



INFLUENZA DRUG DEVELOPMENT

Studying influenza poses unique challenges for our pharmaceutical clients, including: timing the clinical studies to align with the seasonality of the disease, finding the right patient population and managing costs throughout the development process. SGS offers comprehensive clinical trial solutions from Phase I-IIa trials in our Early Phase Unit to conducting late phase trials across the globe, our clinical trial services can help you address the threat of influenza. SGS has performed nearly 500 infectious disease studies in the last 5 years, including successful execution of one of the world's largest influenza clinical trials.

EXPERTISE AND EXPERIENCE

INFLUENZA EXPERIENCE	TRIAL PER PHASE	SUBJECTS & SITES
Clinical Trials	30 studies (20 phase I, 10 phase II-III)	6,141 subjects in 336 sites in Europe, North America and the Rest of the World
Indications	Small and large molecule antivirals and vaccines	

SGS is developing a portfolio of viruses for human challenge trials and actively works with both influenza and regulatory experts to ensure challenge trials meet all the necessary ICH-GCP and CFR 21 requirements. In performing its own

Community Virus Surveillance Program and developing virus candidates into FDA/EMA approved, cGMP stock, SGS has gained experience in all aspects of influenza isolation and testing.

MOVING YOUR PRODUCT FROM EARLY TO LATE PHASE

SGS offers a unique one-stop shop for Phase IIa/b studies and an accelerated

route to worldwide licensing.

CHALLENGING YOUR DRUG CANDIDATE

Using a Human Challenge Trial (HCT) to support pre-clinical evidence of efficacy can help minimize the risk and maximize the outcomes when progressing a new

drug or vaccine into clinical registration studies. HCTs offer a number of advantages:

- Small cohorts (40-60 subjects)
- Defined, controlled environmental and clinical conditions
- High infectivity rate
- Known inoculation date
- Short duration (28 days)
- Low cost (€2-3M)
- Early and informed go / no-go decisions
- Data supports design of follow on registration studies

Unique SGS Facilities & Challenge Virus Availability

- 88 bed, hospital-based, clinical pharmacology unit in Belgium incorporating a 20-bed, BSL 2 compliant quarantine unit for viral challenge testing
- Two SGS Phase I satellite units in Belgium and Hungary
- cGMP manufactured drifted, A/Switzerland/2013 H3N2 virus

SGS

FULL SCOPE OF SERVICES

SGS is able to deliver your influenza studies with benchmark quality and a suite of services (Phase I to IV) tailored to your requirements. Encompassing clinical project management, study monitoring, data management, biostatistics, drug PK/PD, in-silico modeling & simulation and regulatory & medical affairs or a simply a design consultancy package, SGS has a solution to fit your need.

EARLY PHASE:

(FIH / SAD / MAD)

- Pre-clinical data validation
- Scientific Advice meeting
- Modelling and Simulation
- Healthy Volunteer recruitment
- 88 bed CPU / 20 bed Human Challenge Unit
- Biomarker evaluation
- PK / PD / ADME / FE / DDI

LATE PHASE:

(SAFETY / EFFICACY)

- Study design
- Synopsis and protocol MW
- Site identification
- Subject recruitment
- CTM / PV / DM / Monitoring and Audit
- IB / CSR / NDA / MAA

CASE STUDY

HOW WE MAKE IT HAPPEN

EARLY PHASE (HUMAN CHALLENGE TRIAL) CASE STUDY: PHASE IIa STUDY IN INFLUENZA

CONTEXT:

"A randomized, placebo-controlled, double-blind Phase 2a trial was designed to assess the efficacy and safety of a novel mAb in healthy human volunteers challenged with a 2009 pandemic strain of H1N1 influenza virus"

KEY CHALLENGES:

- Identifying susceptible cohort (60-80 healthy volunteers; health associated infections <10)
- 10 day isolation of subjects within a specialized unit
- Intense nasopharyngeal swab schedule of assessments and pre-screen PCR testing schedule

OUTCOMES:

- ✓ A total of 332 subjects were screened; 31 were enrolled - 20 subjects met the definition of laboratory-confirmed infection (mAb, n=13; and placebo, n=7) (AR = 62%)
- ✓ vAUC for mAb treated subjects was reduced by 92% (p=0.019); peak viral load was reduced by 2.2 logs (p=0.009) (interim result data @ 6 months)
- ✓ mAb was generally safe and well tolerated. There were no drug-related discontinuations or serious adverse events (SAEs) reported in the study
- ✓ Based on the interim results - the comparative portion of the trial was ended.

LATE PHASE CASE STUDY: PHASE III STUDY IN INFLUENZA

CONTEXT:

"A global multicenter randomized factorial double-blind, placebo-controlled trial designed to evaluate (i) efficacy and safety of nitazoxanide 600 mg administered orally twice daily for five days compared to a placebo and (ii) efficacy and safety of combination therapy with nitazoxanide 600 mg plus Oseltamivir 75 mg co-administered orally twice daily for five days compared to nitazoxanide monotherapy (600 mg b.i.d. for 5 days) and Oseltamivir monotherapy (75 mg b.i.d. for 5 days) in the treatment of acute uncomplicated influenza."

161 sites in the U.S., Canada, Australia, New Zealand, and Belgium; 1,941 subjects enrolled over five flu seasons (three in Northern Hemisphere and two in Southern Hemisphere)

KEY CHALLENGES:

- Lower than expected flu positivity rate
- Delays in Data Monitoring due to fast enrollment
- Acute nature of indication
- Compliance issues with subject diaries
- Delays in final data cleaning

OUTCOMES:

- ✓ Improved swab collection technique and targeted
- ✓ enrolment timing + re-training for sites
- ✓ Addition of CRAs to study team
- ✓ Tracking of data monitored at the subject and eCRF level
- ✓ Data monitoring and cleaning plan developed between SGS and external DM group
- ✓ Plan resulted in full enrolment and database lock on the original date as agreed with the sponsor

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