Welcome to Trilogy Writing & Consulting

Trilogy is a medical writing consultancy that works with our clients to plan, coordinate and write their clinical documentation to meet aggressive timelines, with a quality that reduces the time for review and approval.

Our Commitment to You
- A crystallized message
- Synthesis of data to illustrate and communicate key messages effectively
- Accurate and consistent documentation
- Proactive interaction with our clients
- A sense of ownership
- Delivery on-time and on-budget

“successful documentation is the key”
The Challenge of Medical Writing

The Documentation of Clinical Development
... drug approval is based upon the documentation of a clinical development programme
... good clinical documentation speeds clinical development and streamlines marketing approval

Good documentation is difficult to achieve
... producing good documentation is often hindered by a lack of sufficient personnel, training and experience in medical writing
... inadequate resources result in missed deadlines, lack of continuity and higher costs

Getting your messages told clearly and in a timely manner is critical to the success of clinical development and justifies the use of a specialist medical writing team.
Trilogy Clinical Documentation Portfolio

Glossary

- ASR: Annual Safety Report
- CSP: Clinical Study Protocol
- CSR: Clinical Study Report
- CTD: Common Technical Document
- CTR: Clinical Trial Report
- E1: Investigator's Brochure
- ET: Informed Consent Form
- MPR: Medical Product dossier
- INO: Investigational New Drug
- PI: Product Information
- RDP: Protocol Deviation Plan
- RDS: Risk Management Plan
- SD: Summary of Product Characteristics
- USPI: United States Prescribing Information

Complete Clinical Documentation Portfolio
Trilogy offers the full range of writing and coordinating skills as well as the scientific expertise and industry experience required to provide the documentation demanded by your clinical programme. This incorporates:

- Coherent and consistent communication of key messages throughout your product lifecycle
- Application of industry best practices and standards in document preparation
- Efficient processes to meet tight deadlines
- Continuous and thorough quality control
- Trilogy can manage your entire documentation lifecycle

Dedicated Team Approach
Trilogy dedicate a writing team to your project to become an integral part of your clinical development by providing medical writers, project management and quality control. The use of a team ensures responsive, flexible and uninterrupted support for your project - even accommodating unforeseen emergencies. This means:

- Key messages are communicated and illustrated effectively
- Documents are structured in a clear and easy to review manner
- Documents comply with international regulatory standards
- Leverage of Trilogy’s extensive experience in clinical documentation
- Relieving the burden on your clinical staff
CSR (Clinical Study Report)
- CSRs are the key means by which regulators can assess the outcome of clinical studies.
- Trilogy’s long experience in writing hundreds of CSRs for all phases of clinical development and across most indications helps our clients to crystallize the essential results that regulators need to know.
- We work closely with clients to meet the challenge of the large numbers of complex subject narratives often required for CSRs.
- The CSRs we prepare optimize and streamline the preparation of ensuing CTDs.

CTD (Common Technical Document)
- CTDs are the end product of the long and expensive clinical development process, and are the ultimate challenge in writing clinical documentation.
- Trilogy has extensive experience in preparing dozens of CTD submissions, from straightforward local variations to complex global submission dossiers for multiple indications.
- Our clients appreciate Trilogy’s proactive involvement in ensuring that all aspects of the clinical development program are appropriately synthesized in a reviewer-friendly manner.
- Trilogy meets deadlines – a vital factor in successful and timely drug approvals.

Training
- Appropriate training by all involved in clinical development is a stipulation of Good Clinical Practice (GCP).
- Trilogy has years of experience running training workshops for organizations such as EMA (European Medical Writers Association) and Management Forum.
- We also provide standard and tailor-made workshops to the pharmaceutical industry world-wide.
- The training provided by Trilogy ensures your staff have the best possible foundation for preparing successful documentation.
Trilogy Philosophy,
Values &
Commitment

Trilogy offers a flexible concept for outsourcing parts or all of your clinical documentation:

• We dedicate a multi-skilled writing team to your clinical development to maximise consistency and productivity while ensuring timely documentation of your results.
• We are flexible and responsive - we adapt the Trilogy approach to the needs of your company and the uncertainties of real-world clinical development.
• We are proactive and have a sense of ownership - your success is our goal.

...Trilogy: Partners in Successful Documentation

Partners in Successful Documentation