EARLY PHASE CLINICAL TRIALS IN PATIENTS: A MULTI-SITE HOSPITAL PARTNERSHIP MODEL FOR RELIABLE PATIENT RECRUITMENT IN COMPLEX TRIALS

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MEETING AN INDUSTRY NEED

The biopharmaceutical industry has a growing need for early phase clinical studies in patients to support more advanced and informed go-no go decisions, ultimately enabling more efficient and productive future development planning.

Proof-of-concept studies provide early and strong pivotal patient data but the on-site execution is often complex requiring a focused and highly trained team of site staff. Patient recruitment is often challenging in these early phase trials considering the low direct patients' therapeutic benefit, the sometimes heavy study procedures and the inter-study competition for the same patient population.

The traditional settings in which the treating physician and his site staff are handling the clinical trial work in the doctors' office in addition to their primary responsibility is far from ideal in the conduct of these demanding phase Ib/IIa trials. A lack of sufficient devotion, focus and technical expertise may lead to difficult patient recruitment, poor clinical data and could even jeopardize the patients' safety. Moreover, the infrastructure, technical equipment and organization of a hospital environment are not always adapted to the strict and technical clinical trial designs.

SGS developed a multi-site hospital partnership model to meet the clients' needs. We believe our model provides the best outcome to sponsors and patients alike.

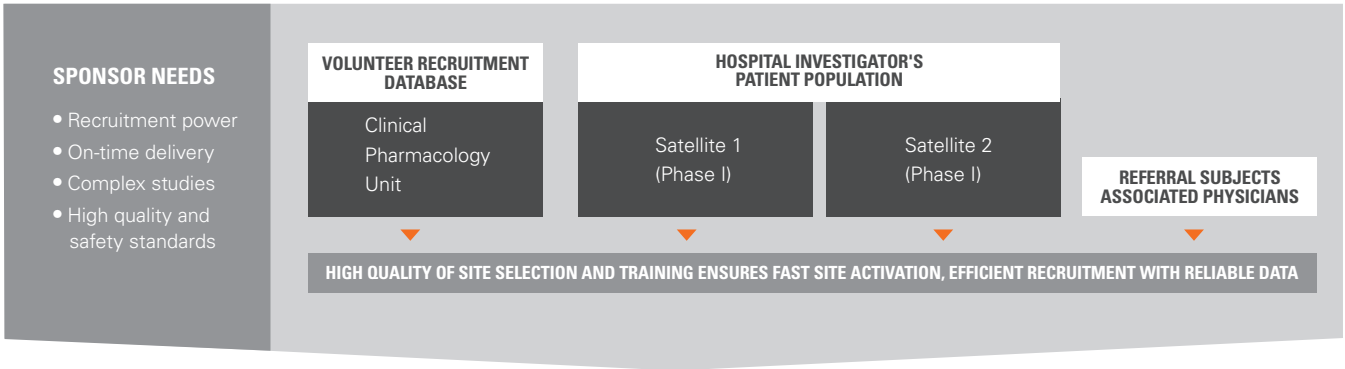
Key to conducting these challenging, early phase clinical trials in patients successfully are:

- A network of hospital based patient units highly equipped and adapted to executing complex study protocols
- Secure access to the right patient population
- A highly trained and a dedicated team of site staff
- Trusted execution and delivery of all critical milestones and endpoints

MULTI-SITE MODEL: SOLUTIONS TO HANDLE COMPLEXITY

To address the challenges, SGS has set up a multi-site hospital partnership model with an intelligent 'Satellite' Network of hospital-embedded investigative patient unit in Western and Eastern Europe. Moving from the single site early phase model to SGS' multi-site model enables a flexible and sponsor tailored approach to meet strict timelines while still reaching the right patient population.

SATELLITE CONCEPT



SGS has hospital based patient units located in Belgium and Hungary. Both countries have a beneficial regulatory landscape for conducting clinical trials. The partnership with the hospital management also enables faster sites activation through efficient Clinical Trial Agreement negotiations with the investigators.

The hospital based patient units allow the access to large and diverse patient populations for a variety of complex and special indications such as: oncology, infectious diseases, respiratory, cardiology, organ impairment, immunology, metabolic disorders, metabolic disorders, dermatology, geriatrics, nephrology, vascular surgery and CNS.

The units are managed by a dedicated team of SGS site staff who are all working in a standardized way across the units. The SGS team has strong collaboration with the treating hospital physicians who can either act as a principle investigator or sub-investigator. In both cases, the SGS site staff will keep the oversight ensuring the protocol is conducted as per SGS quality and safety standards.

The devotion of a specialized SGS patient recruitment team has proven beneficial for reliability and predictability of patient recruitment. The hospital partnership allows the patient recruitment team map an accurate and reliable patient recruitment potential in the various indications. Patients are recruited from the hospital database, may be newly diagnosed or can come from referral physician network that SGS established. Once the study starts, the patients' participation will be activated.

SGS has conducted several hybrid protocols with a healthy volunteer part and a patient part. The hospital based patient units can complement the healthy volunteer Clinical Pharmacology Unit in Belgium.

The SGS satellites are:
- In Belgium, 1 unit with capacity of 8 beds – 5 weeks for regulatory approval
- In Hungary, 1 unit with capacity of 5 beds – 8 weeks for regulatory approval

DRIVING FOR RESULTS: A REAL LIFE CASE STUDY WITH COMBINED PROTOCOL

An established US-based biotech company contacted SGS to develop a European strategy for their new infectious disease compound after the IND submission because their First-In-Human was rejected by the FDA based on non-clinical data. The SGS project team made an in-depth risk analysis of the protocol, the IB and available data and proposed a detailed strategic risk mitigation plan.

To compensate the loss of timelines, SGS proposed a combined protocol approach, performing the First-In-Human study at the Healthy Volunteer Clinical Pharmacology Unit in Antwerp, Belgium and the proof-of-concept patient study in dedicated patient satellite units in Western and Eastern Europe. To mitigate the risk for Health Authority queries or rejection, SGS proposed an upfront meeting with the Belgian Scientific Advisory Committee to justify the study conduct with availability of non-clinical data.

SUCCESSFUL OUTCOME

The scientific advice was positive and the sponsor was able to perform the study that was initially submitted in the US with only very minor adaptations to the original protocol. The multi-site concept was beneficial to ensure a reliable study deliverable within the agreed timelines.
The healthy volunteer arm in Belgium started immediately after the CTA approval was obtained, within one month after submission took place. While the healthy volunteer arm had kicked off in Belgium, the patient arm of the study was being reviewed for approval in the Eastern European countries. By the time healthy volunteer portion was executed the Health Authority and Ethics Committee approval was obtained in Eastern Europe for the patient part of the protocol.

The SGS satellite network, a multi-site hospital partnership model for early phase investigative patient trials has proven its efficacy and met the client's needs. The study recruitment was accomplished on time.

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