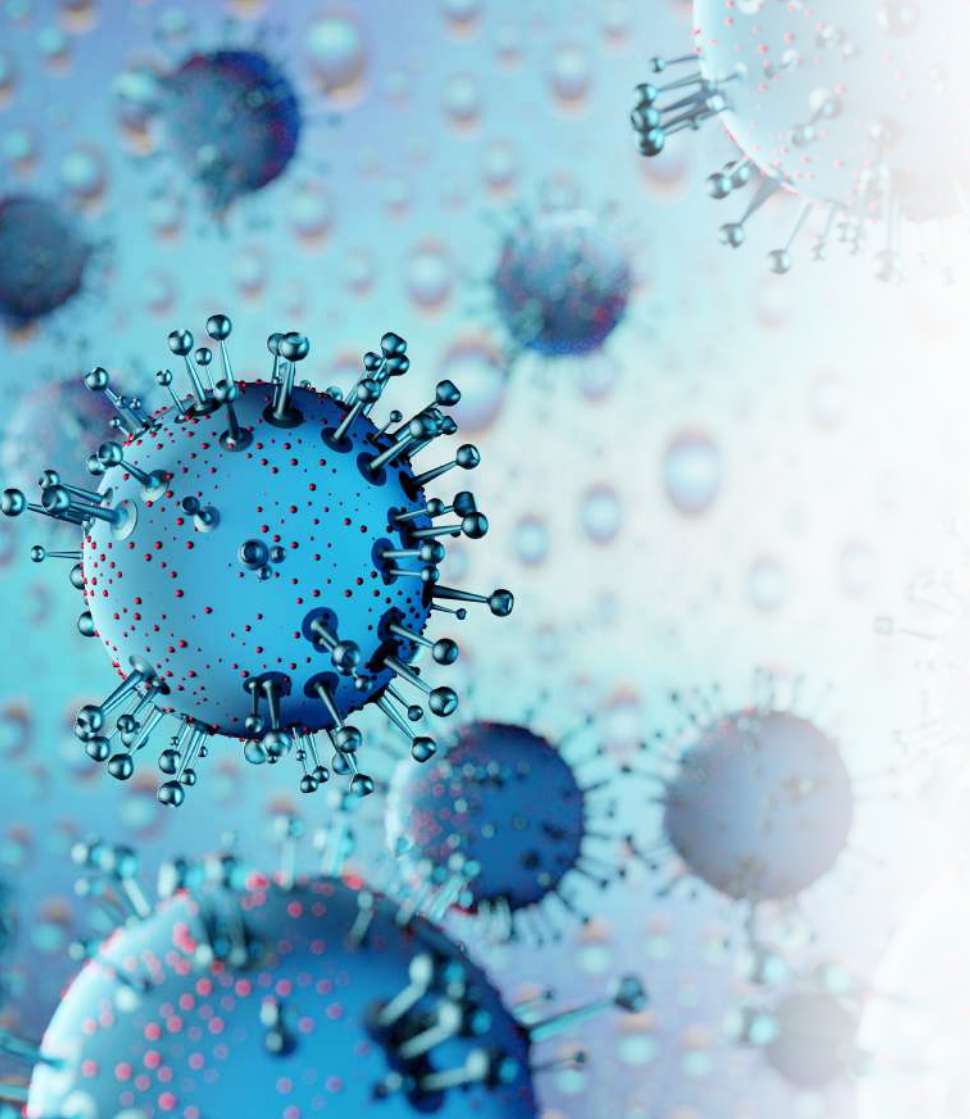


Infectious Diseases

Health Inspired,
Quality Driven.

SGS

Infectious Disease Expertise

SGS has 40 years of experience bringing infectious disease compounds through the complete clinical development cycle. As a global CRO, SGS provides integrated solutions from pre-clinical activities including formulation development, to clinical development consultancy and full service Phase I-IV clinical trials including clinical manufacturing and analytical laboratory services as well as bioanalysis, biosafety testing and immunoassays.

Integrated Services

In the last five years, SGS has completed more than 182 infectious disease clinical projects, spanning the full spectrum of SGS services from Phase I through Phase IV, including scientific consulting for drug development programs, regulatory guidance, clinical site recruitment and management, clinical trial monitoring and management, biometrics, medical monitoring, and pharmacovigilance.

In addition to its hospital embedded Clinical Pharmacology Units in Belgium and Hungary, SGS has developed relationships with a wide network of leading infectious disease experts in the field by means of participation in clinical studies as well as collaboration on scientific advisory boards, specialist consortia, and safety review committees. The entire SGS team is experienced and aligned to current infectious disease challenges with the ability to rapidly initiate, monitor and manage complex drug and vaccines trials.

Site Selection & Feasibility

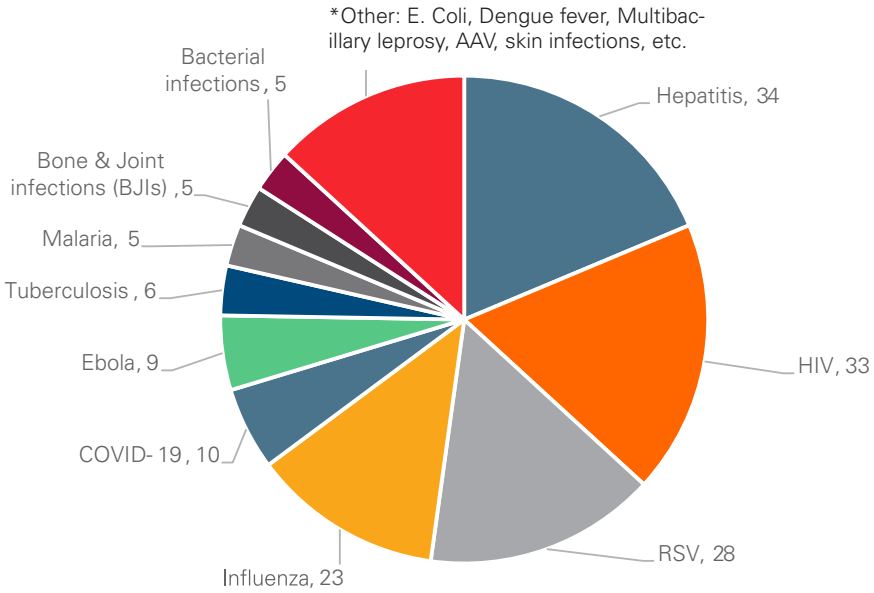
SGS maintains a proprietary database of potential investigator sites with active recruitment and ongoing feasibility studies in infectious disease indications. With this large investigator database, SGS can provide accurate recruitment potential and inclusion/exclusion feedback on a protocol within 2-4 weeks.

Infectious Disease Clinical Trial Experience

For over 40 years, SGS has built up unique expertise in early phase clinical trials including First-In- Human studies, QT/QTc prolongation, human challenge testing, biosimilars and complex PK/PD studies. 182 clinical trials in infectious diseases have been conducted in the past five years, including 55 multi-center clinical trials (Phase 1-IV) in the following diseases:

- Hepatitis
- HIV
- RSV
- Influenza
- COVID-19
- Ebola
- Tuberculosis
- Malaria
- Bone & Joint infections (BJIs)
- Bacterial infections
- E. Coli
- Dengue fever
- Multibacillary leprosy
- Other (AAV, skin infections, etc.)

SGS Phase I-IV Clinical Trials Experience (Last 5 years)



Early Clinical Trial Expertise

Pharmacologic Methods

Dedicated methods for evaluating the pharmacology of anti-infectious drugs performed for clinical trials in healthy subjects as well as in patients, such as:

- PK in plasma, urine, feces, saliva, vaginal fluids/ mucosa and CSF
- Cantharides-induced skin blister
- In vitro, ex vivo bactericidal activity in blood, urine and tissue
- Effect on the intestinal microflora
- Tissue distribution / skin penetration
- Pivotal clinical PK studies assessing the impact of renal and hepatic impairment on the disposition of antiinfectious drug as well as the potential for metabolic drug-drug interaction.
- TQT trials
- Respiratory evaluation techniques, including lung function, sputum induction, bronchoprovocation, bronchoalveolar lavage (BAL) and others
- Human inoculation with live viruses

Analytical Laboratory Services

SGS has more than 60 validated bioanalytical methods for the determination of anti-infectious drug in plasma, urine and tissues that are readily available for the PK evaluation of comparators and interacting drugs. With experience in developing and validating new bioanalytical methods, SGS also provides services encompassing:

- Biosafety testing
- Biomarkers
- Cell based & Immunoassays
- Molecular virology and viral serology

Clinical Trial Management Efficacy

For a faster, targeted clinical trial execution and patient recruitment, clients can rely on SGS's:

- Extensive database of investigators and key opinion leaders with therapeutic experience in infectious diseases.
- Specific skill-sets to successfully execute studies in respiratory and infectious diseases.
- Favorable regulatory environment in Belgium with very short phase I trial approval timelines (14 working days).

Multi-Site Infectious Disease Network for Early Phase Clinical Trials

To ensure proper recruitment and organization, SGS has developed a hybrid hospital network model which encompasses our historical and main clinical pharmacology unit in Belgium, supported by a satellite phase I unit in a major regional hospital, and several partnering hospitals with infectious disease departments. SGS's clinical pharmacology unit is located in Antwerp, Edegem with a total of 110 hospitalization beds.

For optimized early phase clinical trials, the unit features:

- A biosafety Level 2 quarantine facility
- A GMP production facility for on-site formulation
- Full eSource clinic automation (EDC) including sample tracking for safety lab data
- The Clinical Pharmacology Unit (CPU) has successfully passed several US FDA inspections during recent years.

Benefits of The Sites Network Concept

The clinical sites bring the infrastructure and a group of referring infectious disease specialists and general practitioners (GP) who are highly motivated to carry out early phase studies. It guarantees a secured access to the targeted patient population. SGS staff within the network ensures an efficient, harmonized training and study execution level for complex evaluations required in infectious diseases trials. Overall, the multi-site hospital partnership network enables:

- A flexible and tailored approach to meet sponsor timelines
- Faster study start-up and sites activation through established Clinical Trial Agreements
- A high rate and qualitative recruitment level: access to large and diverse patient populations for infectious disease indications. Having a dedicated patient recruitment expert within the CRO team allows reliable and predictable patient recruitment, and the wider the network, the greater the hospitals' databases are, including newly diagnosed patients or referrals from the established physician network.

Health Science

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Quality Driven.

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WHEN YOU NEED TO BE SURE

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