The image shows the exterior of a modern building with a large glass facade on the left and a brick courtyard in the foreground. The building has a white perforated metal screen on the upper levels. A glass entrance is visible, and a white banner with the SGS logo is hanging from the building. The text 'Clinical Pharmacology Unit' is overlaid on the right side of the image.

# Clinical Pharmacology Unit

Health Inspired,  
Quality Driven.

**SGS**

# Clinical Pharmacology Unit

The SGS logo is displayed in a large, bold, grey font. It is partially overlaid by a thin red horizontal line below the letters and a thin red vertical line to the right of the letters, forming a partial crosshair.

SGS Clinical Pharmacology Unit (CPU) is one of the leading Phase I Units in Europe, conducting complex Phase I-IIa clinical trials, in healthy subjects and as well as in different patient populations. SGS CPU is located on the grounds of the University Hospital Antwerp in Edegem, Belgium and occupies a total area of 6.500 m<sup>2</sup>, in a dedicated, purpose-built building connected to the hospital.

## Main CPU Facilities

The SGS CPU has 3 dedicated wards with a total bed capacity of 110 beds:

- (1) a general ward with 64 beds, including a 8 bed special 'High Care' unit,
- (2) a specialized 30 bed isolation unit,
- (3) a 16 bed isolation unit.

Each ward is equipped with dedicated areas to support study execution and assessments: a nurse station, a sample management laboratory and long term storage room and a dedicated material preparation room. Clinical samples

(blood, urine, feces, CSF, PBMC) are handled by a team of dedicated lab technicians, trained to manage complex samples according to the protocol/lab manual.

Study participants will enjoy their long-term stay in luxury individual or 2 to 4-person bedrooms, with dedicated lounge/resto area.

By conducting healthy volunteer studies at SGS CPU, sponsors benefit from favorable regulatory timelines; only 15-day approval for the Ethics Committee (EC) and the FAMHP, the Belgian Health Authority (HA), allows for quicker study and site start-up compared to other Phase I Units in European countries.

## Clinical Experience

SGS CPU performs on average 30 combined protocol Phase I trials per year and randomizes around 3.000 subjects in this period. We have over 13.000 active volunteers registered in our central database.

We are an early clinical development specialist in:

- FIM studies (including complex umbrella and adaptive designs)
- Regulatory Phase I trials (including: TQT/QTc, ADME, BA/BE, DDI, HI/RI trials)
- Particular Phase I trials requiring technical complexities on several fields such as laboratory, nursing, medical and pharmacy complexities
- Exploratory Phase I trials (including: micro-dosing and POC trials)
- Viral (and other) challenge trials





# CPU Production Facility

The SGS CPU production facility is authorized with Good Manufacturing Practices (GMP) by the Belgian Health Authority. As the first Phase I holder of a GMP authorization, SGS routinely delivers extended manufacturing services to its clients, managing the investigational medicinal product (IMP) manufacturing process during the set-up of the clinical trial in the most efficient way. This facilitates ordering and production of small IMP volumes inherent to Phase I trials.

For each clinical trial a study specific production and/or dispensing protocol is set-up and approved by the sponsor. The production facility assembly suite complies with most sponsor requirements for clinical assembly.

A team of production facility staff is dedicated to GMP manufacturing activities, and includes 2 in-house Qualified Persons, a Head Quality, Head GMP Production and GMP operators and QC checkers.

## Formulation and Clinical Manufacturing

Our global Center of Excellence for Formulation and Clinical Manufacturing – provides enhanced formulation research and development services for Phase I, Phase II and Phase III trials. Operating out of MHRA- and FDA-inspected facilities, we support drug manufacturers throughout all stages of clinical development: pre-formulation work, formulation, dosage form design and optimization.

We can perform a variety of manufacturing activities within the SGS production facility, including:

**Manufacturing of non-sterile products (including active pharmaceutical ingredients (API) weighing):**

- Hard capsules (filling with powder or with liquid)
- Solutions, to be used internally

**Primary packaging of:**

- Hard capsules
- Solutions, to be used internally

**Secondary packaging including labeling batch-release of imported products:**

- Sterile products
  - Aseptically prepared
- Biological products
  - Immunological products
  - Challenge agents



# Safety and Bioanalytical Laboratories

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Clinical safety laboratory activities are executed by the laboratory of the nearby hospital. This longstanding collaboration ensures fast turnaround of assays and results. The laboratory is accredited by the Belgian authorities as a hospital safety laboratory.

SGS has three bioanalytical laboratory facilities located in Europe (Belgium, France and Switzerland), which support our Phase I Unit for all bioanalytical laboratory services. With more than 25 years of experience, over 700 methods validated with criteria following guidelines from Food & Drug Administration (FDA) and Crystal City Conference, SGS offers a wide range of bioanalytical services for small and large molecules testing.

SGS labs are GLP/GMP certified. A rapid and efficient sample's logistic, as well results transfer process is in place between these laboratories and CPU in order to respect often tight timing in clinical trials.



## Subject Safety

Our Phase I unit, located next to the Antwerp University Hospital (UZA), has contracted the hospital's emergency crash team, that is on 24/7 stand-by and fully equipped, including monitor and defibrillator.

# Clinical Data Automation (eSource)

Our CPU in Antwerp is equipped with an eSource system, ClinSpark®, allowing for collection of study data directly into electronic format. eSource technology has simplified the Phase I Unit workflow from recruitment, through study conduct, all the way to database lock, and allows access to all study data in one place.

**Subject recruitment:** The eSource includes the full volunteer database, allowing for faster volunteer selection (including configurable inclusion and exclusion rules) and scheduling of appointments.

**Study Design and Direct Data Capture:** Use of (sponsor) specific libraries allow for rapid protocol setup in the eSource system. The design allows for rapid adaptations during the trial.

**Real-time, bar-code driven study data collection** results in a over 90% reduction of paper source/ processes. The DDC ensures direct capturing of data from devices (Vital Signs, ECG, etc.). The process is barcode driven (subject, dose, collection, instruments), and includes edit checks and alerts, thus resulting in increased data quality.

**Automated Sample Management:** barcode driven sample management ensures tightened control of the sample processes.

**Data Monitoring:** The eSource allows for data visualization, verification and query management at the source level. The real-time access allows for continued data monitoring by Medical Monitor, CRA and Data Manager, ensuring faster query resolution.

**Reporting:** Build-in reporting tool with standard reports and the possibility to extract real-time data files for monitoring activities.

**Data Management:** In collaboration with SGS Data Management, direct data transfer into the Clinical database is possible. The eSource design allows for SDTM like annotations transferring the collected data into an SDTM inspired data export file. Available in excel, CSV and XPT format.





# Patient Sites in Belgium and Hungary

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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.

## 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.

## Budapest, Hungary

The Saint John hospital is a renowned and leading facilities in Budapest, Hungary, and offers four bed capacity for early phase trials. This Phase I Patient Site has 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 unit.



# Quality Management

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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.

## Quality Management System

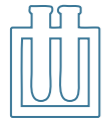
SGS's global Quality Management System (QMS) ensures that all activities are executed according to client and regulatory expectations, with quality assurance and quality control an essential part of our processes. The department conducts internal audits and maintains a corrective and preventive action (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 recruitment capacity for healthy volunteers (> 13.000 active subjects registered in our database) by a dedicated recruitment center, ensuring efficient subject enrolment and study delivery within timelines.



A large bed capacity of 110 beds, of which 8 high care beds and 64 telemetry beds, spread over three wards, allowing for easy and flexible allocation.



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



SGS's CPU has successfully passed multiple US Food & Drug Administration (US FDA) and Belgian FAMHP (Federal Agency for Medicines and Health Products) inspections during the last 5 years.



State-of-the-art electronic data source system allowing for direct data collection in electronic format, real-time data transfer, and remote monitoring, leading to greater efficiencies.



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



A strong team of (sub) Investigators (INV) and Clinical Research Coordinators (CRC), experienced in simple and complex studies, ensuring optimized safety management during the trial.



Fast study start-up due to low turnaround time of only 15 days for Regulatory Authority and Ethics Committee approval (low compared to most countries in Europe).



Dedicated therapeutic, pharmacology and clinical development experts assessing feasibility and ensuring smooth conduct of your study.



# Health Science

Health Inspired,  
Quality Driven.

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## Contact us

✉ [healthscience@sgs.com](mailto:healthscience@sgs.com)

🌐 [sgs.com/healthscience](https://sgs.com/healthscience)

🌐 [sgs.com/healthcommunity](https://sgs.com/healthcommunity)

WHEN YOU NEED TO BE SURE

**SGS**