Biometrics Services

Health Inspired,
Quality Driven.

Biometrics Scope of Services

SGS is a European leader with over 40 years' experience offering full biometrics services for clinical trials.SGS as a functional service provider can offer each of these services as standalone or within full project service outsourcing.

All SGS biometrics services are performed in accordance with international regulatory standards, Food & Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA) and ICH- GCP. As a CDISC registered solutions provider, we perform all trials using CDISC standards.

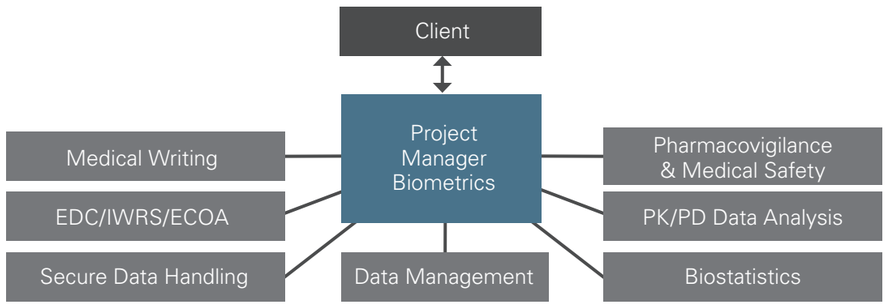
This complete CDISC compliance results in efficiency, time saving, process improvement, reduced time for regulatory submissions, and better communication among team members without delays in reporting final data.

Our services include:

- BIOMETRICS SCOPE OF SERVICES
- DEDICATED PROJECT MANAGER BIOMETRICS
- ELECTRONIC DATA CAPTURE
- DATA MANAGEMENT SERVICES
- DATA VISUALIZATION SERVICES
- SECURE DATA OFFICE
- BIOSTATISTIC SERVICES
- PK AND PD DATA ANALYSIS
- MEDICAL WRITING
- MEDICAL SAFETY
- ELECTRONIC TRIAL MASTER FILE

Dedicated Project Manager Biometrics

On a project level, cross functional teams are managed by a dedicated SGS Project Manager Biometrics who is allocated to a specific project, compound, therapeutic area or client to facilitate the communication and assure consistency across different trials. To gain efficiencies, our biometrics and medical safety team operate under the umbrella of a single business unit.



SGS Key Advantages As Leader In Biometric Activities

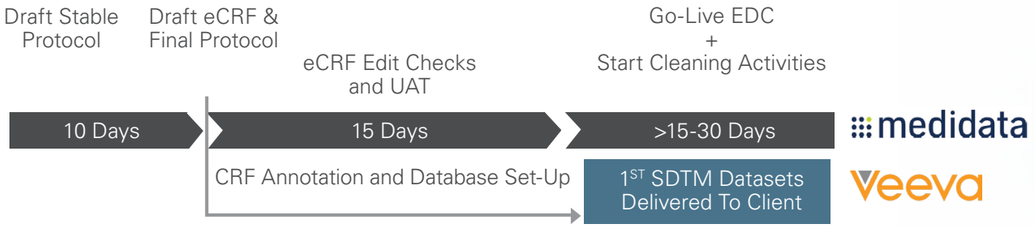
SGS MEANS	Flexibility, Reach & Scalability	Customized client approach for each project Biometrics support for projects across all regions of the world A core team organized for flexible allocation and easy scale-up of resources
	Reliability	Over 40 years experience Continuous investment: infrastructure, operations, and talent recruitment Robust and standardized processes proven consistency over a decade
	Expertise	CDISC registered solution provider for SDTM, ADaM and Define.xml Dedicated teams with expertise across a wide range of therapeutic areas Certified partner of provider Medidata and Veeva
	High Quality & On Time Delivery	Shorter data processing & reporting timelines due to use of CDISC standards and in-house developed tools Tools allowing reuse of validated database structures, rules and macros Ongoing review and monitoring of patients safety (eg; for IDMC/DSMBs)

Electronic Data Capture

Tailored eCRF Design in Medidata Rave® EDC and Veeva Vault CDMS within challenging timeline

Years of experience in building trials across all phases and therapeutic areas allow us to efficiently translate your specific clinical data requirements into a well designed eCRF. With the efficiency that comes with experience, our highly skilled EDC team members can set up your customized EDC trial within 6-12 weeks while still delivering a high quality end product. SGS is able to design EDC applications from scratch including additional study features such as IWRS/IVRS integration and validate these in a limited time frame. The timelines are even sharper when starting from library eCRF screens.

Average Study Start Up Timelines



Advantages

- End-to-end input and review of CRF design by cross-functional teams, enabling downstream efficiencies for data cleaning and statistical analysis
- Extensive in-house eCRF page libraries and support for the development of client-specific libraries to ensure consistency and to secure set-up timelines
- Fully documented test evidence of the entire UAT to guarantee quality

Integrating EDC Trials to Become eClinical Solutions

EDC applications are not necessarily stand-alone systems. To efficiently manage patient randomization, drug dispensation, study blinding, local lab data, etc., the EDC application might require one-way or even two-way data integrations with other electronic applications.

Electronic Patient Diaries and Questionnaires (eCOA/ePRO)

Today, collection of information reported by the patient himself through electronic patient reported outcomes (ePROs), also referred to as electronic clinical outcome assessments (eCOAs), has become increasingly important for drug efficacy and safety information, quality of life assessment and compliance monitoring. SGS partners with leading industry's eCOA vendors to provide you with the right eCOA solution for your clinical trial. Based on the client's preferences, we can offer device-based solutions for both home and site use, or we can offer a device independent approach, enabling patients to complete the questionnaires at home using their own devices, including smartphones, tablets and computers/laptops.

Data Management Services

Clinical data management plays a key role in the set-up and conduct of a clinical trial. Our Data Management teams are organized per therapeutic area/clinical study phase and can be dedicated to one client. As one of the largest biometric groups in Europe, we capture your data in the best conditions, while meeting key and mandatory milestones.

Our areas of service expertise include:

- Development of data management and data validation plans
- Set-up of the database according to our SDTM implementation guideline and/or client requirements
- Validation of SDTM clinical database before cleaning of patient data
- Uploading and validation of external provider data specification and validation of SDTM cleaning package
- Query handling
- Defining and handling protocol deviation
- Serious Adverse Event (SAE) reconciliation
- Coding of medical events (MedDRA) and medications (WHO Drug)

Advantages:

- Flexibility to meet client database requirements
- Access Study Data Tabulation Model (SDTM) datasets shortly after the First Patient In (FPI)
- High-qualitative delivery of the SDTM database with our fully documented quality control of the SDTM mapping, including Pinnacle report
- In-house developed tools combined with metadata repositories to achieve end-to-end automation of SDTM workflow
- In-house built SDTM library rules for data cleaning per therapeutic area or client
- Comprehensive and streamlined cross-functional communication and established workflows with the other biometric departments

We have a separate team of data standards and process improvement coordinators and application developers who are dedicated to developing and maintaining in-house developed tools, data standards, dictionaries, and programming applications. We constantly evaluate and improve our validated processes and guidelines to be on top of latest industry standards.

Medical Review

As part of our Data Management services our drug safety physicians provide support of:

- Medical reviews of all safety data, including AEs and SAEs
- Review and approval of MedDRA and ATC code
- Medical review of lab alerts and lab, ECG and other study specific data
- Medical review of potential endpoints

eSource

Our Clinical Pharmacology Unit (CPU) in Antwerp (Belgium) is equipped with an automated solution that efficiently collects all study data types (trial execution, safety lab, and medical device data) directly into electronic format (eSource system). Within SGS, we embed eSource in all operational processes, from set-up of the eSource to delivery of SDTM compliant datasets.

Advantages

- Direct data capture with bar-code driven study data collection eliminating the data transcription errors and the source document verification
- Remote monitoring and a centralized risk-based monitoring approach
- An automated dataflow between the study eSource and the SDTM database allowing an earlier start of data cleaning activities and database lock
- Real-time access for continued data monitoring by medical monitor ensuring faster query resolution
- Online data visualization reports supporting quick dose-escalations decisions

Data Visualization Services

Pharmaceutical companies and clinical research organizations need to monitor the progress of clinical trials, continually view the latest data and stay on top of key developments. As a result, data visibility is crucial for all parties involved in clinical studies. SGS dashboards provide complete visibility of clinical data during complex clinical trials. SGS leverages Tableau software, the trusted leader in powerful analytics, to produce data visualization dashboards.

Tableau acts as a one-stop-software solution shop for data visualization, combining data from multiple sources into easy-to-understand interactive dashboards. Project managers, clinical data managers and drug safety physicians can drill down into what the data means.

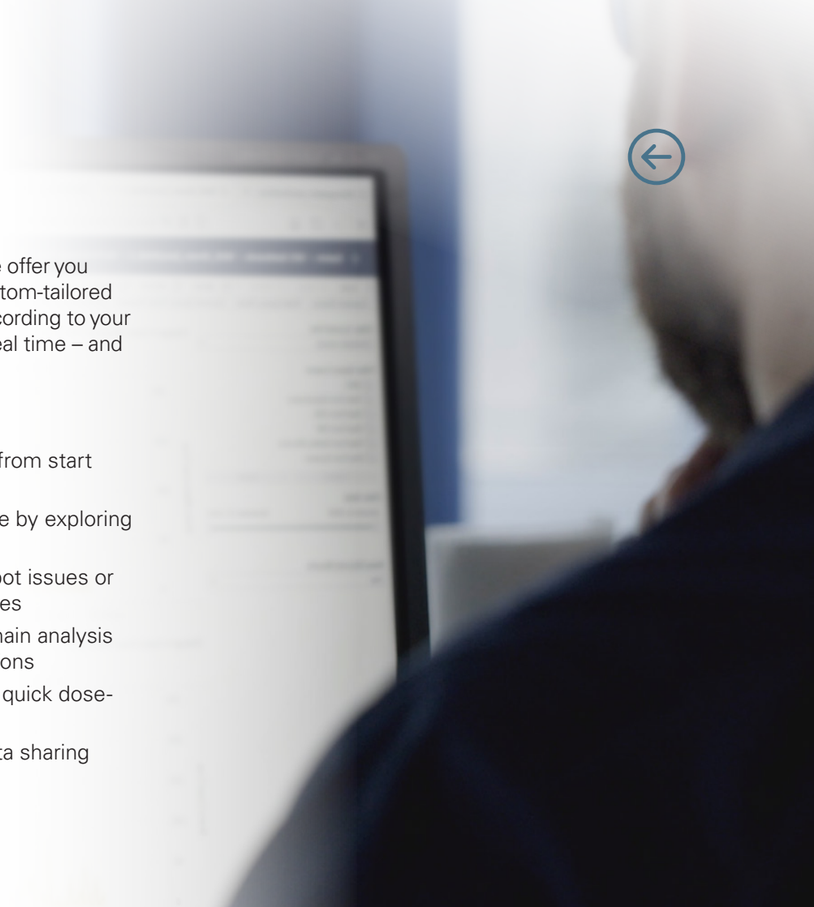
SGS data visualization provides a wide range of interactive standard dashboards including, but not limited to:

- Demographics and enrollment status
- Patient profiles
- Overviews of drug exposure, adverse events and medications
- Overviews of medical history, laboratory, vital signs and physical examination
- Site performance
- EDC query and page status
- Everything you need to perform your study oversight

Next to our standard dashboards, we offer you unrivaled expertise in developing custom-tailored dashboards completely designed according to your needs. Gain meaningful insights in real time – and drive smarter decision-making.

Advantages

- Monitor clinical study progress – from start to finish
- Oversee subject safety in real-time by exploring and analyzing data in seconds
- Access quick trends analysis to spot issues or outliers and respond faster to issues
- Drill down and perform cross-domain analysis and track your medical review actions
- Support safety meetings allowing quick dose-escalation decision-making
- Enhance collaboration and fast data sharing



Secure Data Office

Handling unblinding data requires specialized expertise. Our Secure Data Office (SDO) is an independent group that is authorized to handle all data of potentially unblinding nature, such as randomization data, pharmacokinetic concentrations, laboratory and anti-body data. Our team works in a separate and secured environment with restricted access.

Services offered by our SDO team are:

- Creation, distribution and review of randomization lists
- Creation and distribution of code-breaking envelopes
- Storage of randomization lists until release at database lock
- Review of medication kit misallocation and drug dispensation pages
- Delivery of unblinded datasets in view of SUSAR reporting or emergency unblinding
- Set-up of transfer agreements with the bio-analytical lab (or with other blinded data providers) and handling of blinded data before database lock
- Creation of cleaning transfer for data management by removing data of potentially unblinding nature from the lab data transfer.
- Creation of cleaning transfers by removing data of potentially unblinding nature from the lab data transfer.
- Blinding of data to support pre-lock activities, such as biometric dry-run activities, interim PK calculations
- Set-up and programming of PK input files (Non-Compartmental Analysis (NCA) and Non-linear Mixed-Effect Modeling (NONMEM)) input files) before database lock

Advantages

- Handling of blinded (and limited access) data and cleaning of sample identifiers without the unblinding of the project team leads to fewer inconsistencies and issues at database lock
- A smooth integration of the data before database lock by converting the blinded data to the required database format and merging of the blinded data with the clinical SDTM data
- Fast turnaround in delivery of unblinded datasets to Data Safety Monitoring Boards (DSMBs) or Independent Data Monitoring Committees (IDMCs)
- Trial efficiencies, including reduced timelines by programming of the unblinding NCA and NONMEM PK input files prior to database lock

Biostatistics Services

The biostatistics department is one of the most important contributors to a clinical development program. Working as your partner, expert SGS biostatisticians will review your study's needs and determine the best methods for collecting, analyzing and presenting your data in compliance with regulatory guidelines. We provide creative thinking and analysis optimized for your unique study designs. Our team has a broad range of therapeutic experience and our statisticians hold advanced degrees.

Our services include:

- Design and sample size calculations of clinical trials of any kind, including protocol reviews and co-authoring
- Adaptive trial designs support
- (e)CRF design input
- Analysis of all types of data – from pre-clinical, and clinical trials to epidemiological trials, following a variety of designs respecting the Statistical Analysis Plan (SAP) and mock Tables Listings Figures (TLFs)
- Programming of CDISC ADaM datasets, TLFs and metadata, ready for inclusion in the electronic Common Technical Document (eCTD)
- Interim analyses and defining stopping rules, including an independent statistician for unblinded interim analyses
- Pooling of studies, including safety and efficacy summaries for regulatory submissions
- Independent statistician participating in the Data Monitoring Committee (DMC) board and/or generation of the DMC analysis
- Clinical study report (CSR) review and programming of case narratives / patient profiles
- Preparing clients to present results to the FDA and EMA

Advantages

- Early trial support for optimized protocols
- Our own templates for SAP and mock TLFs
- High-quality analysis within short timeframes, using our library of over 60 validated SAS macros
- Compliance between the used Study Data Tabulation Model (SDTM) and our in-house Analysis Data Model (ADaM) principle of harmonization
- Broad range of therapeutic experience

PK and PD Data Analysis

Understanding the PK/PD behavior of a drug helps design the dose, route, and schedule of administration to maximize effectiveness while reducing adverse effects. Our specialized team includes dedicated pharmacokineticists qualified to customize the PK/PD activities in line with your needs.

To support your phase I-III clinical studies, we offer:

- Input on protocol and study design
- Statistical Analysis Plan (SAP) preparation
- Tailored interim PK analysis and reporting
- PK data analysis:
  - Non-compartmental PK analysis
  - Inferential statistics on PK parameters (group comparisons, BA/BE, dose proportionality, food effect, etc)
- PD data analysis:
  - Immunological response
  - Large range of biomarkers
  - PK/PD relationship
- PK and PD data transfer:
  - Providing the Study Data Tabulation Model (SDTM) CDISC compliant PP dataset
  - Providing the Analysis Data Model (ADaM) CDISC compliant datasets for PK and PD (e.g. ADPP and ADPC)
- PK and PD Tables, Listings, Figures (TLFs):
  - TLFs with all PK and PD results
- PK reporting:
  - Stand-alone report
  - Writing of appropriate PK sections within Clinical Study Report (CSR)
  - Using our own template or client's template

Advantages

- Complete CDISC compliance of your PK/PD data analysis, resulting in trial efficiencies and time saving for reporting of final data for regulatory submissions
- An integrated PK/PD approach with biostatistics and medical writing services that facilitate and reduces timelines for protocol development, SAP writing and data reporting such as TLFs and CSR
- Support towards safety meetings through interim PK analysis and tailored reporting, as per your needs, either blinded or unblinded

Medical Writing

The success of a clinical development program depends on the proper documentation of research plans and results. SGS's expert team of medical writers comprises primarily The success of a clinical development program depends on the proper documentation of research plans and results. SGS's expert team of medical writers comprises primarily PhD-level scientists. All our staff acquired excellent communication skills through training and experience. Our highly qualified writers have broad experience with the whole spectrum of medical communications and regulatory documents, as well as an array of therapeutic areas. Our writers' strong scientific backgrounds and indication-specific knowledge ensures accurate and well-written submission-ready documents.

Our areas of service expertise include the following types of documents:

- Clinical study report
- Clinical trial protocol
- Investigator brochure
- Efficacy and safety summaries
- Clinical overviews
- Publications, abstracts, posters and power point presentations
- Narratives

Medical Review

As part of our medical writing services our drug safety physicians can also provide support of:

- Medical review of patient narratives / profiles
- Medical review of clinical study report

Advantages

- Flexible and broad experience in using client templates, style guides and tailored requirements
- Our own ICH-compliant templates (ICH E3 and ICH E6) in absence of a client template
- Delivery of cohesive documents that meet rigorous scientific quality standards and are compliant with ICH, regulatory standards and your own requirements
- Timely delivery of high-quality documents, ensuring accuracy and clarity through full quality control against source documents

Medical Safety

Patient safety is paramount at every stage of your product lifecycle. We provide comprehensive and flexible solutions for the active management of drug safety, pharmacovigilance and risk management during the complete lifecycle of a medicinal product. Our team consists of multilingual MDs, PhDs and pharmaceutical scientists with broad therapeutic expertise that work according to the latest regulatory requirements.

Our range of services includes:

- Development and implementation of pharmacovigilance systems for investigational and registered products
- Customized safety plan and safety data exchange agreement
- Set-up and management of in-house safety database (Oracle Argus Safety)
- Individual Case Safety Report (ICSR) management
- Literature search (Elsevier Embase), and identification of ICSR and safety issues
- Safety related report writing such as narratives, Development Safety Update Reports (DSUR), Periodic Safety Update Reports (PSUR), safety summaries, benefit/risk assessments, clinical overviews and more
- Medical review of safety reports and documents
- EudraVigilance support
- Safety reporting to Health Authorities (HA) and Ethics Committees (EC) / Institutional Review Boards (IRB)
- Signal detection and ongoing safety evaluation

Medical Review

As part of our Pharmacovigilance services our drug safety physicians can also provide support of:

- Medical reviews of all safety data, including SAEs and ADRs
- Review and approval of MedDRA and WHO drug coding
- Medical support for signal detection
- Medical review of aggregated safety reports (eg DSUR, PSUR,...)

Advantage

- Qualitative and comprehensive end-to-end case processing
- Set-up and management of the in-house safety database for all phases of clinical trials and post-marketing pharmacovigilance
- Business continuity and in-time safety reporting
- Documented quality control checks and KPI calculations to guarantee audit-proof safety reports
- Tailor-made, cost-effective safety systems for small and mid-size companies

Electronic Trial Master File

As part of our clinical research services, we offer the robust electronic Trial Master File (eTMF) system of Veeva Vault to manage all the clinical trial documents. Our eTMF provides easy and timely access to trial documents while maintaining strict security and access control. Use of integrated electronic workflows for review and approval further enhances cooperation between SGS and the client and ensures that on-line oversight of CRO-delegated tasks is available at all times. The eTMF Table of Content is based on the DIA TMF Reference Model.

As unique stand alone service, we offer small biotechnology and pharmaceutical companies to gain experiences with the eTMF system of Veeva Vault small biotechnology and pharmaceutical companies to gain experiences with the eTMF system of Veeva Vault. If you need information on how to implement or manage the eTMF system, our expert team will work closely with you to develop a custom-tailored solution.

We offer different types of services:

- Setting-up a custom-tailored client eTMF system
- Setting-up a study specific eTMF
- Provide training to end users
- Management of client eTMF

Advantages

- User-friendly filling
- Easy 24-hour access to all approved documents
- Integration with our Veeva Vault Clinical Trial Management System (CTMS)
- Real-time inspection readiness

Health Science

Health Inspired,
Quality Driven.

Contact us

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WHEN YOU NEED TO BE SURE

SGS