Clinical Research

Health Inspired,
Quality Driven.

SGS

Clinical Solutions Tailored to Your Research Needs

From varying global regulatory standards to ever more complex trial designs, introducing new products to market has become increasingly demanding. With over 40 years of experience as a world leading Contract Research Organization (CRO), SGS can provide you with expert support in every step of your clinical development, helping you move from First-in Human (FIH) trials executed at the SGS CPU, to Phase II trials, right up through to Phase III trials.

Our comprehensive clinical research solutions can be customized to help you meet increasingly stringent timelines and regulations around product safety and efficacy. Together, we can guide your products to global markets swiftly and efficiently while making sure you meet international and local requirements.

Clinical Development Consultancy

With a multitude of innovative and successful early phase study designs already under our belt, SGS is your partner of choice to guide you through the different phases of drug development. Our expert consultants and clinical pharmacologists will help you optimize every aspect of your clinical development plan and operations.

As a globally recognized expert CRO in early phase clinical trials, we have experience in building early phase clinical development plans and obtaining their subsequent approval by regulators and ethics committees. We can provide you with end-to-end regulatory, clinical development, and consulting services to ensure you meet your strategic goals.

Our experts can fully support you as you move through clinical trial phases. Work with a dedicated multidisciplinary team of clinical pharmacology experts, medical directors, regulatory affairs associates, statisticians, clinical operations leads, medical writers and specific therapeutic area experts who are at your disposal to support your global development strategy or provide consultancy and related services.

Supporting key decision making.
Ensuring best-in-class trial designs.
Managing risks.

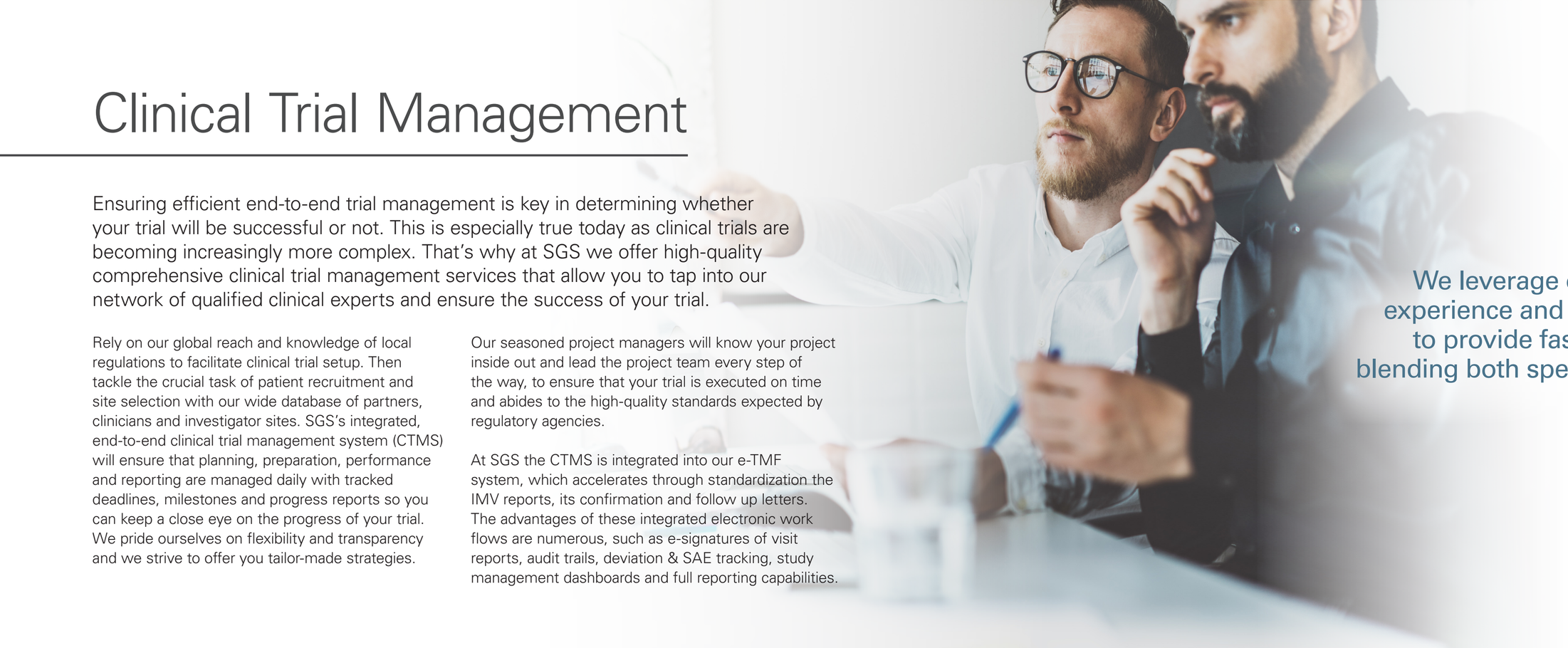
Clinical Trial Management

Ensuring efficient end-to-end trial management is key in determining whether your trial will be successful or not. This is especially true today as clinical trials are becoming increasingly more complex. That's why at SGS we offer high-quality comprehensive clinical trial management services that allow you to tap into our network of qualified clinical experts and ensure the success of your trial.

Rely on our global reach and knowledge of local regulations to facilitate clinical trial setup. Then tackle the crucial task of patient recruitment and site selection with our wide database of partners, clinicians and investigator sites. SGS's integrated, end-to-end clinical trial management system (CTMS) will ensure that planning, preparation, performance and reporting are managed daily with tracked deadlines, milestones and progress reports so you can keep a close eye on the progress of your trial. We pride ourselves on flexibility and transparency and we strive to offer you tailor-made strategies.

Our seasoned project managers will know your project inside out and lead the project team every step of the way, to ensure that your trial is executed on time and abides to the high-quality standards expected by regulatory agencies.

At SGS the CTMS is integrated into our e-TMF system, which accelerates through standardization the IMV reports, its confirmation and follow up letters. The advantages of these integrated electronic work flows are numerous, such as e-signatures of visit reports, audit trails, deviation & SAE tracking, study management dashboards and full reporting capabilities.



We leverage our 40 years of experience and local expertise to provide fast study set-up, blending both speed and quality.

Clinical Pharmacology

Moving through early phases effectively and quickly is crucial in obtaining critical data early. As a leading Phase I-II CRO, we can help you develop and conduct the complex clinical study designs needed to speed up early-stage development all while meeting international regulatory standards.

Our Clinical Pharmacology Unit (CPU) is located on the grounds of the University Hospital of Antwerp (UZA) in Antwerp, Belgium. This strategic location ensures direct access to specialist knowledge and techniques, combined with the Belgian fast regulatory approval cycle. You'll also be able to benefit from our CPU's specialized early phase expertise including complex umbrella protocols, Phase 1 trials requiring technical complexities and controlled human infection model (CHIM) trials. With access to our GMP-licensed Production Facility with extended IMP manufacturing capabilities, we offer a production and dispensing protocol specific to your study needs.

With more than 13,000 active potential study participants registered and a dedicated recruitment call center, you can be sure of rapid enrolment to stay within your set timelines. Our electronic source system allows electronic data collection, sample tracking, linking of the data directly into the clinical database and remote monitoring of clinical data, leading to even greater efficiency.

The SGS CPU in Antwerp offers a large bed capacity with 110 beds and 46 rooms equipped for Human Challenge Trials, as well as a fully licensed GMP production facility with classes D, C and B cleanrooms.

Check out our new CPU

Biometrics

The quality of clinical trial results is only as good as the quality of the data collected, hence why it's vital to make sure that your trial data is accurate and complete. The SGS Biometrics team can provide full biometric services through the clinical development process – leveraging its wealth of biometrics expertise to ensure that all necessary trial data is captured and analyzed to the highest possible standards.

Work with a core team of experts that is organized and ready to scale up to offer global support based on your specific needs. Benefit from our full host of biometrics services including protocol development, (e)CRF design, data management, secure data office, biostatistics, PK/PD data analysis, clinical study report (CSR) development, as well as pharmacovigilance and drug safety services. Each service can be provided within full project service outsourcing, a functional service provider (FSP) model or as standalone services.

All SGS biometrics services are performed in accordance with Food & Drug Administration (FDA), European Medicines Agency (EMA), and ICH- GCP regulations so you can rest assured you're meeting all international requirements. Our CDISC standards ensure shorter data processing and reporting timelines, so you can get quality and on-time delivery that meets your timelines.

The SGS Functional Service Provider Model lets you optimize your clinical data and biometric flow for global clinical studies while reducing your CRO oversight and obtaining high quality deliverables.

Medical Safety & Regulatory

To access markets for medicinal products, you'll need to meet an increasingly complex list of regulatory and safety requirements. To expedite this process, we provide you with a comprehensive range of services in the areas of regulatory affairs, medical monitoring, pharmacovigilance and safety writing from FIH to registration and post-registration.

Get support from dedicated regulatory experts that can assist you in the development and manufacturing of your pharmaceutical and biopharmaceutical products, to ensure you meet the most rigorous regulatory requirements.

Alongside regulatory services, we will support you in all safety matters, including pharmacovigilance, medical support and safety writing. We can ensure the safe delivery and regulatory compliance of your pharmaceutical and biopharmaceutical products.

Our dedicated experts know the complexities from A to Z and are ready to support you with guidance and customized solutions that help you meet all regulatory requirements, allowing you to bring your product quickly to market.

We can ensure your pharmaceutical, biopharmaceutical and medical device products are safe and conform to the highest regulatory requirements.

Clinical Trial Laboratory Testing

At SGS we offer you a large variety of laboratory tests for your clinical development: from routine safety testing, bioanalysis to customized testing solutions. In SGS you find a well experienced partner who will support you with all laboratory related aspects of your clinical development.

From protocol design through development and to market our experts will deliver the highest quality and customized laboratory solutions. As central lab we provide your clinical trial sites with harmonized, visit-specific, blood collection kits. This will already lay a solid foundation for high quality data. Afterwards our highly motivated and experienced project managers will take care of the sample logistics, considering sample stability for determining the most appropriate temperature range and longest turnaround time for conducting the best possible and most cost-efficient transports. After reception of the samples at our excellently equipped and qualified facilities, meeting all requirements for clinical trials, samples are either stored at the required temperature or immediately analyzed. From routine safety lab testing , through immunologic tests, biomarkers, genetics to bioanalysis , we will provide you with high quality tests and consistent and reliable results. Last but not least our client-oriented data management will take care of customized lab reports and data transfers that seamlessly integrate into the clinical database. While each service can be provided within full project service, a standalone service is of course also available.

SGS is your global central lab partner of choice providing fully-integrated, or standalone, multi-disciplinary central laboratory services to support your clinical development needs.

Clinical Trial Bioanalysis

We can support your quantitative analytical data needs. With four GLP compliant laboratories, we are able to serve you with a range of tests for drug development that can accurately guide your clinical decision making from early to late phase clinical trials.

As pioneers in bioanalytical services, we have over 700 validated assays, and a group of highly skilled and trained analysts that oversee testing. This means you can take advantage of rapid high-volume analyses that use a range of innovative techniques, including, mass spectrometry (LC-MS/MS), immunochemistry, UPLC technology, and automated sample preparation.

With a global network of testing facilities, we can help smooth your products' route to market. Our cost-effective testing capabilities enable you to reduce risk, shorten time to market and demonstrate the quality and safety of your product. These include, but are not limited to physical, mechanical, chemical tests, and bioanalytical tests.

SGS is one of Europe's largest bioanalytical service providers, with four GLP compliant laboratories.

End-to-End Clinical Research Solutions

We know that each product has its unique and often unexpected challenges, which makes planning and finding the support you need at every step of your product's development cycle an even bigger challenge. By working with SGS, you'll be able to tap into our global network of qualified clinical experts and international resources to ensure the success of your trials.

While each of our departments' services can bring you value on their own, you can also benefit from end-to-end clinical trial solutions that provide support from ideation all the way to successful market entry. Enjoy the ease of working with several departments all housed under one roof that work in cohesion to quickly address your organization's specific needs.

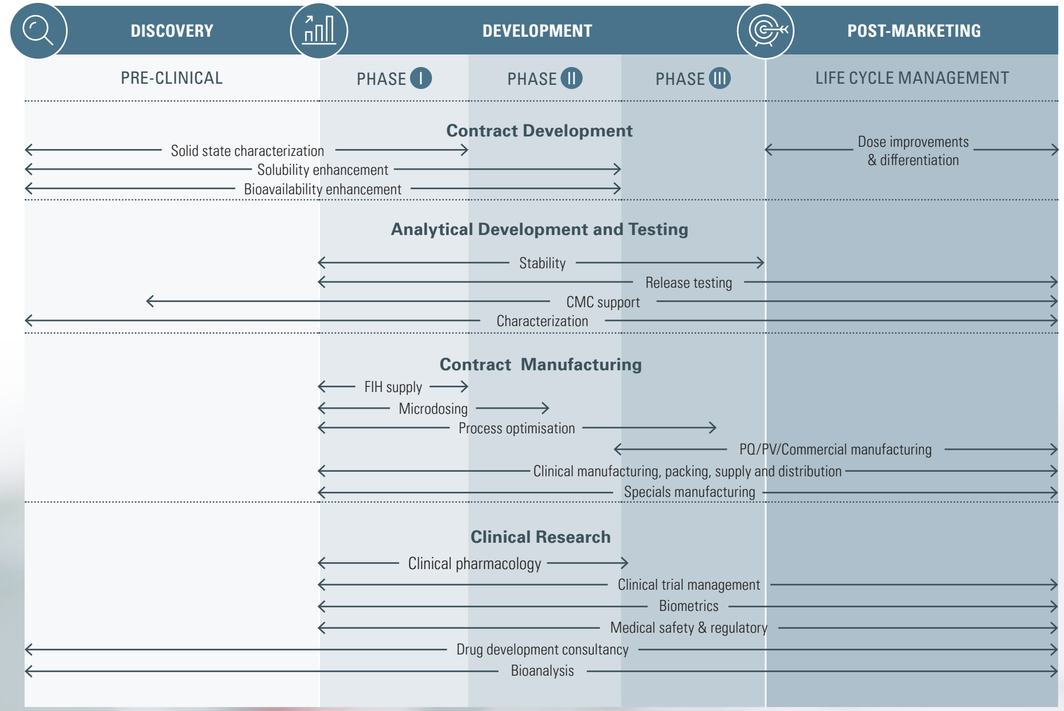
SGS is a large and well-structured organization with deep clinical research experience, which means we have the flexibility to provide you with tailored solutions for all the clinical research challenges you might face. Our international teams of experienced medical professionals have the ability to work together within limited timeframes and provide you with the rapid set-up times to accelerate your product's development life cycle and efficiently meet your clinical goals.

Support for a Wide Range of Therapeutic Areas

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

Scope of SGS Health Science

Next to clinical research solutions SGS Health Science delivers industry-leading contract development and manufacturing (CDMO) and analytical development and testing to support you every step of the way as you deliver first-class, fully compliant biopharmaceutical and pharmaceutical drugs and medical devices.



Health Science

Health Inspired,
Quality Driven.

Contact us

healthscience@sgs.com

sgs.com/healthscience

sgs.com/healthcommunity

WHEN YOU NEED TO BE SURE

SGS