Medical, regulatory and safety writing

Health Inspired,
Quality Driven.

SGS

About SGS Clinical Research

We're a global, mid-sized CRO across Phase I to IV clinical trials for biotech and pharmaceutical companies. With more than 40 years of experience, we work across complex therapeutic areas, including CNS, oncology, dermatology, infectious diseases and respiratory diseases.

Our teams bring together the services that shape a clinical development program: clinical operations, biometrics, clinical pharmacology, central laboratory services, regulatory expertise, medical safety and medical writing. Depending on the need, sponsors work with SGS for full-service support, functional service support, embedded staffing or targeted expertise for specific studies, documents or development challenges.

That connection strengthens our medical, regulatory and safety writing. Our writers work close to the science, the data and the operational reality of the trial. When needed, they can consult directly with SGS in-house experts, including investigators, safety physicians, pharmacokineticists, biostatisticians and clinical data managers, so documents reflect the full clinical picture.

The result is documentation that is scientifically accurate, operationally realistic and consistent across the development path.

When you need to be sure, choose SGS.

“The value of SGS lies in combining scientific expertise with practical document ownership, so sponsors gain clarity where development becomes complex.”

LUC BRAEKEN
DIRECTOR BIOMETRICS, SGS

Medical, regulatory and safety writing

A successful clinical development program depends on documents that are clear, complete and consistent. From early-phase research to late-stage development, registration and post-marketing commitments, every document needs to tell the same scientific and regulatory story.

We support sponsors with medical, regulatory and safety writing across the full development path. Our writers combine scientific understanding with practical experience in clinical research, Health Authority expectations and cross-functional review.

They help turn complex, multidisciplinary input into documents that are ready for submission, review and decision-making.

> “Strong medical writing is not just about producing a document. It is about understanding what the data need to prove, what regulators need to see and what the study team needs to decide next.”

THOMAS LODEWEYCKX
ASSOCIATE MEDICAL DIRECTOR, SGS

Partnering with SGS gives you:

Highly experienced medical, regulatory and safety writers

with broad therapeutic expertise allowing them to rapidly understand disease biology, treatment paradigms and scientific considerations.

Ownership from first draft to final version

Our writers do more than write. They coordinate input from multidisciplinary teams, manage review rounds, follow up on open points and keep documents moving.

Continuity when timelines are tight

Our team-based model gives you backup, scalability and fast turnaround when workload increases, without losing document quality.

Clear, consistent, submission-ready documents

Every document is written with regulatory review in mind and supported by structured QC to check accuracy, consistency and compliance.

Documents that fit your way of working

We work with SGS ICH-compliant templates, including ICH E3, E6 and M11, or with your own templates and style guides.

Direct access to in-house experts

Writers can draw on in-house SGS expertise in clinical pharmacology, pharmacokinetics, biostatistics, clinical data management, drug safety and medical input.

Central coordination of cross-functional input

Writers act as the central point for scientific, clinical, regulatory, safety, statistical and operational input. While all functional experts remain connected, the writer drives the documentation process and helps turn complex expertise into one clear, consistent document.

Regulatory expertise across regions

Access to the SGS regulatory affairs team and intelligence database covering more than 80 national Health Authorities.

Protocol and submission support

A strong clinical trial starts with a protocol (CTP) that needs to be scientifically sound, operationally realistic and aligned with regulatory expectations. We support sponsors with clinical trial protocols and submission documents from first-in-human trials to pivotal Phase 3 studies and beyond.

Our writers ensure

- Strong protocol ownership from trial concept to finalization
- Coordination of input from cross-functional teams, investigators, sites and external stakeholders
- Scientific and operational questions are addressed efficiently through direct communication with SGS in-house experts, including investigators, physicians, pharmacokineticists, biostatisticians and clinical data managers
- Alignment between scientific rationale, study design and operational feasibility
- Timely follow-up on Health Authority questions and protocol amendments within short turn-around times

Documents and submission support

- Clinical Trial Protocols (CTPs)
- CTP-related Scientific Advice procedures and Health Authority briefing packages
- Clinical Trial Application (CTA) documents
- Investigational New Drug (IND) documents
- Investigational Medicinal Product Dossiers (IMPDs)
- CMC documentation for eCTD Module 3
- Investigator's Brochures
- Informed Consent Forms (ICFs), including Patient Information Sheets (PIS)
- CTA and IND submissions in EMEA and North America
- Safety Management Plans, IDMC/DSMB charters, benefit-risk assessments, and more

> “In complex development programs, medical writing becomes the memory of the project: what was decided, why it was decided and how it affects every next document.”

ISABELLE HALLEMANS
HEAD MEDICAL WRITING, SGS

Submission-ready CSR

A Clinical Study Report (CSR) is often the document where the study becomes regulatory evidence. It needs to present the design, conduct, results and interpretation of the trial in a way that is clear, accurate and easy to follow. Our writers work with cross-functional study teams to deliver CSRs that meet global regulatory expectations.

Our writers ensure

- Clear coordination across contributors such as physicians, biostatisticians, investigators, pharmacokineticists and other subject matter experts
- Attention to detail and consistency
- Concise summaries that meet regulatory expectations
- Structured quality control with least 2 QC steps consisting of 100% data verification versus source documentation

CSR-related documents and other scientific communication

- Lay Language Summaries
- Microbiology and biomarker reports
- Subgroup Analysis reports
- Participant-level narratives, including SUSAR and IDMC-related narratives
- Scientific publications, abstracts and posters that help sponsors share results clearly with external audiences
- Meeting minutes for Advisory Boards, IDMC/DSMB meetings, so decisions, actions and rationales are captured clearly

Scientific advice and strategy

Beyond individual clinical studies, successful drug development relies on a solid foundation of strategic regulatory documents that are clear and aligned with the full development path. We support sponsors from early Health Authority interactions to long-term development planning.

Our writers ensure

- A clear structure for scientific background, development rationale, questions and company positions
- Consistent messaging across strategic documents and Health Authority interactions
- Well-supported arguments that help Health Authorities understand the sponsor's position
- Close alignment between writing and regulatory experts for submission and follow-up

Strategic documents and services

- Scientific advice package and its submission
- Health Authority briefing books
- Support advice procedures for end-of-Phase 1 and 2 strategy, pivotal Phase 3 trial design, PRIME, breakthrough and orphan drug designation-related discussions
- Epidemiology reports
- Pediatric Investigation Plan (PIP)

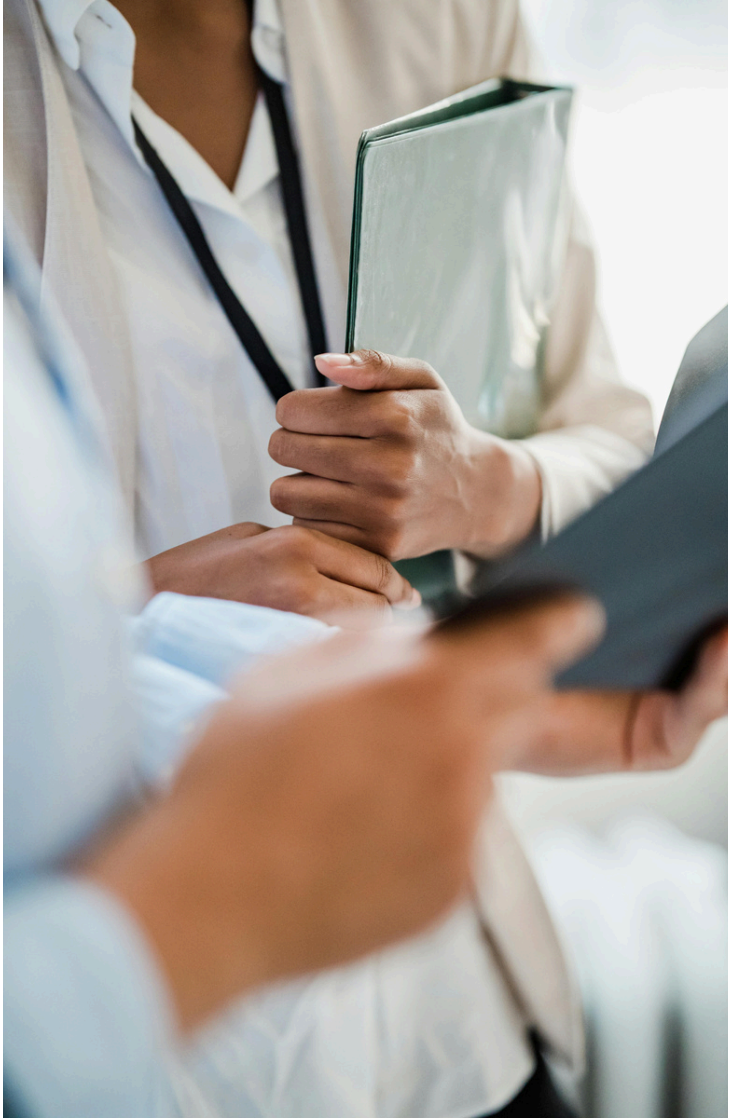
Case study

A global pharmaceutical company was preparing a Phase 3 program in a rare neglected tropical disease, without validated clinical endpoints to guide the path forward.

SGS assigned a lead medical writer to bring coherence to the complexity of repeated feedback rounds from different Health Agencies and the sponsor – continuously aligning the protocol, Scientific Advice packages and strategic documents as the development path evolved. An approved CTP was achieved, enabling the company to drive groundbreaking progress in the field of the targeted neglected tropical disease.

Read more

bit.ly/scientific-advice



Drug registration submissions

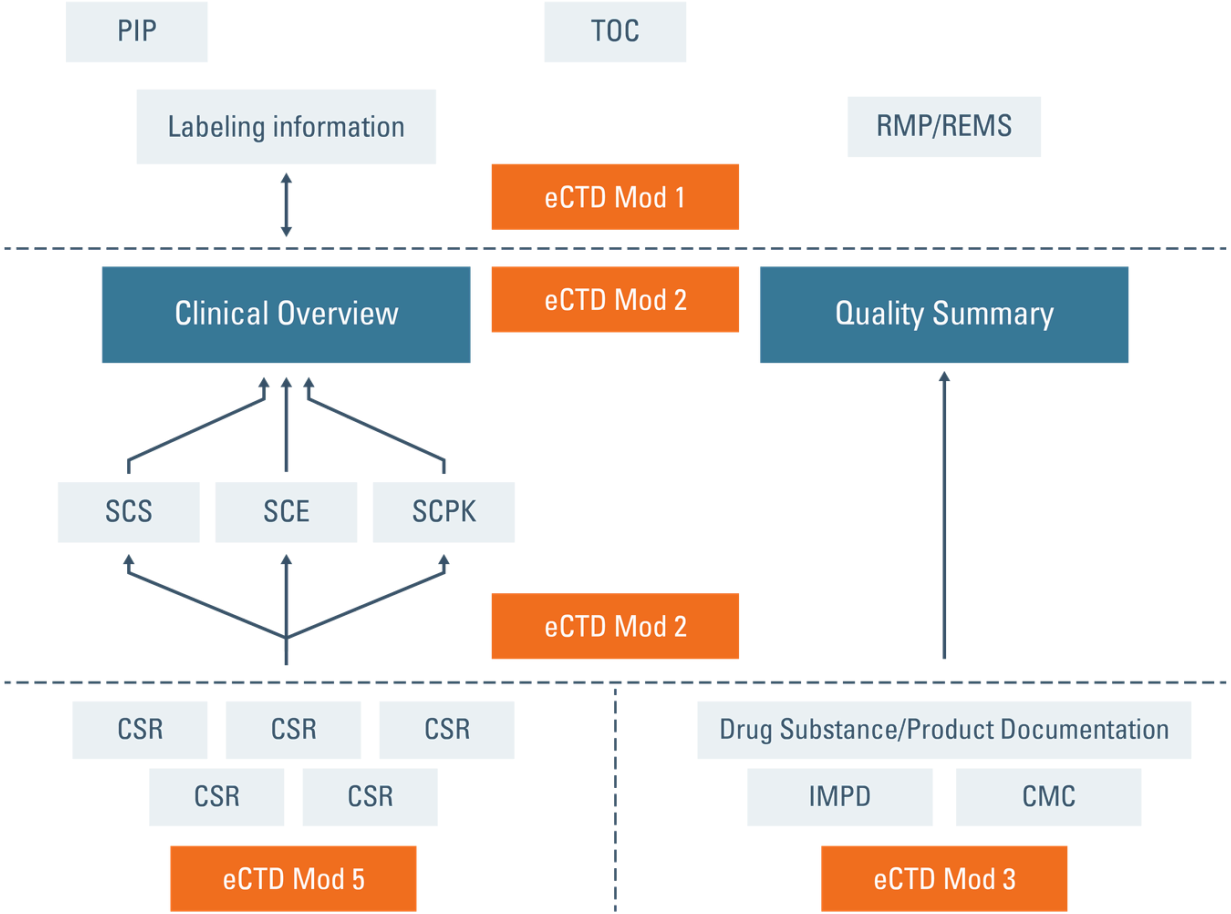
A drug registration submission is a major development milestone. The full dossier needs one coherent scientific story, with consistent messaging across submission documentation. We support sponsors with medical writing for MAA, NDA/BLA and internationally recognized dossier frameworks, helping create clear, coherent documents for registration submissions and Health Authority review.

Our writers ensure

- Accurate scientific communication of data, interpretation and conclusions
- Consistent messaging across the submission package
- Clear document structure to support efficient team and Health Authority review
- Cross-functional and inter-document coordination throughout the writing process
- Documentation developed with inspection and audit readiness in mind
- Alignment with global regulatory requirements and Health Authority expectations

Document and submission support

- Full submission packages
- eCTD package, including modules 1, 2, 3 and 5
- MAA, NDA/BLA documentation
- Individual registration documents
- Health Authority communications during the registration process and responses to requests for information


PIP
TOC
Labeling information
RMP/REMS
eCTD Mod 1
Clinical Overview
eCTD Mod 2
Quality Summary
SCS
SCE
SCPK
eCTD Mod 2
CSR
CSR
CSR
CSR
CSR
eCTD Mod 5
Drug Substance/Product Documentation
IMPD
CMC
eCTD Mod 3

Specialized safety writing

Safety writing plays a direct role in patient protection, regulatory decision-making and the direction of clinical development. Safety documents need to be timely, accurate and medically interpreted in a clear and consistent manner. We deliver safety writing support across the full spectrum of pharmacovigilance documentation needs, from targeted support during peak workload to fully outsourced safety writing.

Our writers ensure

- Clear, structured interpretation of new and evolving safety information
- Accurate and consistent inspection-ready safety documents
- Strong therapeutic area, pharmacovigilance and medical expertise
- Scalable support during high-pressure periods, including PSUR cycles, product launches and urgent Health Authority requests
- Experienced use of leading safety databases, including Argus, SafetyEasy, Veeva Vault Safety and LSMV

Safety writing support

- Aggregate safety reports: DSUR, PSUR/PBRER, ISS
- Risk management documents
- Signal management reports
- PSMF input and updates
- CCDS/CCSI and SmPC review and updates
- Ad-hoc safety documents, such as benefit-risk assessments
- Safety documentation supporting Health Authority interactions

Case study

When an emerging safety concern triggers Health Authority questions, the pressure is immediate.

For a global pharmaceutical company with a marketed product under review, our safety writers supported a signal evaluation report by bringing together clinical trial data, post-marketing surveillance, literature and spontaneous ICSRs into a clear benefit-risk rationale. Working with pharmacovigilance, medical, regulatory and biostatistics teams, we helped deliver a defensible report within the required deadline.

Read more

bit.ly/benefit-risk-assessment

Staffing

Some sponsors prefer to keep medical, regulatory and safety writing in-house but need additional expertise for complex documents, capacity or continuity. We provide experienced medical and regulatory writers who integrate into your organization and work within either your or SGS' processes, SOPs, templates and systems.

Our writers bring

- 9+ years of average writing experience
- Broad therapeutic and document expertise
- Fast onboarding to address urgent submissions, resource gaps or document backlogs
- Full integration into your tools, workflows and document standards
- Coordination of stakeholders, review cycles and timelines
- Knowledge sharing to strengthen internal writing capability

Flexible staffing support

- Dedicated long-term staffing
- Temporary writing support
- Peak workload and backlog support
- Scalable capacity that increases or decreases as workload evolves
- One writer or a coordinated multi-writer team
- Engagement by time, task, project or compound

> “Staffing adds seniority, structure and continuity to the writing process, while allowing the sponsor to stay in control of the way documents are developed.”

ISABELLE HALLEMANS
HEAD MEDICAL WRITING, SGS

Pharma

Health Inspired, Quality Driven.

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SGS

When you need to be sure

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