL COMPANIES
- INTERNATIONAL NETWORK OF 400+ INVESTIGATIONAL SITES
- 2 MAJOR CLINICAL TRIAL HUBS – MECHELEN, BELGIUM AND GERMANTOWN, MARYLAND, USA
- MORE THAN 20 THERAPEUTIC AREAS WITH A SPECIAL FOCUS ON INFECTIOUS DISEASES AND VACCINES, RESPIRATORY DISEASES AND NEUROLOGY/CNS
- 90 BED CLINICAL PHASE I UNIT WITH ACCESS TO MORE THAN 10,000 HEALTHY VOLUNTEERS
- 97% OF RECRUITMENT GOALS ACHIEVED OVER THE LAST 5 YEARS

PROVIDING FLEXIBILITY, GLOBAL COVERAGE
LOCAL EXPERTISE

Clients benefit from our global reach and local knowledge of regulations, procedures and timelines, providing great advantages for facilitating and managing clinical trial setup.

When planning for clinical trials, tailor-made strategies are required and so, at SGS, we pride ourselves on customized solutions. We help our clients determine the best, most efficient pathway forward, which we then execute with precision, focusing on data required for endpoints and associated analyses, without compromising on budget, timelines or quality.

FLEXIBLE & TAILORED SOLUTIONS

- Fast study set up with local expertise
- Full service offering: convenience of a one-stop shop
- Robust and systematic approach to clinical site evaluation and selection
- Strategic data-driven feasibility, allowing quick and easy access to patient groups
- Comprehensive site management and quality-focused clinical monitoring
- International network of highly qualified and trained, locally based CRAs
- Medical monitoring and pharmacovigilance
- Experienced, customer-focused project managers, based in offices across Europe and North America
- Integrated data cleaning approach in collaboration with a highly experienced biometrics team
- Medical and regulatory advice for clinical development plans and study protocol designs

FULLY INTEGRATED SOLUTIONS

Delivering solutions for bio-pharmaceutical companies, SGS provides comprehensive Phase I-IV clinical trial management services encompassing clinical project management and monitoring, biometrics, medical monitoring, pharmacovigilance and regulatory consultancy, either as standalone services or as a full service project.

We offer comprehensive clinical trial management solutions, as well as "à la carte" services to meet your specific needs; from initial planning through to study closure.

- Strategic Clinical and Regulatory Consultancy
- Feasibility
- Clinical Operations & Trial Management
- Medical Writing
- Clinical Data Management
- Biostatistics
- Pharmacokinetic and Pharmacodynamic Data Analysis
- Drug Safety Management
- Quality Management
- Regulatory Affairs
- Clinical Pharmacology Unit (CPU)
- Laboratory Testing Facilities

CRITICAL TOUCHPOINTS FOR ENSURING SUCCESS

Protecting your endpoints: we know the importance of refining primary and secondary endpoints and then delivering to ensure time and investment is optimized.

Study feasibility: our robust and multifaceted approach to study feasibility, getting inputs from a wide range of stakeholders and thoroughly evaluating entire program needs, ensures all critical needs are covered.

Site selection and patient recruitment: our database of partners, clinicians and investigative sites are used to present our first, second and third-tier recommendations for your approval. Once the sites are confirmed, we build a patient recruitment and retention plan tailored to your study, continually re-visiting it to proactively modify if needed.

Project management: SGS Project Managers are highly experienced in managing ad hoc requests and full scope services; from small PhI and PhII studies to larger, global PhIII programs, they will know your project inside and out, taking accountability for managing the team, scope, schedule and budget.

Site management and monitoring: Clinical Research Associates (CRAs) at SGS do not just verify source documents; they train, advise and communicate continuously with site staff. They closely follow-up the study progress and ensure that the plan is being followed while maintaining relationships with sites for a constructive and cost-effective collaboration.

Biometrics services: The SGS biometrics group is a European leader with all services performed in accordance with international regulatory standards, the Clinical Data Interchange Standards Consortium (CDISC), the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice (ICH-GCP). Over the last 10 years, we have delivered services for over 800 trials, for small, medium and large companies, and processed over 1 million case report forms (CRF) per year, allowing for economies of scale.

Medical monitoring: Our medical monitoring team, alongside the different study teams, support timely eligibility evaluations, smooth patient recruitment, and ensure quality of collected data, and safety follow-up, including working with our biometrics department to support medical reviews of safety data, including adverse events and serious adverse events.

"WE NEVER TAKE OUR EYES OFF OF THE MOST CRITICAL TOUCHPOINTS FOR ENSURING YOUR SUCCESS."

TRIAL MANAGEMENT SYSTEMS

SGS's integrated, end-to-end clinical trial management system (CTMS) will ensure that planning, preparation, performance and reporting are managed daily with tracking deadlines, milestones and the issuing of progress reports.

- Clinical Trial Management System (CTMS) with integrated Electronic Trial Master File (e-TMF): VEEVA systems
- Experience with Interactive Voice/Web Response Systems (IVRS)/ IWRS
- Build and integrate electronic Patient Reported Outcomes (ePRO) or electronic Clinical Outcome Assessment (eCOA) systems
- Central electrocardiogram (ECG) reading
- Electronic Data Capture (EDC)

OVERVIEW OF
THERAPEUTIC EXPERIENCE

SGS has performed many clinical trials covering numerous therapeutic areas:

- Cardiovascular
- Dermatology
- Ear, Nose, Throat
- Endocrinology
- Gastroenterology
- Genetic Disorders
- Immune Disorders
- Infectious Diseases
- Neurology/CNS
- Oncology
- Pediatrics
- Renal and Urinary Disorders
- Respiratory
- Surgical and Medical Procedures

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WHEN YOU NEED TO BE SURE