



BIOMETRICS SERVICES

SGS' Life Science Services, part of the SGS group (53,000 employees) is a global contract service organization providing integrated solutions from preclinical activities to Phase I-IV trials, bioanalytical and QC testing.

With over 15 years of experience, processing one million CRF pages per year and 30 EDC studies in the past 7 years, SGS' Biometrics team provides unparalleled service with an understanding for individual clients' needs. Clients benefit from SGS' commitment to use the latest state of the art technology for better efficiency and meeting project timelines, without compromising Quality or Integrity.

LEADERS IN CLINICAL DATA MANAGEMENT

As one of the largest independent groups in Europe with over 130 professional staff, SGS' experienced Biometrics department supports all in-house and external project needs for clinical trials. The significant group size and full data processing services provide clients with competitive advantages including:

- High flexibility: complete services or stand alone solutions; sponsor's database template and formats
- Quick reactivity in resource allocation: meeting project size requirements & deadlines
- Integrated, expert Biometrics services from Phase I to Post-approval trials
- Strong scientific support from SGS' own internal clinical research team
- Full EDC integration & CDISC compliant trials
- Complete validated systems & environment (21 CFR Part 11, ICH compliance)

FULL DATA PROCESSING SERVICES

TRIAL DESIGN - PROTOCOL WRITING - CRF DESIGN - DATA MANAGEMENT

- Database model establishment according to the sponsor's specifications
- Hard copies of CRFs: double-entry interactively in a database, set-up according to the sponsor's specifications or an e-database is uploaded into our cdms
- Electronic tracking of CRFs and DCFs
- Delivery of CDISC compliant data models for e-submission to the Authorities
- Database cleaning/validation of CRF data
- Identification of protocol deviations
- Coding according standard coding conventions, as specified by the sponsor, reviewed by a physician – MedDRA, WHODRUG
- Serious Adverse Event reconciliation
- Software tools: CLINTRIAL™ 4.6. or Oracle Clinical under client environment. The Biometrics Department uses fully validated data management software packages for data entry with electronic audit trailing, validated checks and auto-encoding.



SGS

ELECTRONIC DATA CAPTURE EXPERIENCE

SGS has experience in performing large EDC trials with several leading vendors. The Data management team delivers full EDC solutions in-house using Central Designer™ and InForm™, setting up EDC systems for Phase I to post-marketing trials. SGS also has extensive experience in the creation of validation documents for user acceptance testing, performing user acceptance testing, and providing training on the EDC system for site, monitor and sponsor users.

CDISC COMPLETE COMPLIANCE

- Databases locked according to the CDISC SDTM model and Statistical Analysis based on the ADaM model
- Successful e-submissions in CDISC SDTM and ADaM format to the FDA
- Over 140 legacy trials converted into the CDISC models

BIOSTATISTICS EXPERTISE

- Statistical Consultancy by experts
- SAP (Statistical Analysis Plan) creation in agreement with the sponsor
- Randomisation
- Analysis of all types of data from clinical (Phase I-IV) and epidemiological trials with a variety of designs
- Classical and population PK/PD analysis
- Interim analyses
- Design and sample size calculations of clinical trial protocols

- Validated SAS macro library
- Pooling of studies (including ISS/ISE)
- Membership in Data Safety Monitoring Board
- Software tools: SAS®, PROC StatXact®, Sigmaplot facilities, Sample size software (nQuery Advisor®, PASS®, Data TreeAge®)

PHARMACOKINETICS SERVICES

- Consultancy
- Study Design
- PK/PD
- Modeling and simulation
- NCA and compartmental analysis
- Population PK
- Phase I protocols
- Software tools: WinNonlin Professional®, NonMEM®, Kinetica®, Watson LIMS

MEDICAL WRITING SERVICES

- Multilingual writers/speakers
- Clinical Research Reports and appendices according to the ICH-E3 guideline "Structure and Content of Clinical Study Report"
- Writing of safety and Efficacy summaries
- Preparation of submission packages in collaboration with Regulatory Affairs Dept
- Clinical Trial protocols, Investigator Brochures, publications, abstract writing, PowerPoint presentation
- Use of specific sponsor's format report when required

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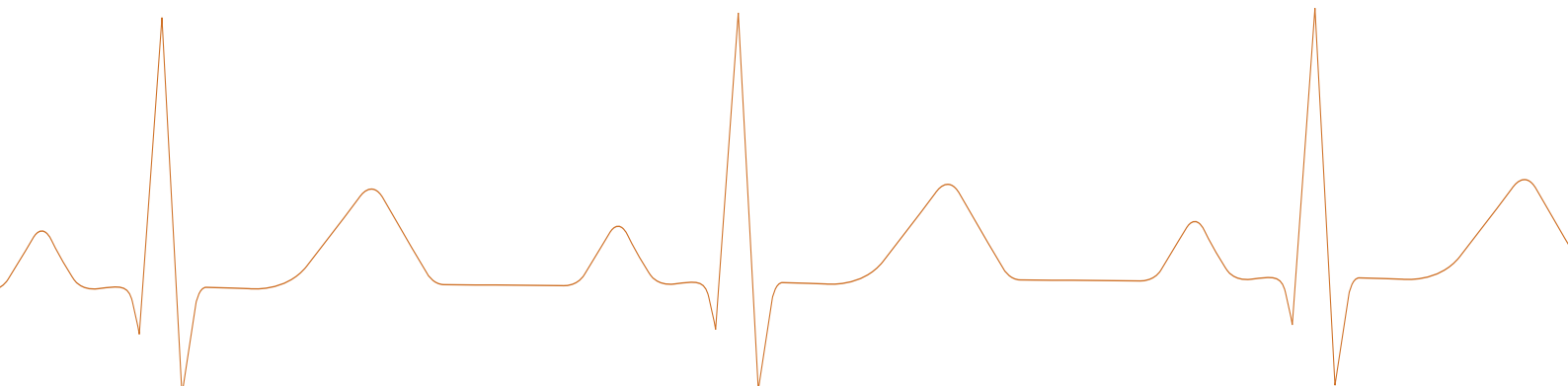
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SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY



WHEN YOU NEED TO BE SURE

SGS