

# GOLDEN RULES FOR CLINICAL DOCUMENT DEVELOPMENT: MAKING THE MOST OF YOUR MEDICAL WRITER



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## INTRODUCTION

Medical writing is a broad field, as testified by the many different names applied to the profession: medical writing, scientific writing, and regulatory writing to name but a few. The field covers the development of a whole spectrum of document types from medical communication documents such as posters, slide sets and journal manuscripts to regulatory documents such as clinical study reports (CSRs) and Investigator's Brochures (IBs). Some writers have experience with the whole spectrum; others mainly develop expertise with a subset of document types. But the ultimate challenge in any case is to tailor style and level of detail to suit the intended audience.

Medical writing not only covers various document types, it also encompasses diverse therapeutic areas, diseases, drugs and several specialized fields such as early phase clinical research, imaging, medical devices, or orphan drugs. In-depth knowledge of a therapeutic area, disease or even a drug is undoubtedly an asset but not a prerequisite for efficient and

qualitative medical writing. A majority of the specific expertise will be contributed by other clinical research professionals; each specialized in their own field. In the same light, the ability to acquaint oneself rapidly and effectively with a new topic is a fundamental quality for a medical writer. Freelance and CRO-based writers typically don't have the opportunity to

attain the level of knowledge of a product that in-house writers in a pharmaceutical company accumulate. They are, however, trained through frequent practice to adjust their writing to new topics and new requirements. In addition, they gather a broad experience of dealing with different obstacles or different approaches to similar hurdles.

## MORE THAN A WRITER

A medical writer should cultivate a successful blend of linguistic and scientific skills. In addition, since a significant amount of a writer's time is invested in sorting through large amounts of complex data and discussing them with other clinical research professionals, a critical and communicative mind is also invaluable.

Indispensable skills and qualities in a medical writer are:

- Ability to synthesize, analyze and summarize large amounts of complex data
- A critical mind that does not lose itself in inconsequential details
- Ability to convey a clear, meaningful message with a limited amount of text
- Ability to communicate with and reconcile comments of various clinical research professionals;
- Ability to deal with substantial time pressure
- Knowledge of ICH guidelines (e.g., ICH E3, E14, ...), regulatory requirements, and at least the basics of statistics

### From Start to Finish of a Clinical Trial

The answer to the question "when is a medical writer involved in a clinical trial?" will often be: "at the very end, when the data are analyzed and ready

to be summarized in a CSR.” But since the development of a CSR involves close collaboration of the writer with clinical trial managers, data managers, biostatisticians, regulatory affairs representatives and clinical or scientific experts, it pays to involve the writer earlier in the process. A medical writer is uniquely suited in function and experience to monitor the interrelation of documents with each other and promote consistency of format and even content across a range of documents.

What can a medical writer do?

- **Write or edit the clinical trial protocol**

While the design of the trial is in the hands of the clinical research team and protocols are often written by global project managers, a medical writer can deliver added value towards document structure, clarity and consistency. Apart from directing trial conduct, the protocol will be the basis for a range of other documents such as the Case Report Form (CRF), Informed Consent Form (ICF), Statistical Analysis Plan (SAP), and ultimately the CSR. Therefore a well-written, clear, unambiguous and consistent protocol can save a lot of people a lot of time and effort.

- **Write the ICF**

The writing of informed consent forms demands a simple, straightforward style. Here more than in any other document, the writer needs to ensure not only that the information is correct, but also that it will be understood correctly.

- **Review the CRF**

The quality of the data collected during a clinical trial hinges on the quality of the CRF. A small oversight or an ambiguous phrase can mean a valid question left unanswered at the end of the trial. From their first-hand experience with the ultimate destination of the gathered data, medical writers can make valuable contributions to a CRF.

- **Review the SAP**

Medical writers can sometimes have a more nuanced picture than statisticians do of what readers of study reports will find clear and straightforward. Therefore, a writer can make useful suggestions at the time of SAP development.

- **Participate in the review of blinded data listings before database lock**

Data managers generally look at data in a context of individual subjects while writers look from a perspective of study groups and objectives. The combination of both approaches before database lock can prevent having to elaborate on (apparent) discrepancies in the CSR.

- **Review draft statistical tables**

After the statistician, the medical writer will be the one spending most time with the statistical analysis. Quite apart from detecting errors at an early stage, a writer’s suggestions for organization and presentation of data can save both writers and other users of statistical output valuable time.

- **Write the CSR**

A medical writer will take the protocol, SAP and statistical analysis, and in some cases also the CRF, and rearrange carefully selected parts of them into an integrated description of the conduct and outcome of the clinical trial. The resulting draft will then be revised in close collaboration with the clinical research team in charge of the study. The ultimate goal is a multipurpose document that satisfies the demands of science, clarity and applicable guidelines such as ICH E3.

- **Prepare a poster, slide presentation or journal manuscript**

These documents require a different writing style than the above-mentioned documents as their purpose is not only to present results accurately and concisely but also to capture and hold the interest of the intended audience.

## ACROSS CLINICAL TRIALS

The writing of documents that summarize information across clinical trials (such as IBs and integrated summaries) requires the writer to take a step back from the data and rearrange it into a more concise, logical, manageable and navigable whole. It is essentially the same process as CSR writing, but on a larger and more comprehensive scale.

Besides being the actual document author, the writer often also acts as a coordinator of the efforts of an interdisciplinary team throughout the document’s life cycle.

## USEFUL INVESTMENTS OF TIME

During document development major and minor questions regarding content and format inevitably arise. Many of these questions will recur numerous times or perhaps worse, may not be asked explicitly, leading to wrong assumptions and wasted effort. This can be prevented by investing a little extra effort at the outset to build mutual understanding and agreement among all parties involved.

- Pre-writing meeting: whatever the type of document, it is imperative for efficient writing to know beforehand what the expectations are, where the focus should be, which data are most relevant, etc.

- Template: a good template should incorporate preferred formatting and structure. It can even supply paragraphs of preferred wording provided the whole remains flexible.
- Style guide: a style guide promotes consistency and can prevent a lot of repetitive discussion thereby yielding a manifold return on the invested time.

Medical writers are clinical research experts who need to be familiar with all steps in the conduct of a clinical trial. In close collaboration with an interdisciplinary team, medical writers deliver documents

that meet rigorous scientific quality standards and are compliant with ICH, regulatory and company requirements. With their dedicated team of flexible, motivated and highly qualified writers who have a broad experience with the whole spectrum of medical communications and regulatory documents as well as an array of therapeutic areas, SGS can provide a wide scope of rigorous medical writing services, which can be limited to the writing a single document or framed in the larger context of full clinical trial management.

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