



# **EARLY DRUG DEVELOPMENT CONSULTANCY & SERVICES**

**CLINICAL RESEARCH SOLUTIONS**

**SGS**

As a full service contract research organisation performing phase I to IV clinical trials across Europe and the Americas for 40 years, SGS understands the strategic importance of preclinical and early drug development phases to your success. Taking informed decisions at every step is essential to compounds development and to ensuring it reaches patients in a timely manner.

SGS supports numerous biotech companies to answer the complex requirements of health authorities and also successfully perform IND and CTA submissions.

# MOVING YOUR DRUG CANDIDATE FROM NON-CLINICAL DATA TO PATIENT TRIALS

With our experience in drug development consultancy, SGS is your partner of choice to guide you through the different phases of development.

We have designed a multitude of innovative early phase clinical development plans and study designs, as well as obtained their subsequent approval by regulators and during due diligence exercises.

A dedicated multi-disciplinary team of qualified regulatory, toxicology, pharmacology and therapeutic area specialists is at your disposal to support your global development strategy, or provide consultancy and related services.

## SGS SERVICES

### ■ Early phase development strategy & tactics

- Regulatory strategy
- Candidate selection: early characterisation, formulation and stability testing; review of pre-clinical data/reports
- Lead optimisation: CMC, non-clinical and clinical development plans
- Target Product Profile (TPP)
- Set-up and participation in Scientific Advisory Boards
- Study design & clinical study protocol writing
- Due diligence/opportunity assessment

### ■ Validation of strategy with Regulators

- Scientific Advice meetings with the European Medicines Agency (EMA) and European National Agencies
- Pre-IND and End of Phase meetings with the Food and Drug Administration (FDA)
- Support in discussions and preparation of answers to Agency questions

### ■ Development and redaction of official health authorities' trial documents (FDA, EMA...)

- Writing and development of Investigational Medicinal Product Dossier (IMPD) and Investigators Brochure (IB)

### ■ Scientific/Medical input

### ■ Modelling & simulation

### ■ Early phase clinical trials in healthy volunteers and patients

## SGS'S UNIQUE EXPERTISE:

- Worldwide recognised expertise in early phase clinical trials
- Experience in all clinical development stages
- Full access to in-house experts working as a team and as not individual consultants
- Capability to translate strategy into tactics and solid data for dossier
- Client management policy considers each customer as the most important

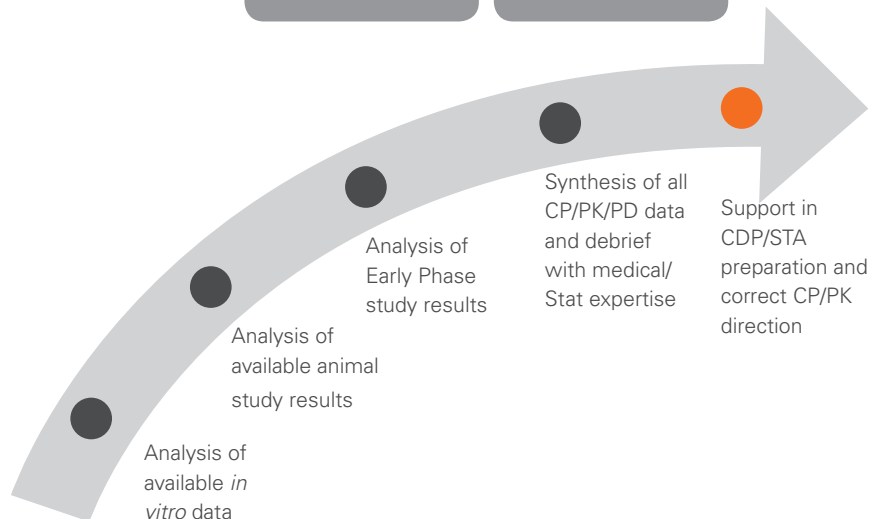
# SUPPORTING KEY DECISION MAKING – MANAGING RISK

Along the drug development cycle, anticipating risks and making the right decisions are crucial to ensure you secure a return on your investment. Our experts will support you by:

## 1 RAISING THE RIGHT QUESTIONS



## 2 BRINGING ROBUST SCIENTIFIC & REGULATORY SOLUTIONS



## 3 FACILITATING CLINICAL TRIAL PERFORMANCE PREDICTION & SET UP

- **PK/PD simulation and modelling** predicts the expected results of prospective complex trials, while optimising study design to increase the probability of a successful efficacy and safety outcome.

With many years experience, over 300 modelling and simulation projects performed, and the latest software, our modelling and simulation experts provide input that can lead to more informative studies, fewer study failures, improved investment decisions and better justified label claims.

- **Early phase clinical trials** from First In human to Proof of Concepts and Patients trials, ensure your drug candidate will successfully navigate the long and expensive late phase clinical trials.

At SGS we have our own clinical unit in Belgium, including a viral challenge testing facility, and two phase I patients units based in Belgium and Hungary. We have a wealth of expertise in FIH studies, viral challenge testing, biosimilars and complex PK/PD studies with a high therapeutic focus in Infectious Diseases, Vaccines, and Respiratory.

# CASE STUDY: 1

## VIRTUAL BIOTECH DEVELOPING AN ORAL INSULIN

### CONTEXT

**A biotech company with an oral insulin in pre-clinical stage contacted SGS to support the transition to clinical trials.**

The SGS Medical, Clinical Pharmacology and Regulatory teams examined the available pre-clinical data, and advised which additional pre-clinical trials would be required, and designed the first-in-human study. The SGS regulatory group suggested that a Scientific Advice would be suitable to have the agreement of the regulators on the pre-clinical program.

### OUTCOME

Scientific Advice was successful and followed by swift CTA approval. Two Phase I studies were successfully executed at the SGS Phase I unit.

The study was designed as an adaptive umbrella design with interim analysis after each step for the first-in-human study. This approach permitted execution of the study in an efficient and safe manner and the identification of the therapeutic dose for the next Phase I study assessing the administration regimen in food (prandial insulin).

SGS is currently preparing a Clinical Development Plan (CDP) and Target Product Profile (TPP) for the drug.

### SERVICES INVOLVED

Regulatory Affairs - Medical Director - Clinical Pharmacology and Pharmacokinetics Expert

# CASE STUDY: 2

## BIOPHARMACEUTICAL COMPANY DEVELOPING NEW MOLECULES FOR THE TREATMENT OF NEURODEGENERATIVE DISEASES

### CONTEXT

**A European company asked SGS to investigate the difficulties in the pre-clinical and FIH development process, and for support in planning the future of their bioactive molecule.**

The SGS Medical, Clinical Pharmacology and Regulatory teams examined the available pre-clinical and FIH data and investigated the reasons for failure of an FIH study. Targeted in vitro and animal studies were advised in support of a new FIH study design. The points to be considered in the new FIH study design were suggested to avoid any safety, pharmacokinetic and/or regulatory problems.

Considering the particularities in the pharmacokinetic properties of the new molecule (non-linearity in PK) and the pathology, the early involvement of Modelling and Simulation (M&S) services was advised, in support of further development processes.

### OUTCOME

Several scientific discussions/meetings were organised between SGS and client's experts. The objective was met; a detailed further investigations plan was developed, supported by a M&S optimal design exercise.

### SERVICES INVOLVED

Regulatory Affairs - Medical Director - Clinical Pharmacology and Pharmacokinetics Expert - SGS Exprimio M&S Service

## CASE STUDY: 3

### SMALL PHARMACEUTICAL COMPANY WITH ONE KEY COMPOUND UNDER DEVELOPMENT

#### CONTEXT

**A European pharmaceutical company contacted SGS for support in EMA Scientific advice discussions and to propose Early Phase trials at pre- and post-submission period in order to have an acceptable dossier for a new indication of their compound (in Phase II-III for initial indication).**

The SGS Medical, Clinical Pharmacology and Regulatory teams examined the pre-clinical and clinical data available for the compound, independently of the indication. The Scientific Advice meetings reports and EMA answers/questions were carefully examined from a scientific and regulatory point of view. Considering the change in the indication and properties of the compound, the studies to be performed at pre-and post-submission periods were identified, and the designs of those studies developed. Support in preparing answers to EMA questions was also provided.

#### OUTCOME

The trials packages recommended, and high level designs were in line with EMA expectations, enabling the company to plan its trials in the required order. Some will be carried out at the SGS Phase I unit, and for others SGS will provide relevant services.

#### SERVICES INVOLVED

Regulatory Affairs - Medical Director – Statistics - Clinical Pharmacology and Pharmacokinetics Expert

## CASE STUDY: 4

### SCIENTIFIC ADVISORY BOARD MEETING FOR RSV COMPOUND

#### CONTEXT

**An established US biotech company contacted SGS LS to assist them in designing a development strategy for their new antiviral compound. The company intended to further develop the antiviral as RSV drug and set-up a Scientific Advisory Board meeting.**

The SGS Project Director Infectious Diseases and Regulatory team examined the available pre-clinical and Phase I safety data, benchmarked the compound against other RSV treatments and evaluated how the new antiviral could be positioned. SGS joined the Scientific Advisory Board meeting with the sponsor's KOLs and played an active role in translating the scientific strategy into a feasible clinical and regulatory strategy.

#### OUTCOME

The Scientific Board Advice was successful, and the development plan for the compound, designed by SGS, was approved by the sponsor. The compound is currently in a Phase IIb trial.

#### SERVICES INVOLVED

Project Director Infectious Diseases - Regulatory Affairs - Medical Director - Associate Director Clinical Pharmacology

## CONTACT INFORMATION

#### EUROPE

+ 32 15 27 32 45

[clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)

#### NORTH AMERICA

+ 1 877 677 2667

[clinicalresearch@sgs.com](mailto:clinicalresearch@sgs.com)

[WWW.SGS.COM/CRO](http://WWW.SGS.COM/CRO)

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