The SGS Clinical Pharmacology Unit (CPU) has a network of patient site facilities and a team of experienced staff to offer a comprehensive service for early phase trials or specialized early and late phase patient trials. SGS’s Early Phase activities are situated in different locations.

**CLINICAL PHARMACOLOGY ANTWERP, BELGIUM**

Occupying a total area of 4,500 m², the SGS CPU in Antwerp, Belgium, has four subunits and is located within the Antwerp ZNA Stuivenberg hospital. Our CPU in Antwerp has successfully passed multiple United States Food and Drug Administration (US FDA) and Belgian Federal Agency for Medicines and Health Products (FAMHP) inspections.

**Hospitalization**

The main hospitalization area is split into:

- Two subunits with 22 beds
- One subunit with 24 beds
- A Human Challenge Unit with 20 individual bedrooms

Each ward is equipped for (long-term) overnight stays, study assessments and pharmacokinetic (PK) sampling, as well as medical examinations, and a laboratory for sample handling. Samples are kept in a central long-term sample storage area. For the comfort of study participants there is a lunch room, recreational area, bathrooms, and toilets.

**CPU Pharmacy**

As the first Phase 1 Holder of a Good Manufacturing Practices (GMP) authorization in Belgium, the SGS CPU Pharmacy routinely delivers extended pharmacy services, allowing flexible dosing during the clinical trial. The pharmacy manages the investigational medicinal product (IMP) manufacturing process of small volumes during the clinical trial, under the supervision of the SGS internal Qualified Person (QP). GMP activities may include:

- Manufacturing of non-sterile products (including active pharmaceutical ingredients (API) weighing):
  - Hard capsules (filling with powder or with liquid)
  - Solutions, to be used internally
  - Semi-solid products
  - Other: liposomes, gel
- Primary packaging of:
  - Hard capsules
  - Solutions, to be used internally
  - Semi-solid products
  - Other: liposomes, gel
- Secondary packaging, including labeling
- Batch-release of imported products:
  - Sterile products
    - Aseptically prepared
  - Biological products
    - Immunological products
    - Challenge agents

For each clinical trial, a study specific production and/or dispensing protocol is set-up and approved by the Sponsor.

**Safety and Bioanalysis Laboratories**

Clinical safety laboratory activities are managed by the hospital’s laboratory in Antwerp, which ensures a quick turnaround time of assays and results. SGS also has two Good Laboratory Practices (GLP/GMP certified bioanalytical laboratories located in Europe, which support our Phase 1 Unit. With more than 25 years’ experience and over 700 methods validated following guidelines such as those from the US FDA, SGS offers a wide range of bioanalytical services for small and large molecules testing.
Clinical Experience
The SGS CPU has become an early clinical development specialist in:
- First in man (FiM) studies, including complex umbrella and adaptive designs
- Regulatory Phase 1 trials: TQT/QTc, BA/BE, DDI, HI/RI, food effect
- Particular Phase 1 trials requiring technical complexities on several fields, such as laboratory, nursing, medical and pharmacy
- Exploratory Phase 1 trials: proof of concept (POC) trials
- Controlled Human Infection Model (CHIM) trials, using viruses, parasites, histamines and other challenge agents

eSource
Our CPU in Antwerp is equipped with an eSource system, ClinSpark®, allowing for collection of study data straight into electronic format. eSource technology has simplified the Phase 1 Unit workflow from recruitment, through study conduct, all the way to database lock, and allows access to all study data in one place. The eSource offers multiple benefits to the phase I unit and its clients:
- Efficient subject recruitment and easier scheduling
- Rapid study design with realtime, bar-code driven direct data capture
- Automatic receipt of lab results through interface for realtime access to safety data
- Direct link to ECG devices or telemetry systems with online ECG analysis
- Automated sample management with tight control of processes
- Data visualization, verification and management for quicker query resolution

Easy safety reports make safety review meetings more productive
Standardized, built-in reporting tool with the ability to extract real-time data for (medical) monitoring activities
CPU and data management together supporting data standards (SDTM)

PATIENT SITES IN HUNGARY AND BELGIUM
As part of the SGS CPU clinical network, our patient sites, research facilities with full Phase I infrastructure, are equipped to perform phase I/IIa/POC trials in special populations and patients, across multiple therapeutic areas.

Budapest, Hungary
The Medical Center of Defense Forces and Saint John hospitals are renowned and leading facilities in Budapest, Hungary, and offer respectively five and four bed capacity for early phase trials. These Phase I Patient Sites have reliable access to most patient populations in multiple therapeutic areas. The safety and quality of studies are ensured thanks to highly experienced, multilingual SGS professionals and the facilities’ location within a large hospital close to emergency and intensive care units.

Mechelen, Belgium
Located within the Sint-Maarten Hospital in Mechelen, Belgium, this Phase I Patient Site has variable bed capacity and due to its close proximity to our primary CPU in Antwerp, allows for easy multi-site coordination and cross-site support. There is solid recruitment capacity for special populations and patients through dedicated therapeutic/medical experts, and access to a variety of techniques.

QUALITY MANAGEMENT
The SGS Clinical Research Independent Quality Assurance department focuses on ensuring that the trial is performed, and the data is generated, documented and reported, in compliance with good clinical practice and applicable regulatory requirements. SGS’s global Quality Management System (QMS) ensures that all activities are executed according to client and regulatory expectations, with quality assurance and quality control an essential part of our processes. The department conducts internal audits and maintains a corrective and preventive action (CAPA) database, ensuring appropriate plans are defined and open CAPAs are followed up until resolution.

In addition, the SGS CPU ensures continuous process improvement, through real-time, in-process quality control and independent quality control of operational techniques and activities.
BRINGING ADDED VALUE TO YOUR STUDIES

Our CPU’s extensive experience and expertise in early clinical trials can enhance your study experience.

- Extensive and successful track record in early clinical development. On average, our CPU performs 30 studies every year with a population of healthy volunteers, special populations as well as patients, and uses a wide range of study design.

- Large bed capacity at CPU Antwerp – 90 beds, with 46 equipped for intensive telemetric monitoring, spread over different subunits, allowing for easy and flexible allocation.

- Fast study start-up due to a low turnaround time of only 15 days for Regulatory Authority and Ethics Committee approval.

- Large recruitment capacity for healthy volunteers – more than 10,000 active subjects registered and a dedicated recruitment call center, ensuring rapid enrolment, and study delivery within timelines.

- Close collaboration to hospital Specialists, General Practitioners and patient organizations, enabling efficient recruitment of patients and special population across a variety of therapeutic areas.

- A strong team of (sub) Investigators and Clinical Research Coordinators (CRC), experienced in simple and complex studies, ensuring optimized study and volunteer safety management.

- Technical resources and expertise to ensure excellent execution of complex procedures next to the bedside, as well as optimal sample management throughout the study.

- On-site GMP pharmacy and in-house QP, allowing flexible dosing during the clinical trial.

- State-of-the-art electronic source system allowing for collection of data directly into electronic format, direct data transfer and remotely monitoring of clinical data, leading to greater efficiencies.

- Successfully passed four US FDA and five Belgian FAMHP inspections during the last five years.

- Contractual agreement with the emergency department of the local hospital to ensure the safety of volunteers at all times, including 24-hour supervision by nurses and on-call physicians.
CONTACT US

Contact us today to discuss your specific early clinical trial needs.

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