

LIFE SCIENCES

# BIOMETRICS SERVICES

LIFE INSPIRED, QUALITY DRIVEN



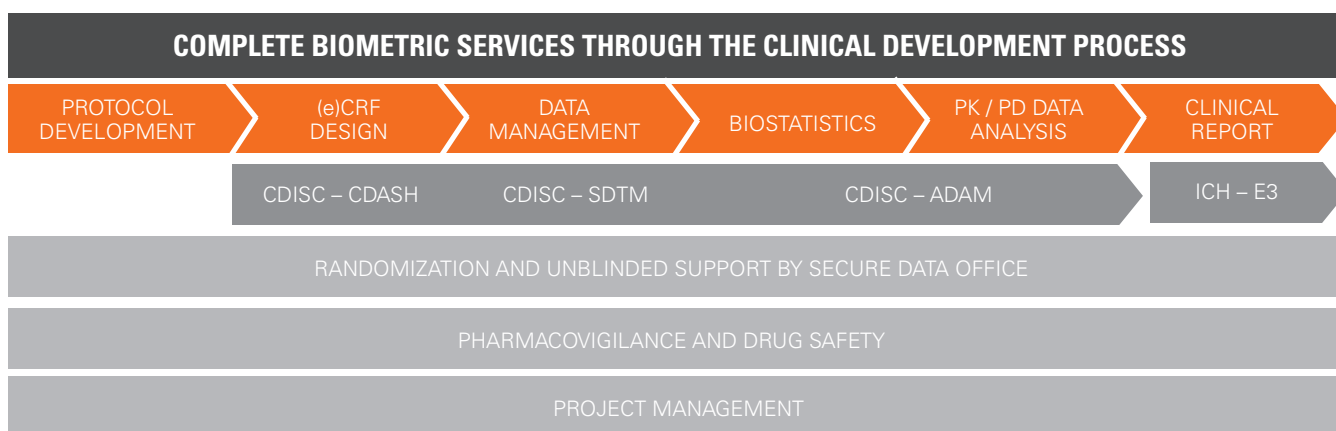
SGS is a leading life sciences contract service organization providing clinical research, analytical development, biologics characterization, biosafety, and quality control testing. Delivering solutions for bio-pharmaceutical companies, SGS provides full Phase I-IV clinical trial management services encompassing clinical project management and monitoring, biometrics, medical monitoring, pharmacovigilance and regulatory consultancy. We are committed to our clients' satisfaction and we will leverage the full strength of our more than 1,600 employee organization and global experience to make your projects a success.

## BIOMETRICS SCOPE OF SERVICES

The SGS biometrics group is a European leader with over 40 years experience. SGS offers full biometrics services encompassing protocol development, (e)CRF design, data management,

secure data office, biostatistics, PK/PD data analysis, clinical study report (CSR) development, as well as pharmacovigilance and drug safety services.

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), and ICH- GCP. During the last 10 years we delivered optimized functional services for over 800 trials, for small, medium and large

pharma companies, ranging from phase I to IV and processed over 1 million CRF pages per year, allowing for economies of scale.

## CDISC REGISTERED SOLUTION PROVIDER

SGS has used the SDTM structure for many years, and all trials are processed 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.

In December 2010, SGS succeeded in obtaining qualification as an official CDISC Registered Solution Provider for the following standards:

- Study Data Tabulation Model (SDTM)
- Analysis Data Model (ADaM)
- Define.xml

Since then, we have continued to progress and strengthen our CDISC experience. We have:

- Reached CDISC Platinum membership

- Developed our own implementation guide for SDTM
- Implemented CDISC ADaM in the Pharmacokinetics department
- Advised multiple clients on CDISC implementation guides for SDTM and ADaM
- Successfully supported multiple FDA submissions
- Become a member of the CDISC Advisory Board
- CDISC Subject Matter Experts in the biometrics team
- Trained employees on Standard for the Exchange of Nonclinical Data (SEND)

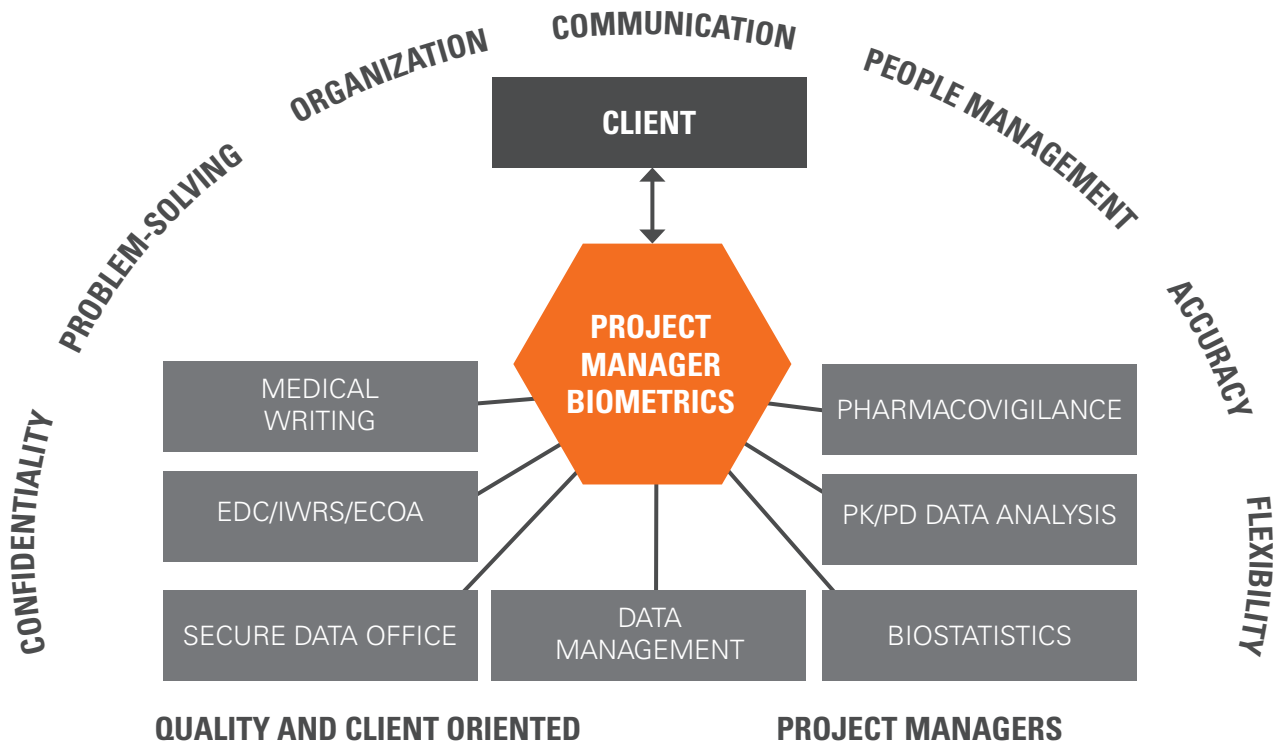


# CLIENT DEDICATED BIOMETRICS PROJECT MANAGEMENT

On a project level, cross functional teams are managed by a dedicated SGS Biometrics Project Manager 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 pharmacovigilance team operate under the umbrella of a single business unit.



With such a comprehensive and experienced Biometrics group, SGS is capable of working on a large volume of trials while still remaining very flexible. The Biometrics Project Manager,

together with the line managers, is able to anticipate upcoming resource needs whenever the workload of a project increases or timelines shift. With this approach SGS can handle every client

request for services from full package projects to stand alone activities, providing full end-to-end project solutions with integrated project teams.

## SGS KEY ADVANTAGES AS LEADER IN BIOMETRIC ACTIVITIES

<b>SGS MEANS</b>	<b>FLEXIBILITY, REACH &amp; SCALABILITY</b>	<ul style="list-style-type: none"> <li>• Customized client approach for each project</li> <li>• Biometrics support for projects across all regions of the world</li> <li>• A core team organized for flexible allocation and easy scale-up of resources</li> </ul>
	<b>SUSTAINABILITY</b>	<ul style="list-style-type: none"> <li>• Over 40 years experience</li> <li>• Continuous investment: infrastructure, operations, and talent recruitment</li> <li>• Robust and standardized processes proven consistency over a decade</li> </ul>
	<b>EXPERTISE</b>	<ul style="list-style-type: none"> <li>• CDISC registered solution provider for SDTM, ADaM and define.xml</li> <li>• Dedicated teams with expertise across a wide range of therapeutic areas</li> <li>• Official partner of the major EDC providers (Oracle, Medidata, IBM Clinical Development)</li> </ul>
	<b>QUALITY &amp; ON TIME DELIVERY</b>	<ul style="list-style-type: none"> <li>• Shorter data processing &amp; reporting timelines due to use of CDISC standards</li> <li>• Tools allowing reuse of validated database structures, rules and macros</li> <li>• Ongoing review and monitoring of patients safety (eg; for IDMC/DSMBs)</li> </ul>

# ELECTRONIC DATA CAPTURE

Our Data Management team has significant experience managing EDC trials for all types of early and late phase

projects. We began building our EDC experience in 2002 in collaboration with several EDC providers.



## TAILORED eCRF DESIGN IN RAVE®, INFORM™, AND IBM CLINICAL DEVELOPMENT™

The SGS project team guides the client in making the best choice to fit trial and program specific needs. Years of experience in building trials across all trial

phases and therapeutic areas allow us to efficiently translate your specific clinical data requirements into a well designed eCRF.



HEALTH SCIENCES

IBM Clinical Development

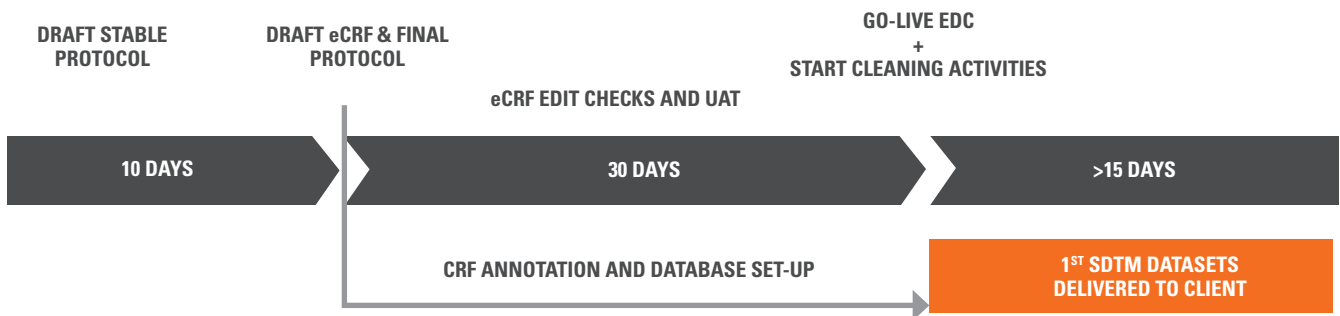
## ... WITHIN CHALLENGING TIMELINES

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

thanks to the large pool of experienced UAT-testers. The timelines are even sharper when starting from library eCRF screens.

## AVERAGE STUDY START UP TIMELINES



## 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.



## 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, follow-up on (Serious) adverse event reporting etc., the EDC application might require one-way or even two-way data integrations with other electronic applications.

Our team takes the lead in:

- Writing or reviewing the integration requirements
- Defining a solution for all technical challenges to enable a seamless implementation
- Setting up cost-efficient integrated IWRS solutions in collaboration with secure data office
- Designing electronic Serious Adverse Events forms for standardized documentation of the adverse events in collaboration with our Pharmacovigilance department



## CERTIFICATIONS & ACCREDITATIONS

SGS staff has extensive experience and in-depth knowledge of the EDC platforms via intensive training and mentoring programs:

- The team obtained several Medidata product accreditations (Rave EDC, Rave Coder, Rave RTSM, Rave eCOA/ePRO and Edge Targeted SDV) demonstrating our extensive capabilities in EDC, IWRS and ePRO/eCOA services via the Medidata platform.
- SGS benefits of in-house InForm™ Train-the-trainers to make optimal usage of the Oracle InForm™ product suite.
- Certified designers at SGS guide the team on all IBM Clinical Development modules (EDC, IWRS).

## USER ACCEPTANCE TESTING

Before Go-Live, your InForm™, Rave®, IBM Clinical Development™ or other eClinical solution (IXRS, ePRO/eCOA) will be subjected to high quality User Acceptance Testing. During this testing

process, our well-trained SGS staff will execute detailed test scripts that cover the testing of all clinical trial requirements and 21 CFR Part 11 regulations.

At the same time, the client and site users are invited to participate in the User Acceptance Testing.

## ADDITIONAL EDC SUPPORT SERVICES

The advanced skills of SGS bring an important advantage to your EDC trials, including:

- CDASH compliant eCRF screens
- EDC User Management
- EDC end-user training on demand for sites, monitors and clients
- 24/7 multilingual helpdesk support in partnership with the EDC vendor
- Delivery of EDC data in CDISC SDTM datasets

## eSOURCE

Our Clinical Pharmacology Unit in Antwerp (Belgium) is equipped with an automated solution to support the running of Phase I trials by a trial design framework that drives key operations. The automated solution efficiently collects all data types (trial execution, safety lab, and medical device data)

directly into electronic format (eSource). Within SGS we embed eSource in all operational processes, from set-up of the eSource to delivery of SDTM and ADaM compliant datasets. Using eSource rewards the client with important additional efficiencies by eliminating source document verification from the

process flow, thus allowing a Centralized Risk-Based Monitoring approach, as well as retaining the classic benefits of EDC tools. These benefits include an earlier database lock and online availability of clean data in real-time allowing quick dose-escalation decisions.

# DATA MANAGEMENT SERVICES

The SGS Data Management team works closely together with the other biometric departments in cross-functional teams that are responsible for delivering a clean database at the time of database lock. The Data Management teams are organized per therapeutic area/phase, or can be dedicated to one client. Our team is committed to help you capture clean, accurate and high quality data, while meeting key deadlines and budget requirements.

## Areas of service expertise include:

- Generation of Data Management Plan and Data Validation Plan
- Set-up of the SDTM database according to SGS or client requirements
- Set-up of data transfer agreements and integration of data coming from third party providers
- Validation of the data entry application or eCRF (UAT) and the back-end database
- Specification and validation of SDTM based rules
- Cleaning of (e)CRF and external data by means of programmed rules
- Query handling
- Defining and handling protocol deviation

- Serious Adverse Event (SAE) reconciliation
- Coding of medical events (MedDRA) and medications (WHO Drug)
- Submission ready datasets

The different services are supported by robust procedures that have proven consistency over a decade and that are designed to make every part of the data management process more efficient and more predictable. We have a separate team of data standards and process improvement coordinators who are dedicated to improving in house developed data management tools, maintaining data standards, dictionaries, and programming applications.

## MEDICAL REVIEW

As part of our Data Management services our drug safety physicians can also 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

## ADVANTAGES

- Flexibility to meet client database requirements
- Communication throughout the project to meet client requirements and expectations
- Fast SDTM delivery after first patient in
- Adaptive approach to clinical trial design
- Ongoing process improvement through a dedicated team
- A metadata driven approach (+ metadata repository) to achieve end to end automation of the SDTM workflow



# SECURE DATA OFFICE

The Secure Data Office (SDO) is an independent team within our Biometrics group. This team works in a secured environment (i.e., separate database and server folders with restricted access, data non accessible to other SGS employees) and is authorized to have access to unblinding data. This unique approach is supported by well defined and strict procedures describing in detail how the unblinding data will be handled and who is authorized to receive access, offering our clients a solution to an unmet need.

Services offered by our SDO team are:

- Creation and distribution of randomization lists
- Creation of code-breaking envelopes
- Storage of randomization lists until release at database lock
- Delivery of unblinded datasets in view of SUSAR reporting or emergency unblinding

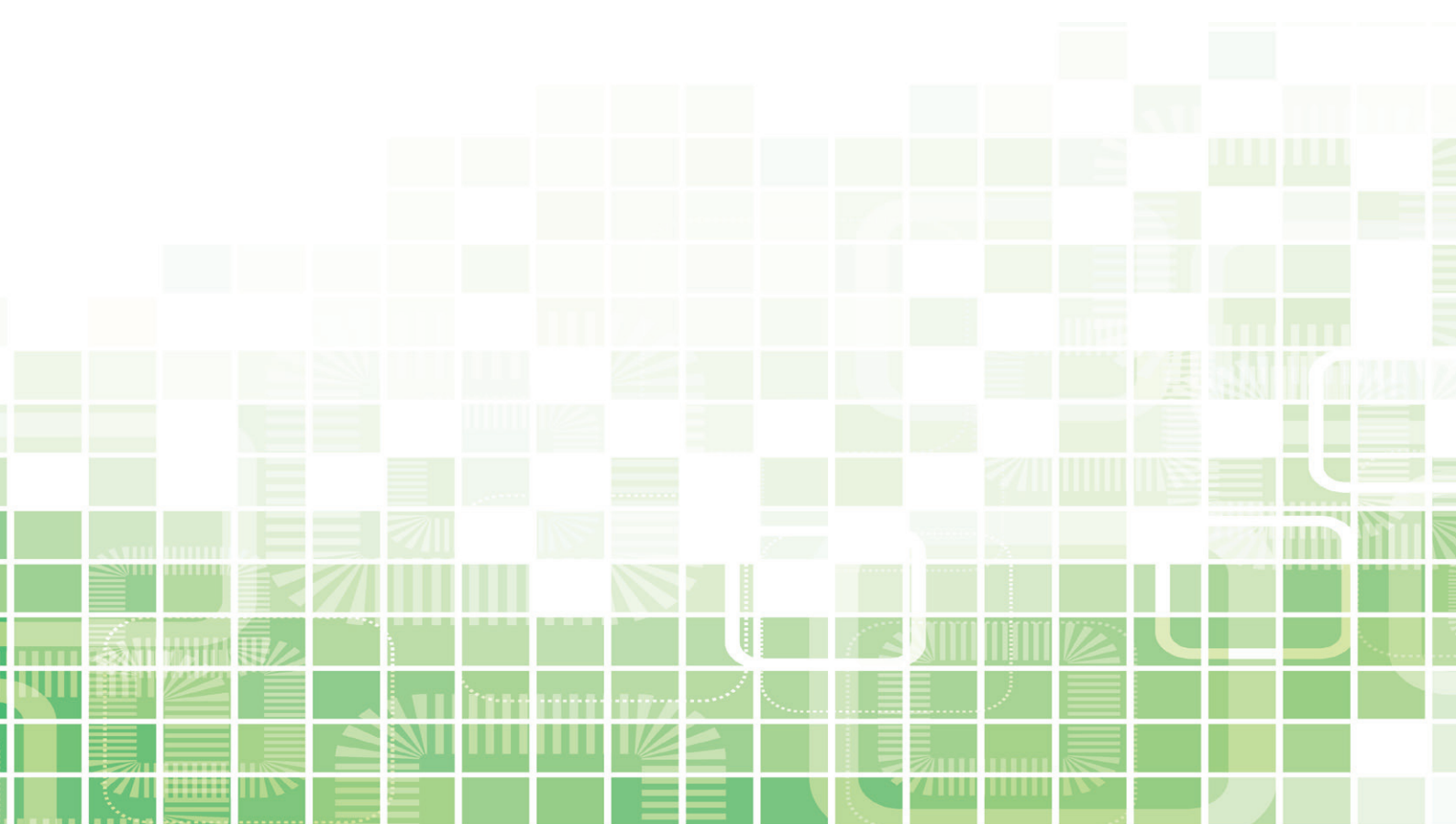
- Set-up of transfer agreements with bio-analytical lab (or with other blinded data provider) and handling of blinded data before database lock
- Review medication kit misallocation & drug dispensation pages
- Set-up and program PK input files (NCA and NONMEM files) before Database Lock

If you need information on how to handle unblinding data in a trial, our expert team will work closely with you to develop a custom tailored solution by:

- Defining study specific blinding requirements
- Creating detailed blinding specifications
- Setting up a customized secure data flow

## ADVANTAGES

- Blinded (and limited access) data can be handled and controlled without the unblinding of the client and project team, leading to less inconsistencies and issues at time of database lock
- Delivery of unblinded datasets to DSMBs or IDMCs
- Trial efficiencies gained by programming of the unblinding PK input files (eg NCA, NONMEM) 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.

Specific services provided by our Biostatistical team are:

- Design and sample size calculations of clinical trials of any kind; including protocol reviews and co-authoring
- Support in adaptive trial designs
- Provide input on the (e)CRF design
- Analysis of all types of data from pre-clinical, clinical and epidemiological trials, following a variety of designs respecting the Statistical Analysis Plan (SAP) and mock TLFs
- Interim analyses and defining stopping rules, including providing an independent statistician for your unblinded interim analyses
- Pooling of studies, including safety and efficacy summaries for regulatory submissions
- Data Monitoring Committee: independent statistician participating in the DMC board and/or generation of the DMC analysis
- CSR review and programming of case narratives
- Programming of the CDISC ADaM datasets and metadata
- Providing assistance to clients when presenting results to the FDA and EMA
- Programming of patient profiles

## ADVANTAGES

- Early trial support from the biostatistics team for optimized protocols
- Efficiencies in analysis with a library of over 60 validated SAS macros
- Broad range of therapeutic experience





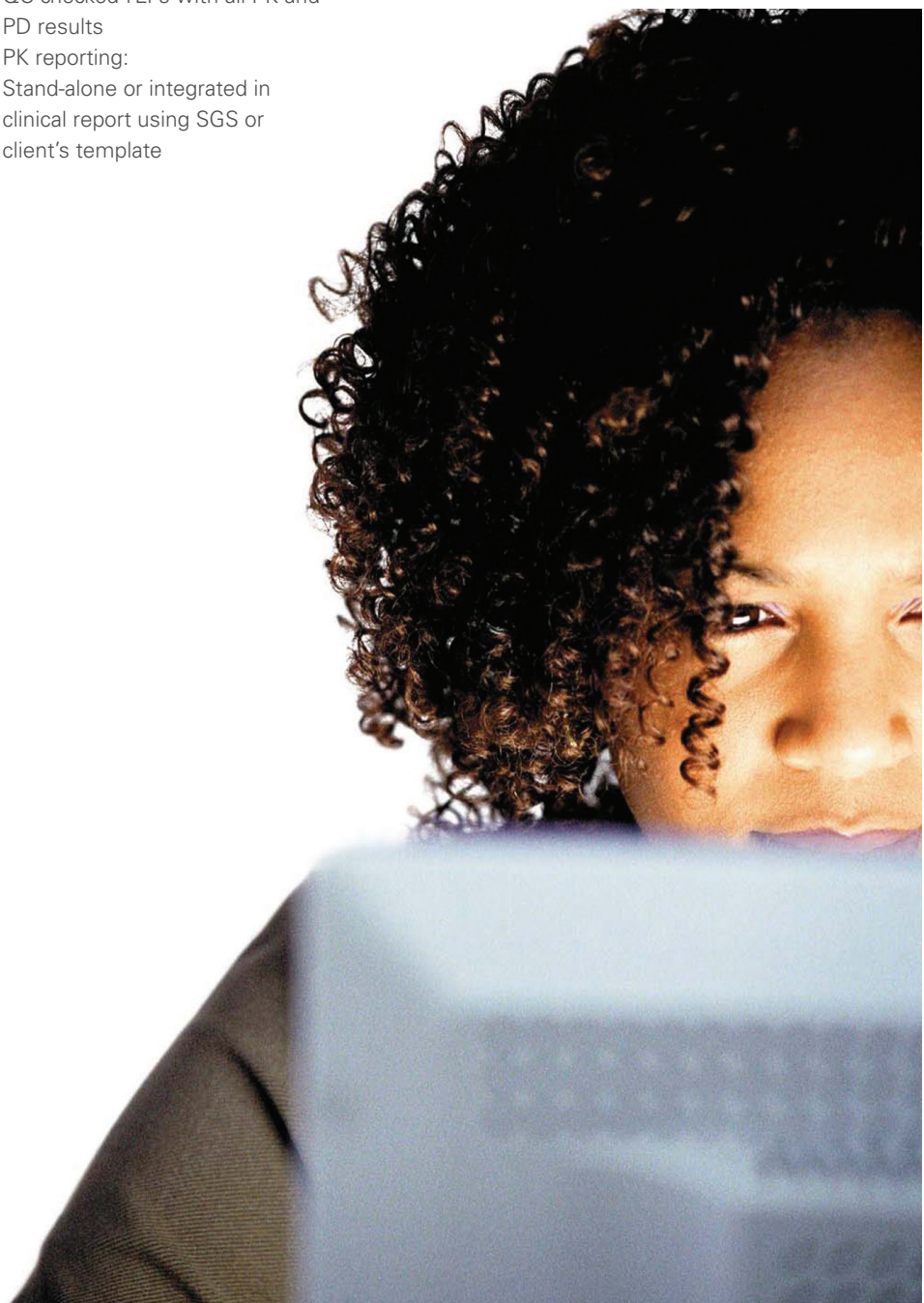
# PHARMACOKINETICS / PHARMACODYNAMICS DATA ANALYSIS

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 Biometrics department holds a team specifically dedicated to pharmacokinetics (PK) and pharmacodynamics (PD). They provide high-quality, regulatory-compliant PK/PD analyses that are the basis of your regulatory submission package. In order to support you in pre-clinical and phase I-III clinical studies, we offer:

- Planning (protocol and SAP)
  - Input on study design
  - Sample size calculation
  - Input on sampling schedule
- PK analysis:
  - Non-compartmental PK analysis
- Inferential statistics on PK parameters (group comparisons, bioavailability (BA)/bioequivalence (BE), dose proportionality, food effect, etc.)
- PD analysis:
  - Immunological response
  - Large range of biomarkers
  - PK/PD relationship
- PK and PD data transfer:
  - Providing with the analysis data model (ADaM) CDISC compliant datasets for PK and PD (e.g., ADPP, ADPC, etc.)
- PK and PD tables, listings and figures (TLFs):
  - QC checked TLFs with all PK and PD results
- PK reporting:
  - Stand-alone or integrated in clinical report using SGS or client's template

## ADVANTAGES

- Complete scope of PK/PD analytical services
- PK/PD Integrated approach with biostatistics and medical writing facilitates protocol development and data reporting including SAP, TLFs, and CSR.
- Innovative PK/PD modeling services provide insight to optimize study strategy and design



# MEDICAL WRITING

The success of a clinical development program depends on the proper documentation of research plans and results. SGS offers a range of flexible MedicalWriting services to support various clinical study documentation needs. SGS's expert team of medical writers comprises primarily PhD-level scientists with excellent communication skills acquired through training and experience. They have strong scientific backgrounds and apply indication-specific knowledge to provide accurate and well-written submission-ready documents.

We work closely with SGS medical experts, biostatistics, PK/PD and project management teams to deliver accurate, timely, and cost effective documents to the highest ethical and scientific standards. All SGS medical writers have broad experience in using client's templates and style guides. In case no client template is available SGS will use its own CSR and protocol template compliant to ICH E3 and ICH E6.

Services offered by our Medical Writing team are mainly focused on developing/writing 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 (e.g., for DSMB and CSR)

## 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

- Flexibility in client templates and requirements
- Close collaboration with biostatistics and PK/PD teams for cohesive and regulatory compliant reports
- High quality documents, ensuring accuracy and clarity through rigorous quality control

# ELECTRONIC TRIAL MASTER FILE (eTMF)

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 v3.0.

## ADVANTAGES

- User friendly filling
- 24h access to all approved documents
- Real-time inspection readiness
- Integrated with the SGS Clinical Trial Management System (CTMS)

Our Document Management team offers the unique stand alone services to 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

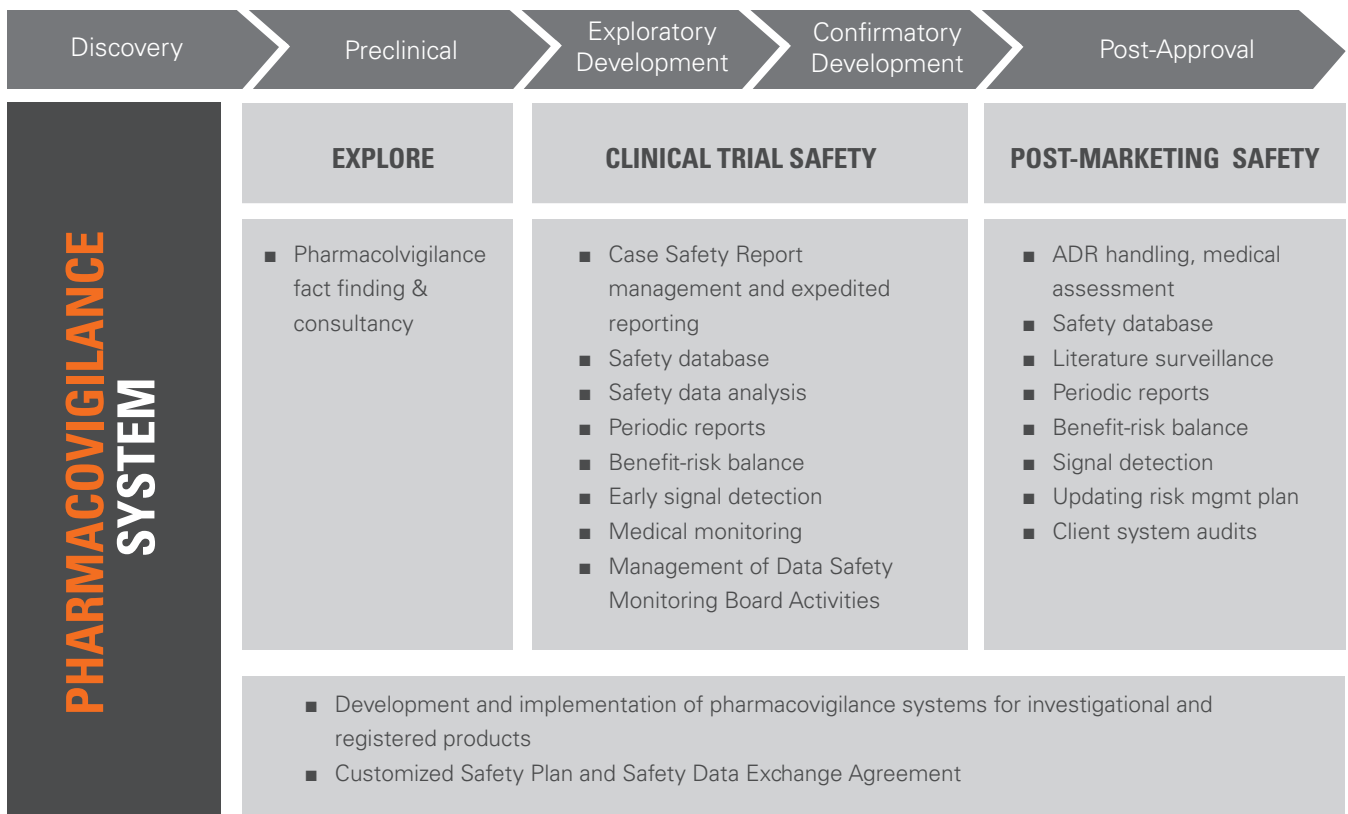
# DRUG SAFETY & PHARMACOVIGILANCE SERVICES

SGS provides 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 includes MDs, PhDs and Pharmaceutical scientists that are multilingual and work closely with Regulatory Agencies worldwide.

## ADVANTAGES

- Tailor-made, cost effective safety systems for small and mid-size companies
- Flexible outsourcing of safety functions
- Set-up and management of in-house Oracle Argus safety database
- Design of electronic SAE form in collaboration with the EDC team
- Broad therapeutic expertise for medical review and signal detection

## DRUG SAFETY FROM MOLECULE TO MARKET



## CONTACT US

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WHEN YOU NEED TO BE SURE

