

CLINICAL TRIALS PHASE II-IV

SGS Life Science Services has 30 years of experience as a global Contract Research Organization (CRO) with US, European and Asia operations and offices, providing a large range of services from preclinical activities to Phase I-IV trials. With over 3.800 trials performed, SGS has served the pharmaceutical and biotechnology industries with a focus on Integrity, Quality and Flexibility.

FROM RESEARCH TO MARKET

FULL MANAGEMENT OF:

Clinical trials or compound development from trial design to marketing application, including:

- Phase II-IV clinical trials
- Clinical Research consulting
- ICH/GCP training
- Regulatory services
- Medical Affairs services
- Biometrics

30 YEARS EXPERIENCE

Over 1.000 late phase clinical trials in Western/Eastern Europe, Russia & USA across a broad number of therapeutic areas (see reverse for details).

THERAPEUTIC EXPERT IN:

- HIV/Infectious Disease
- CNS Disease
- Cardiovascular Disease
- Respiratory Disease

TAILOR MADE CLINICAL TRIALS

SGS offers "a tailor made" approach to outsourcing your project. Stand alone or full service according to your global or local needs:

STRONG IN-HOUSE REGULATORY INTELLIGENCE - COUNTRY-BY-COUNTRY

- Regulatory guidelines and dedicated team of experts in place for 76 countries
- Drug import regulations and procedures by country for every country in Europe
- Regulatory IND/NDA submission experience in Europe (Eastern/EU), Canada and USA
- FDA and Canadian health authorities inspections in 2006

DEDICATED PROJECT MANAGERS AND CRAS ARE MULTI-LINGUAL

(many are tri-lingual), allowing flexibility in communication with various countries; 5-10% turnover/year

- Fully GCP trained/ACRP accredited staff: MSc, Nursing degree or MD
- Preparation of integrated summary of safety and efficacy reports for FDA submission
- Relationships worldwide with thought leaders
- E-submission experience

INNOVATIVE PROJECT MANAGEMENT TOOLS

- Experience with Interactive Voice Response System (IVRS)
- Proprietary Clinical Trial Management System (CTMS): CLINMASTER®
- Central ECG reading
- Electronic Data Capture (EDC) & CDISC: 25 large EDC trials processed/ongoing with over 10,000 patients included



SGS

OVERVIEW OF ACCOMPLISHED PROJECTS

Cardiovascular

- Angina
- Atrial fibrillation
- Hypertension
- Hypotension
- PAOD
- CV event prevention

Ear, Nose, Throat

- Antitussive
- Antibiotics
- Local antiseptic
- Nasal corticotherapy

CNS/Musculoskeletal

- Alzheimer
- Anti-inflammatory
- Depression
- Epilepsy
- Low back pain
- Migraine
- Mental retardation
- Pain management
- Psychoses
- Osteo-arthritic pain
- Schizophrenia
- Spondylitis
- Stroke
- Vertigo

Dermatology

- Anti-inflammatory
- Alopecia androgenetica
- Onychomycosis
- Pityriasis vesicular
- Psoriasis
- Seborrheic Dermatitis
- Tinea corporis
- Tinea cruris
- Tinea manus

- Tinea pedis
- Venous leg ulcers

Surgical and medical procedures

- Anaesthetics
- Haemodialysis

Gastroenterology

- Constipation
- Diarrhoea
- Irritable Bowel Syndrome
- NERD
- Peptic ulcers
- Pharmaco-scintigraphy

Genetic Disorders

- Cystic Fibrosis

Infectious Diseases

- Influenza
- Fungal infections
- Hepatitis B
- Hepatitis C
- HIV/AIDS

Immune disorders

- Allergy
- Rheumatoid arthritis

Oncology

- Bladder cancer
- Breast cancer
- Hodgkin Lymphoma
- Leukemia
- Lung cancer
- Multiple Myeloma
- Oral cancer
- Prostate carcinoma
- Rectal cancer

Renal and urinary disorders

- Chronic renal disease
- Incontinence

Respiratory

- Antibiotics
- Asthma
- ARDS

Endocrinology/Reproductive System

- Diabetes
- Dysmenorrhoea
- Hormonal replacement
- Menopause
- Obesity
- Contraceptives
- Osteoporosis
- Postmenopausal disorders

Paediatrics

- Chronic idiopathic urticaria
- Ichthyosis
- Cystic fibrosis
- HIV

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WHEN YOU NEED TO BE SURE

SGS