



ONCOLOGY

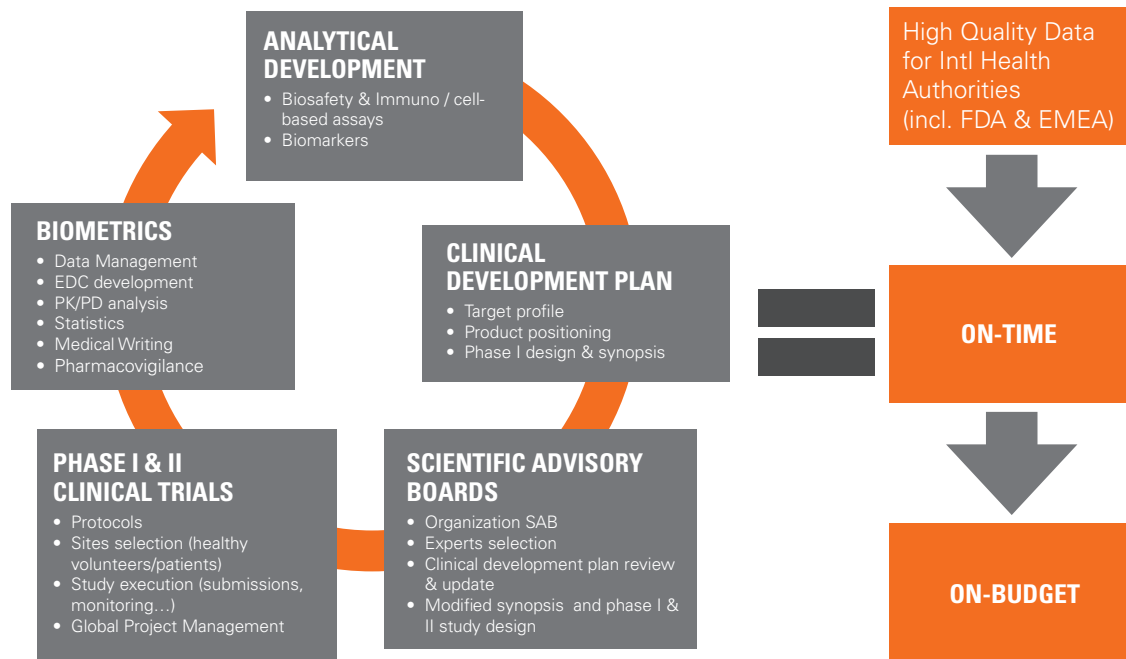
DRUG DEVELOPMENT **SOLUTIONS**

SGS

SGS Life Science Services has 35 years of experience as a contract service organization providing integrated solutions from preclinical activities to phase I-IV clinical trials, bioanalytical, quality control testing, biosafety, and biologics characterization. Serving the pharmaceutical, biotechnology and medical device industries across Europe and North America, SGS operates a state-of-the-art clinical pharmacology unit and the world's largest network of GMP/GLP compliant laboratories. We have more than 1,600 employees and provide a complete range of services along the pharmaceutical development process.

FROM LEAD COMPOUND TO MARKET

SGS provides oncology services from stand-alone to a complete service package across Europe and the Americas encompassing:



SGS has comprehensive experience in oncology with its staff having worked on over 150 oncology drug development programs for a wide variety of anti-cancer drugs in a broad range of tumor types. The expert team is composed of:

- >2 senior consultants with more than 25 years of cancer research and clinical oncology experience
- 5 clinical and 3 biometrics project managers specialized in oncology trials
- 20 CRAs experienced in oncology & infectious diseases
- >20 data managers dedicated to oncology including data reviewers and data programmers

CONSULTANCY SERVICES

- Reviewing preclinical and clinical data
- Analyzing competitive landscape
- Prioritizing target indications
- Outlining a risk adjusted clinical development program
- Collecting feedback from clinical experts upon the strategy
- Organizing and sharing Advisory Boards with oncology experts
- Delivery of decision making reports for investors, boards, management and operational teams
 - Clinical Development Plan
 - Executive summary
 - Expert meeting report

CLINICAL OPERATION SERVICES

- In-depth feasibility studies to ensure appropriate site selection
- Protocol writing
- Regulatory Submissions & Clinical trial applications

Early & late phase clinical trials

- Clinical pharmacology in healthy volunteers, special populations, & patients
- Phase One Clinical Unit in Antwerp, Belgium with 88 beds
- Clinical trial management & monitoring in cancer patients

- Premium level network and multilateral collaboration with EU leader academic oncology centers and cancer institutes in Belgium (UZ Gent, UZ Leuven, UC St Luc, Jules Bordet Institute)
- SGS Satellite Centers for oncology trials with implemented SOPs and dedicated medical teams for oncology trials in Belgium and Hungary
- Extended networks of leading oncology sites in Hungary, Poland and Czech Republic to cover EEC region.
- Dedicated US oncology team with site, KOL, and vendor network
- Exclusive cooperation with SMS Oncology (Amsterdam, NL), a state-of-the-art oncology CRO

BIOMETRICS SERVICES

- Experience in complex oncology studies
- Specific Oncology experience & expertise for:
 - eCRF set-up (Inform®/Rave)
 - eClinical OS™ including end point adjudication module
 - ePRO
 - Database set-up/structure
 - Review conventions / coding
 - Response criteria (RECIST, CHESON)
 - Interaction with Medical Monitor
 - PK and biomarker samples
 - Imaging data
- Ongoing monitoring of patients safety enabling periodic high quality data transfers to independent drug monitoring committees
- Independent Secure Data Office (SDO)
 - Handling of blinded data
 - Preparation of PK/PD input files (NCA, NONMEM) before DB lock to ensure time gain

- Pharmacovigilance (Safety Recording and Reporting)
- Medical Writing
 - Clinical Study Report
 - Scientific Papers
 - Abstracts and Publications

ANALYTICAL SERVICES

- PK, PD and Immunogenicity testing
- Soluble biomarkers
 - Platforms for targeted proteomics (for validation of oncology biomarker candidates)
 - Expertise for sample processing (e.g. tumour tissues and whole cell lysates)
 - Pre-qualified panels of biomarkers on high sensitivity multiplexing platform for early diagnosis of cancer and for efficacy testing

- Cell based assays
 - Tumour sensitivity assay
 - Apoptosis testing
 - Cell viability, cytotoxicity and proliferation
 - Cell kinase and protein phosphorylation assays
 - *In vitro* angiogenesis testing
 - ADA neutralization assays
- Biosafety of cell therapies, gene therapy & cancer vaccines
- Oncolytic viral therapies –biosafety testing of the vector manufacturing
- Full characterization of monoclonal antibody therapies & DNA vaccines

ONCOLOGY EXPERIENCE

PER SERVICE

SERVICES	NUMBER OF PROJECTS
Biometric activities: DM, ST, MW, PK/PD, SDO	77
Regulatory affairs	31
(Pre)Clinical Development Plan	22
Clinical monitoring	21
Drug development advice	20
Medical affairs: Medical monitoring, Drug safety and Pharmacovigilance	19
Project management	14
Full service	13
Scientific Advisory Board	9
Oncology training	8
Clinical study conduct (SGS Phase 1 unit)	5

PER DRUG CLASS

DRUG CLASS	NUMBER OF PROJECTS
Small molecule	61
mAb	16
Other	5
Oligonucleotide	4
Arnthacycline	3
Cell therapy	2
Gene therapy	2
Vaccine	2
Biomarker	1
Hormone	1
Opioid	1
Photosensitizing agent	1
Radiolabeled protein	1

CONTACT INFORMATION

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WHEN YOU NEED TO BE SURE

SGS