Regulatory Matters

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Editorial

As young medical writers still learning the craft, we may be more than eager to prove ourselves to our bosses, managers, or clients. We may take on work beyond our capacity, be afraid to speak up, or be afraid to ask questions because that may indicate weakness or inexperience. In this issue, Tiago Silva offers medical writing tips to writers new to the job and important things to think about when starting a project.

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I did it so you don't have to: Lessons learned as a young writer struggling with a regulatory document

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Medical writing is not easy, especially for new writers still learning the ropes. We are exposed to new documents, therapeutic areas, procedures, and challenges regularly and the fast-paced and ever-changing environment can be stressful. Nowadays, there are resources and initiatives available to equip writers with the right tools to get started, which is a tremendous development.[1-3] Nevertheless, mistakes will happen, regardless of experience, and it is part of our professional journey to acknowledge, learn, and grow from them.

In this reflection article, I share the story of one of my earlier regulatory writing projects, the lessons I learned, and how they improved my craft. I hope it will be valuable for other regulatory writers who are starting their journey.

The story

Back in my early years as a medical writer, I was tasked to write a protocol for an investigator-initiated clinical study (i.e., a study conceived, developed, and sponsored by an independent investigator) that assessed a new ocular surgical technique. I received an outline from the principal investigator, which included the study objectives, design, endpoints, and schedule of assessments. I was assigned a team of subject matter experts within various functions such as operations, regulatory, and biometrics with whom I would work. I was also tasked with completing the document under aggressive timelines. I did not attend the kick-off meeting and only joined the project afterwards.

I was still a bit inexperienced in regulatory documents at the time and, considering that I was leading several other projects in parallel, I was overwhelmed. Still, I wanted to prove that I could get the job done without support. In discussion with the team and management, I was clear that the study design was final so I did not dive deeper into its contents. This meant that after receiving the operational and statistical information, I would focus on putting the document together from an editorial perspective. This allowed me to meet the timelines and still work on my other projects. After some quick drafting and reviewing, the team was happy with the final output. However, at the very end when I was preparing the document for approval, I noticed one problem in the design: it allowed for treatment to both eyes of the same patient on the same day (assuming both were eligible for surgery). This raised all sorts of concerns related to biases and patient safety. Even though we were on the verge of approval, I could not let it slide, so I asked the team about it. It turned out that everyone missed this, leading to a redesign of the study and the timelines being extended. The team was frustrated with this delay and I felt terrible for not having noticed this problem earlier (even though I realise now that the fault was not mine alone, as nobody else noticed it either). Still, we were able to finish the protocol after adjusting the design and the study ran its course.

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Lessons learned

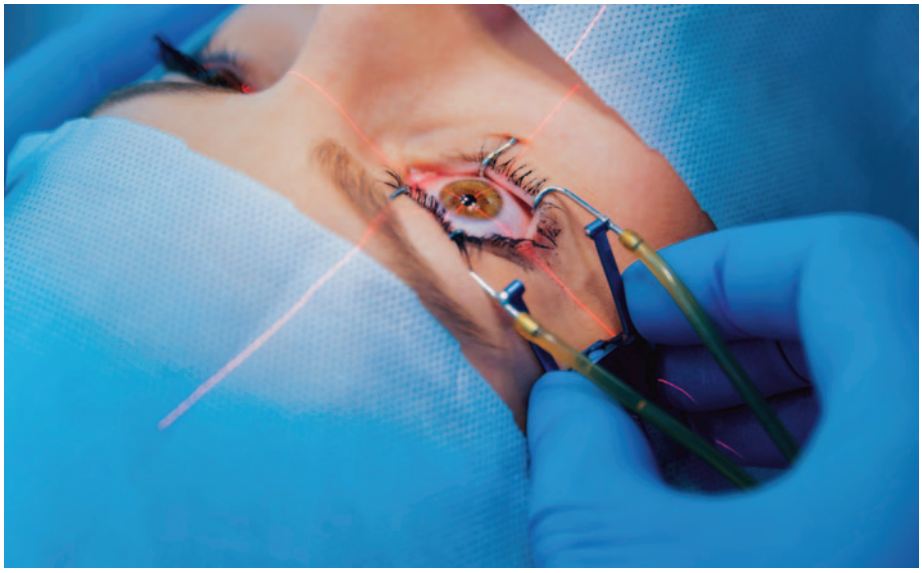
Embrace and clarify the role of the medical writer

Regulatory documents are mostly cross-functional. Medical writers work with teams of various technical and scientific subject matter experts, who provide the content from their line function and make the final decisions regarding content and document approval. However, unlike the name suggests, the scope of the medical writer goes beyond just writing. We are tasked to lead the process as efficiently as possible, along with critically appraising and incorporating input from subject matter experts and literature into a cohesive document that clearly delivers the right message to the target audience. This means that understanding, synthesising, analysing, and discussing information are part of our scope, not just writing and editing.

To do this successfully, as medical writers we must place ourselves at the centre of the collaborative effort and communicate openly

with all team members (Figure 1). We must clarify our role as consultants who advise the team on the best practices to ensure document quality and compliance. We must also be ready to challenge the team when needed, by openly discussing potential concerns raised by contradictory or incomplete input or review comments and offer solutions and alternatives that will help the team make the best decisions.

Doing this requires strong leadership and teamwork skills, which have already been identified as important skills for the medical writing profession.[4,5] These skills can be gained by formal training, but must be nurtured with experience. Thus, it is normal for inexperienced writers to feel insecure about leading teams right away (which I do not think is an entry level task). Writers starting out can work alongside more experienced colleagues, to see how they write and run the process, and to become more familiar with the documents. With time and experience, younger writers will be able to start leading their own projects and take their place in the team as an equal brain in the brainstorm.



The kick-off meeting is key

Expectation management is vital in medical writing. My experience taught me that we cannot assume teams will know what our roles as medical writers are or how the process works in the first place. This is why we should have well-structured kick-off meetings at the start of every document: to ensure the whole team is on the same page and to set clear expectations (Table 1).[5,6] However, it is important to communicate continuously after kick-off to ensure that the project is going as planned, and that everyone is up to speed with any shifts in scope and timelines. Sometimes, the plan can deviate, and everyone needs to stay in the loop.

In the example I gave, I did not attend the kick-off meeting and was only later introduced to the team. This had a negative impact, as I was not able to establish myself as the process lead or even an equal team member. This is why I believe that lead medical writers should lead all kick-off meetings concerning their documents. It allows us to introduce ourselves as the process leader and the main contact for questions, concerns, or updates that may impact the document. This meeting is also an excellent opportunity to create a good first impression. A well-planned and well-led meeting will make the team feel safe and trust the writer to lead them.

Writers not yet experienced in leading these calls may ask senior colleagues to attend one of theirs and see how they lead the discussion and establish a working relationship from the very start.

After kick-off, the writer should prepare and circulate the meeting minutes, so that everyone (including non-attendees) can stay on the same page.

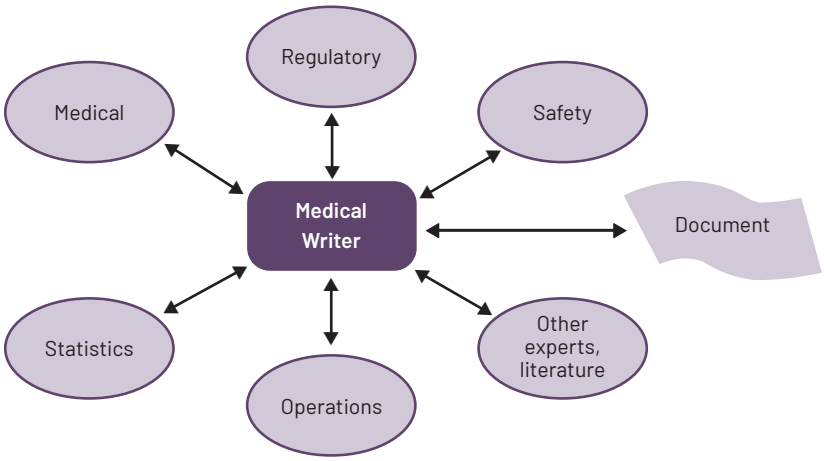


Figure 1. The role of the medical writer in cross-functional documents

Medical writers are at the centre of the collaboration: collecting and triaging all input and comments received from subject matter experts. They are tasked with critically analysing, discussing, and incorporating all comments and information in order to achieve a high-quality, fit-for-purpose document.

Do not underestimate document complexity

Regulatory documents are complex by default:

- They require a cross-functional team to provide input and review the contents.
- They include a high density of scientific information condensed into strict templates that must adhere to numerous regulations, templates, and guidelines.
- There is a large variety of regulatory documents available, each with unique characteristics and challenges.
- Regulatory timelines can be stressful.

Writers who are starting out on a new type of document should ideally start by supporting experienced colleagues on their projects. Getting formal training (hands-on and theoretical) either from the employer or another way is also important to gain familiarity with these documents.

In addition, writers should always confirm they are following the correct standard operating procedures, style guides, and templates when

Table 1. Topics to discuss at kick-off meetings

Topic	Considerations
Background	• Provide background information so that everyone has a clear understanding of the project and its scientific/regulatory environment.
Team	• Identify all team members by line function, including the lead writer and other supporting writers. Make sure all line functions are included as per standard operating procedure. • Clearly identify authors, reviewers, viewers, approvers, and other tasks (e.g., separate tables for each task). • Ensure that the team has time to check the list and identify any mistakes, missing personnel, or potential delegates, if necessary.
Process	• Provide an overview of the process as per standard operating procedure. • Clarify your role as the lead medical writer and any supporting writers involved. • Clarify the role of the team members, including other authors/contributors, reviewers, and approvers. • Clarify how the document will be drafted, reviewed, approved, and published, including any specific software and document management platforms, if applicable. • Establish a communication plan with the team, including preferred communication methods (e.g., email, phone, chat) and, if needed, regular catch-up calls.
Timelines	• Timelines should include all tasks required by the standard operating procedure, including drafting, reviewing, and approving periods, as well as slots for important meetings (e.g., comment resolution meetings after each draft review), and publishing steps, if applicable. • The team should confirm their agreement with the with the proposed timeline and their availability when needed. In case of absences, delegates should be assigned to ensure line function involvement.

writing a document. I also suggest asking the team for examples of similar, recently finished documents. I do this regularly as an agency writer, as each client has preferences that may not be clear by using templates and style guides alone. This allows me to achieve consistency between documents from the same client and better understand their expectations.

In my example, I underestimated the complexity of a clinical study protocol. These documents are particularly challenging, because study designs depend on the full alignment of many items (Figure 2), and even a small change can have a profound impact in the whole document, just like a game of Jenga. In my case, a seemingly tiny oversight resulted in the study being redesigned.

Ensure appropriate timelines

In my example, timelines were a major issue. I felt uncomfortable raising my concerns, as I thought I was seen as a service provider instead of an equal member of the team. I also assumed that the pressure was considered the norm in medical writing. In retrospect, if I was more assertive in ensuring proper timelines, the whole situation could have turned out differently.

Medical writers should, whenever possible, have an active role in defining the timelines for their projects. We should also raise concerns as soon as possible when faced with an unfeasible timeline. It is true that the regulatory environment we work in will sometimes put us in tight spots, but a high-quality document needs time for its development; this may include time to think and discuss the strategy with the team, to draft, to review, and to further align everything at the end. If this is not done, the quality will be

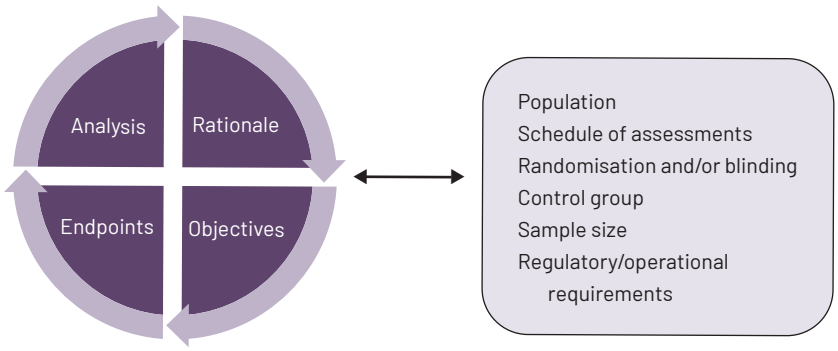


Figure 2. Requirements to write a clinical study protocol

Protocols require full consistency between the rationale, proposed objectives, endpoints, and statistical analysis, to answer the questions proposed by the study. Moreover, several factors (see box) must also be aligned with the methods proposed. Changes made to a single topic may have a profound impact on all others, making protocols particularly sensitive documents.

subpar and result in forced timeline extensions or even amendments/addendums, leading to further delays, additional costs, and increased risk of quality issues.

Also, timelines are not always "non-negotiable". Knowing the context of the document and the programme it is in may help understand if there is flexibility. In my experience, if there is no strong reason to push a document forward at breakneck speed (e.g., a regulatory deadline), teams will likely be fine with an extension. In my example, no reasons were provided for the timelines proposed; it is possible that the timeline was initially proposed by someone unfamiliar with the writing process and assumed to be reasonable, hence why medical writing input when setting up timelines is important. If I had spoken up at the beginning and highlighted the importance of having adequate time required to draft and review the document, either I or the team would likely have spotted the error earlier and addressed it without the need for a late-stage rewrite.

Writers feeling overwhelmed with a difficult timeline can ask a senior colleague or manager for assistance (if possible), and never make promises they cannot keep. It is important to keep an open line of communication with the team, so that expectations can be managed properly.

If not comfortable, speak up!

It is tempting, especially for those starting out, to try to prove their worth and gain as much experience as possible. However, this can be overwhelming, so writers should not underestimate the job. The regulatory environment (including document strategies) can change at any time, leading to shifts in timelines and scope of work. So, if possible, writers should avoid working on too many documents in parallel.

If the writer feels that a project is too much to handle, or a shift in a timeline is going to give them a difficult time, and support is available, they should reach out for help. A colleague sharing the workload, overseeing the project, or just providing advice or a sanity check, may be a huge relief.

In the example I provided, I did not voice my concerns over my workload because I saw that as a failure on my part, even though my team (and management) never gave me reasons to be concerned. Knowing when to reach out when necessary is not a sign of weakness. Instead, it shows strong foresight and project management skills. Writers who do this are adapting their work to improve efficiency and to attain high-quality output.

Conclusion

As medical writers, our work is about protecting patients and public health, while helping the advancement of medical science. It is a high-responsibility and high-pressure job, and mistakes can happen. However, writers can improve their chances of success by understanding and clarifying their place in the project and establishing clear roles, expectations, and communication lines. Writers uncomfortable with a new document type, timeline, or excessive workload should be comfortable asking for help. In my experience, medical writers are a friendly and supportive bunch, and always love a new challenge.

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The author declares no conflicts of interest.

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