

CONFERENCE

Session Reports

BEST PRACTICES FOR MEDICAL WRITING WITH A DISCLOSURE MINDSET

Speaker

Thomas Wicks, MBA, *Chief Strategy Officer, TrialScope/Informa, Jersey City, NY*

By Nisreen Shumayrikh, PhD

Clinical trials are conducted almost everywhere worldwide, and trial disclosure requirements continue to expand, with an average of 2 new trial registries going live every year. This global expansion can lead to inconsistent public disclosure of study protocols, trial results, and associated documents.

The inconsistency becomes apparent when the information is disclosed through various registries, company trial websites, and publications and then assessed by recruiters, industry and financial analysts, and patient advocacy groups.

Regulators in various countries have started to include disclosure compliance in their inspection regime, whereas industry critics and transparency advocates continue their detailed assessments of transparency practices. Beyond these regulatory inspections and assessments, sponsors face additional risks if the disclosure decisions are not well harmonized.

In his presentation at AMWA's 2021 conference, Thomas Wicks, Chief Strategy Officer at TrialScope/Informa, suggested best practices to regulatory medical writers for authoring source documents such as protocols and clinical study reports (CSRs) with disclosure requirements in mind.

Efficient Disclosure

To support disclosure, Mr Wicks suggested creating a protocol "disclosure template" that includes the main registration data, including the trial identification number, public and scientific titles, brief description, eligibility criteria, and others. A good starting point is adopting the registration data set developed by the World Health Organization and providing the protocol registration information from clinicaltrials.gov or [EudraCT](https://eudract.europa.eu) (if available) to local affiliates, partners, and contract research organizations (CROs) to use as their source data for registration to local registries.

Mr Wicks then discussed some disclosure considerations regarding study endpoints.

These include

- alignment: explain clearly how each endpoint aligns with objectives,
- measure: document how each endpoint will be measured,
- scales: explain scales and indicate the best and worst scores,
- objective: include measurement objective,
- classification: classify endpoints and structure them (eg, primary, exploratory, secondary),
- templates: ensure that objective has one or more endpoints,
- definitions: define study process (eg, study dates, enrollment), and
- summaries: summarize all nonserious adverse events in a test.

"Each study objective has to be backed up with an endpoint," Mr Wicks said.

Incorporating Plain Language

When preparing source documents such as the clinical trial protocol or CSR, consider the information needs of patients and potential trial participants.

The information relevant to patients and participants should be written in plain language as part of the protocol, including

- the study title and a brief description,
- the description of the health condition,
- the product description,
- the key inclusion/exclusion criteria,
- description of study procedures/assessments,
- primary and, possibly, key secondary outcome measures,
- additional context around age range and sex of the participants, and
- length of participation.

The advantage is that submitting these plain language elements to trial registries improves patient communication and benefits users like recruiters and patient advocates. Regarding the source documents, Mr Wicks emphasized integrating plain language elements in the protocol, CSR, and even the informed consent form, which is often not

a clear as could it be. Additionally, he suggested adding a plain language abstract to the study synopsis, especially when the sponsor does not plan to provide a separate plain language summary. Other handy tools include developing a plain language glossary and templates.

Prepare for Redaction and Anonymization

For participant information, AVOID the following:

- using pronouns in patient narratives; consider using “the patient” instead,
- using “verbatim” with quotes by the investigator, as these may include unique circumstances that could describe a patient, or
- including patient IDs in images of tables. If patient IDs are required, then either include tables with selectable text (instead of copied as an image) or keep table formatting consistent across all images to ease redaction.

For study or sponsor staff information and other identifiers, AVOID the following:

- adding names of the study staff with their organizational titles; instead, use only their study role,
- including contact information such as fax, phone, or email,
- incorporating CVs or certificates or adding them to an appendix,
- adding personal identifiers to bookmarks (such as patient IDs, names, study admin), or
- providing treatment allocation and group information throughout the document.

Other final considerations:

- Limit duplication that requires duplicate redactions, for example, providing a table with patient narrative information followed by text with some of the same information.
- In the sample Case Study Report Case Report Form (CRF), use a clearly fake patient ID like XXXX or 0000 (not even “1234”).
- Aim to keep page numbering consistent between the CSR and the PDF copy to help remove out-of-scope information.
- Because foreign language pages are out of scope, you may keep these in an appendix or remove them.

These are some best practices for medical writing with a disclosure mindset. It is part of your job as a regulatory medical writer to have a basic knowledge of disclosure regulations and support trial transparency.

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BRIDGING THE GAP: TRANSITIONING INTO REGULATORY MEDICAL WRITING

Speakers

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Savannah Mageau, PharmD, *Medical Writer, Merck, Rahway, NJ*

Shengjie Xu, PhD, *Medical Writer, Merck, Rahway, NJ*

By Stephany Panlilio, MS

The role of a medical writer is everchanging and requires a range of technical knowledge and soft skills to create cohesive documents in preparation for submission to regulatory health authorities. Medical writers come from a variety of different backgrounds with varying levels of experience. For those looking to enter the field, there are a number of transferable skills from previous experiences, training opportunities, and techniques to bridge knowledge gaps in preparation for transitioning into a regulatory medical writing role. This article summarizes the experiences of Dr Carr, Dr Mageau, and Dr Xu as they each transitioned into regulatory medical writing.

Skills Leveraged from Previous Experiences

In their presentation, Dr Carr, Dr Mageau, and Dr Xu shared their previous roles in experimental research, pharmacy practice, computational research, and teaching and medical communication and the skills they gained from each that were transferable to their role as medical writers. The skills they found most applicable to medical writing are summarized into the following 3 categories: soft skills, technical skills, and core knowledge.

Soft Skills

The soft skills of self-management and project management that Dr Xu gained from her time in experimental research have helped in her medical writing role. Managing time, setting priorities, and working independently are critical as a medical writer, and developing these skills can increase productivity. Medical writers must be able to manage multiple project timelines and have the flexibility to adjust when something unexpected arises (eg, shifting research