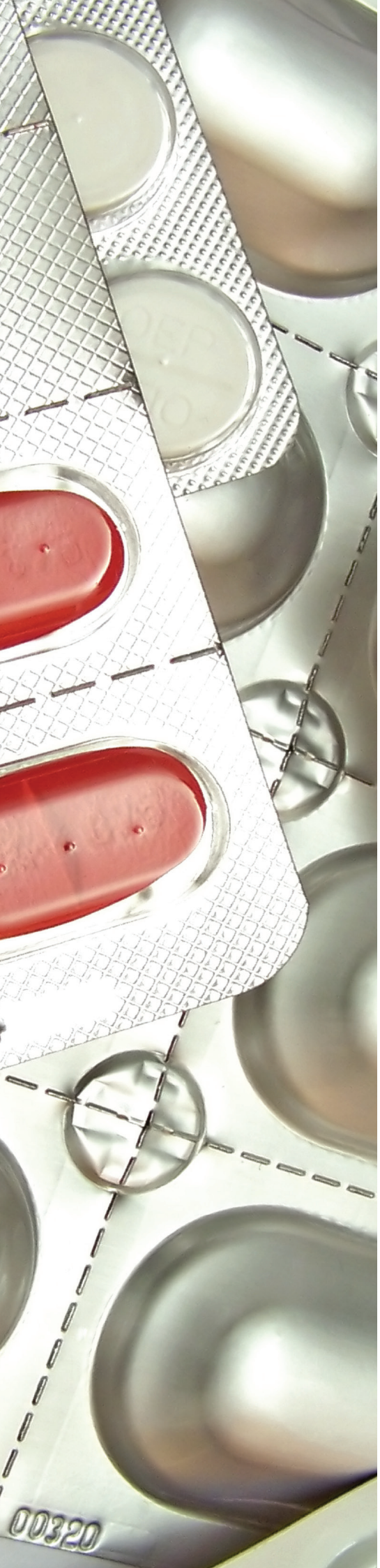

CLINICAL

CLINICAL TRIALS
PHASE II-IV

SGS has over 35 years of experience as a life science, global contract service organization, providing integrated services from preclinical activities to Phase I-IV trials, bioanalytical and QC testing. With more than 1,600 employees, SGS serves the pharmaceutical, biotechnology and medical device industries throughout Europe, North America and Asia.

When moving forward into Late Phase clinical trials, more than ever, clients need to receive tailor-made solutions. With a highly experienced team of Project Managers and CRAs, SGS provides clients with the confidence that their project will be successfully completed on time, on budget and exceeding quality standards.

SGS offers competitive advantages in late phase clinical development:

- Consultative trial design, collaborating with Key Opinion Leaders
- Fast and reliable trial feasibility within 2 to 4 weeks
- Rapid access to special patient populations
- Highly focused therapeutic area expertise
  - Infectious Disease HIV / HCV
  - CNS Disease
  - Cardiovascular Disease
  - Respiratory Disease
- Dedicated, experienced team of Project Managers and CRAs with ownership of each project

GLOBAL COVERAGE LOCAL KNOWLEDGE

GLOBAL COVERAGE

- Geographic coverage in:
  - Western & Central Eastern Europe
  - USA & Canada
- 7 offices based in USA, Belgium, France, UK, Spain, Poland, and Czech Republic
- Clinical trial team of 80 people including project managers, CRAs and CTAs

LOCAL KNOWLEDGE

- Centralized project management working with Multilingual CRAs (including many trilingual) covering: German, Dutch, Spanish, French, Italian, Polish, Portuguese, Czech, Russian
- Large network of therapeutic specific Key Opinion Leaders and pre-qualified investigator trial sites
- Regulatory guidelines and dedicated team of experts in place for 70 countries

SGS

- Regulatory IND / NDA submission experience in Europe (Eastern / EU), Canada, and USA
- Drug import regulations and procedures by country for every country in Europe
- FDA and Canadian health authorities inspections in 2006||

FULLY INTEGRATED SOLUTIONS

SGS offers full clinical trial management solutions as well as standalone services to meet the specific needs of each client. SGS's clients also benefit from the global office presence as and the staff's local knowledge of regulations, country specific procedures and timelines.

TURNKEY PROJECT EXECUTION

Full Management Of:

Total compound development or individual clinical trials from trial design to marketing application, including:

- Before:
  - Pre-trial consulting
  - Accurate feasibility studies
  - Protocol development
  - Project plan
  - Monitoring guidelines
  - Site evaluation & selection
- During:
  - Trial monitoring & management
  - Regulatory services
  - Safety & Pharmacovigilance
- After
  - Data Management & Biostatistics

Medical Writing Dedication to Quality:

- Fully GCP trained / ACRP accredited staff: MSc, Nursing Degree or MD
- Preparation of integrated summary of safety and efficacy reports for FDA submission
- E-Submission experience
- Adherence to International guidelines FDA/ICH/GCP
- Global SOPs

OVERVIEW OF EXPERIENCE

Over the last 15 years, SGS has performed over 850 late phase projects covering numerous therapeutic areas with a particular focus:

- Infectious Diseases
- Cardiovascular
- Ear, Nose, Throat
- CNS/Musculoskeletal
- Dermatology
- Surgical and Medical Procedures
- Gastroenterology
- Genetic Disorders
- Immune Disorders
- Oncology
- Renal and Urinary Disorders
- Respiratory
- Endocrinology / Reproductive Systems
- Pediatrics

TRIAL MANAGEMENT SYSTEMS

- Experience with Interactive Voice Response System (IVRS)
- Proprietary Clinical Trial Management System (CTMS): CLINMASTER®
- Central ECG reading
- Electronic Data Capture (EDC) & CDISC: Over 30 large EDC trials processed/ongoing with more than 15,000 patients enrolled

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WHEN YOU NEED TO BE SURE