INFECTIOUS DISEASES

DRUG DEVELOPMENT SOLUTIONS

SGS

SGS Life Sciences has 40 years of experience bringing infectious disease compounds through the complete clinical development cycle. As a global CRO, SGS provides integrated solutions from pre-clinical activities to Phase I-IV clinical trials and analytical laboratory services including bioanalysis, biosafety testing and immunoassays.

INTEGRATED SERVICES

In the last five years, SGS has completed more than 380 infectious disease clinical projects in some 38,400 healthy volunteers and patient populations, spanning the full spectrum of SGS services from Phase I through Phase IV, including scientific consulting for drug development programs, regulatory guidance, clinical site recruitment and management, clinical trial monitoring and management, biometrics, medical monitoring, and pharmacovigilance.

In addition its hospital embedded Clinical Pharmacology Units in Belgium and Hungary, SGS has developed relationships with a wide network of leading infectious disease experts in the field by means of participation in clinical studies as well as collaboration on scientific advisory boards, specialist consortia, and safety review committees. The entire SGS team is experienced and aligned to current infectious disease challenges with the ability to rapidly initiate, monitor and manage complex drug and vaccines trials.

SITE SELECTION & FEASIBILITY

SGS maintains a proprietary database of potential investigator sites with active recruitment and ongoing feasibility studies in infectious disease indications.

This large investigator database, SGS can provide accurate recruitment potential and inclusion/exclusion feedback on a protocol within 2-4 weeks.

SOLID EXPERIENCE IN EARLY AND LATE PHASE TRIALS

SGS has successfully performed clinical trials targeting a wide variety of pathogens including:

INDICATION FOCUS

- HIV: IMPs (non-inferiority), drug/drug interaction, formulation, AE studies
- Hepatitis: drug and vaccine (therapeutic and preventative)
- Influenza (H1N1 / H3N2), RSV and rhinovirus (viral challenge)
- Upper respiratory tract diseases; unusual vaccine and drug delivery mechanisms e.g. electroporation and inhaled drug devices
- TB: novel compounds, immunomodulators, vaccines

- Human Challenge Trials with H1N1pdm and H3N2 as well as studies in HBV and HCV
- Contributions to three HIV products approved by the FDA (one designated as Fast Track) and EMEA
- Proven track record of focused site selection targeting fast recruitment including enrollment of 38 HCV patients in 5 days of recruitment
- Combined protocol (SAD, MAD, FE, POC, DDI) enrolling 45 healthy volunteers and 27 HCV patients in Belgium. SAD/MAD duration 5 months, POC duration 7 months.
- Conducted largest global, well controlled, community based acute influenza treatment study
- Uncomplicated and hospitalized influenza studies

SGS PHASE I-IV CLINICAL TRIALS EXPERIENCE

(LAST 5 YEARS)

INFECTIOUS DISEASES

- **34%** INFLUENZA
- **34%** HEPATITIS
- **19%** HIV INFECTION
- **6%** HIV 1
- **3%** RESPIRATORY SYNCYTIAL VIRAL INFECTION (RSV)
- **3%** CRYPTOSPORIDIUM PARVUM/ GIARDIA LAMBLIA INFECTION

RESPIRATORY DISEASES

- **30%** ASTHMA
- **26%** COPD/ASTHMA
- **17%** CYSTIC FIBROSIS
- **9%** PEDIATRIC ASTHMA / COPD
- **4%** PERSISTING ASTHMA
- **13%** OTHER

PHARMACOLOGIC METHODS

Dedicated methods for evaluating the pharmacology of anti-infectious drugs performed for clinical trials in healthy subjects as well as in patients, such as:

- PK in plasma, urine, feces, saliva, vaginal fluids/mucosa and CSF
- Cantharides-induced skin blister
- *In vitro, ex vivo* bactericidal activity in blood, urine and tissue
- Effect on the intestinal microflora
- Tissue distribution / skin penetration
- Pivotal clinical PK studies assessing the impact of renal and hepatic impairment on the disposition of anti-infectious drug as well as the potential for metabolic drug-drug interaction.
- TQT trials
- Respiratory evaluation techniques, including lung function, sputum induction, bronchoprovocation, bronchoalveolar lavage (BAL) and others
- Human inoculation with live viruses

ANALYTICAL LABORATORY SERVICES

SGS has more than 60 validated bio-analytical methods for the determination of anti-infectious drug in plasma, urine and tissues that are readily available for the PK evaluation of comparators and interacting drugs. With experience in developing and validating new bioanalytical methods, SGS also provides services encompassing:

- Biosafety testing
- Biomarkers
- Cell based & Immunoassays
- Molecular virology and viral serology

HCV CASE STUDY

Design: A double blind, randomized, placebo controlled SAD/MAD, in healthy volunteers and genotype 1 HCV patients

Recruitment: 46 healthy volunteers were recruited within a period lasting for approximately 4 months; 2 patient panels (out of 28 patients in total) were recruited within 4 months

Challenges / Solutions:

- Recruitment for the specific HCV patient population would not be possible through the traditional means used to recruit healthy volunteers. / SGS used its SMO network of physicians to locate six specialists from different hospitals who could refer suitable HCV patients enabling SGS to meet the recruitment targets.
- Patients enrolled in the PK substudy were required to come back to the Phase I Unit frequently for samples to be taken. The patients raised concerns about the practical and financial burden associated with the trips. / In order to maintain protocol compliance, study subjects were offered hotel rooms near the unit during the PK sampling period.

Initially a positive urine result for cannabis was an exclusion criterion. However, cannabis is a legal substance in the Netherlands, and a urine sample will screen positive for the substance for a substantial time after discontinuation of cannabis use. A protocol amendment was made changing the urine detection method to a plasma assessment which is a more accurate measure of recent cannabis use.

INFLUENZA CASE STUDY

Design: A double blind, placebo controlled trial studying an antiviral medication in patients with uncomplicated influenza

Recruitment: 650 patients in a formal period from December - March

Challenges / Solutions:

- Recruitment of flu positive patients in a moderate flu season (45% tested positive for the flu) / extensive education of site staff for clinical signs and symptoms
- Collection of accurate and complete paper patient diaries / continual education/training of study staff and linking of patient diary stipend to diary completeness (i.e. if diary wasn't complete, no payment made per ICF)
- Selection of a central lab capable of performing quantitative and qualitative testing for flu types A & B / Through evaluation of central lab network to find a lab with capabilities to perform protocol testing
- Selection of 75 US and Dominican Republic based sites with focus on urgent care or extended office hours (weekends) with prior flu experience / Through review of SGS investigator database and flu literature review

With innovative study designs, optimal clinical and analytical facilities and strong regulatory intelligence, SGS can favourably impact client's drug development timelines and decision-making processes.

Read about SGS's Infectious Diseases Clinical Trial Solutions
Join the scientific community, connect with SGS on LinkedIn: www.sgs.com/LinkedIn-Life

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WHEN YOU NEED TO BE SURE

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