# You get what you give

**Julia Forjanic Klapproth**, co-founder of Trilogy Writing & Consulting, explains how to prepare good requests for information and proposals in the field of medical writing.

If you have ever been involved in the process of selecting a company to provide medical writing services, you may have been baffled by the huge diversity in the answers to your request for information (RFI) or request for proposal (RFP). How can the information provided in response to the same questions – and the final costs – be so different? The reasons are twofold: the experience of the providers to whom you have sent the RFI or RFP, and the quality of those documents.

There is a vast difference in the experience of companies that offer medical writing services. Unlike with other skilled professions, medical writing does not require that people providing the service have any training or relevant experience in the trade for them to offer those services. Thus, responses to RFIs and RFPs can vary highly due to large differences in the knowledge base of the medical writers. Those who have been in the profession for years will be aware of secondary considerations that can affect timelines and resources, whereas inexperienced writers may not.

A second reason for the variance in responses is that the RFI/RFP was probably not designed to obtain information relevant for a medical writing project. As senior partner of a large medical writing company, one of my roles is to respond to requests from clients, and the majority of requests have several common flaws. Most typical is the use of RFIs and RFPs designed for selecting a CRO to run a clinical study and not a medical writer. These often ask questions that are far too general and to which it is almost impossible to give a precise answer. Asking how much it will cost to write a clinical overview for an oncology programme by a given date is truly the equivalent of asking 'how long is a piece of string?'. Yet, we regularly get RFPs that ask precisely this type of question.

To obtain meaningful information that will facilitate comparable responses between candidates, you need to tailor your questions for medical writing. Remove all questions specific to running and monitoring studies, statistics and data management. Making a medical writer provide answers to these questions is a waste of their time and increases the amount of meaningless information you will need to review. Your goal should be to hone the RFI/RFP down to a streamlined set of questions that will give you insight into the company's experience and staff retention, and how they will plan, resource and run the project. This makes it easier for them to complete it and for you to review it, saving time all around.

## Know your needs

Having cleared away the clutter of irrelevant questions, you need to think about the project from the perspective of the end product (a document) and the process of getting there (writing by committee). The medical writers should have experience in writing the type of documents that you need in the expected work environment. Is your company a small one with only a few people on the authoring team and simple review cycles? Or is it a multinational organisation with complex processes and long-winded review processes? The latter requires a writer who has worked in this kind of environment on several occasions, and has the confidence and interpersonal skills to herd your team, and get the information needed to write the

document. This is no easy feat. So, ask questions that will help you understand whether the writers can work well in your company's environment and on the specific types of documents you want them to write.

It is all well and good if someone has written 50 periodic safety update reports and 20 risk management plans but, if what you need is a clinical study report and they have never seen one, they may not be very effective. That is why you should ask for details on which documents a company has written. Also ask them about the different types of companies they have worked with (global, small, medium or generic, for example) to see if they will be comfortable working in the setting of your company and its teams.

In addition, ask about their approach to medical writing. How does their approach match with your expectations of how they should interact with your teams? Can they articulate their philosophy of medical writing? Are they wallflowers or will they step in when your teams get stuck, and find ways to make things move forward? A good medical writer needs to be an integral part of the clinical team, so look for medical writing companies that understand this and aim to provide this service.

### Sufficient information

In the RFP, make sure you give medical writers enough information to truly understand the scope of work. Contrary to popular belief, telling a writer how many subjects there were in a study is not very enlightening. The things that make a difference to the amount of time spent on writing are the number of things to actually write about. For example, how many efficacy variables did the study assess? How many sensitivity analyses will be made and how many subgroups will be analysed? Are there any extra safety parameters beyond the standard adverse events and laboratory assessments, such as prolonged QTc analyses? If you need someone to update an investigator's brochure (IB), how many new studies will be added? The time needed to summarise one study is a fifth of that needed to summarise five studies. Does the IB need a radical reduction now that there is considerable clinical data, or is it fairly streamlined already? Will authors provide text that the medical writer only needs to weave together or will the writer need to produce all the text from scratch? These are the things that have a direct impact on how much time will be spent on writing, and, without this information, it is impossible to make an accurate estimate of what the cost will be.

The boxout (right) offers suggestions for the type of information an RFP should provide to help define the scope. You may decide not to give the writer all of this information simply to see if they are experienced enough to come back and ask for it themselves. But you should be prepared to give them all this information when they ask. Often, the easiest way to provide the information is by giving them key source documents that outline most of the important details, such as study protocols and statistical analysis plans. Spend some time internally assessing what your process is so that you can accurately describe it to the writer. Think about what a typical review process at your company involves and how many people contribute to the documents. In general, the more people involved, the longer it will take to get a document written.

Finally, give the companies to whom you send an RFI or RFP sufficient time to properly respond. Good medical writers are not sitting around with nothing to do and waiting for the next request to come through the door. It takes time to look at the material provided, assess the complexity of the document(s) to be written, develop a budget that is tailored for the specific project, and respond to questions about the company and its experience. If you expect them to turn around a response within three days, it is likely not going to be very accurate or detailed simply because there was not enough time to make it so. Plan for at least ten working days for candidates to respond to your requests.

The key takehome message is that RFIs and RFPs are a two-way process. You are seeking information but the quality of the answers you get will be a direct reflection of what you have provided. Take the time to craft an RFP that is focused on medical writing activities and seeks to understand the writer's experience while giving them sufficient information to have a clear understanding of the scope of the project to be done. This will improve the nature and comparability of the responses you get, and it will make it that much easier for you to select a suitable medical writing provider. ■

**Julia Forjanic Klapproth**
Julia Forjanic Klapproth co-founded Trilogy Writing & Consulting, a company specialising in providing regulatory medical writing. In addition to managing the company as senior partner, she writes a wide array of clinical documents including study protocols, study reports and clinical parts of CTD submission dossiers.

## Checklist of items for good RFPs: providing the vendor with the right information

- How many SOPs and guidance documents does the client have in place for the writing processes?
- Will comments on review cycles be provided in a consolidated format? Does the client use reviewing software?
- How many reviewers will be involved in each round of review? Will the same people be involved in each review?
- Are data outputs (tables, figures and listings) provided in a format that can easily be pasted into the body of the document without the need for reformatting? Or will the writer need to manually create in-text tables?
- For summary documents, how many studies will be included? Will there be an integrated database? If yes, for safety only or also efficacy?
- For study reports or summary documents, how many variables will need to be reported for efficacy, safety, pharmacokinetics and quality of life? Are there other variables? How many subgroups will be analysed for efficacy and safety?
- For IBs, is this a first edition or an update? How many new studies will be added? Is a considerable rewrite needed to reduce and consolidate the document? Will any text be provided by authors or will all text need to be written de novo?