

Medical Writing: Outsourcing Guide

Julia Forjanic Klapproth of Trilogy Writing & Consulting makes some practical recommendations on how to optimise outsourcing with professional medical writers and improve the efficiency of an entire clinical development programme

Medical writing activities are needed throughout a clinical programme. Ideally they begin as early as writing the clinical development plan, and continue through the many stages of a study life cycle (see Figure 1). These activities culminate in writing the clinical dossier of a common technical document (CTD) and responses to questions raised by the regulators and supporting teams at European oral hearings or FDA advisory committee meetings.

However, it is a significant challenge to find experienced, professional medical writers and to manage the outsourcing process so clinical teams have the right support at the times needed. The job of outsourcing medical writing can be broken down into four main stages:

- Identifying what and when best to outsource
- Finding and selecting the medical writing company
- Managing the activities of the services provided

- Evaluating performance – of both the provider and the client – at the end of the project

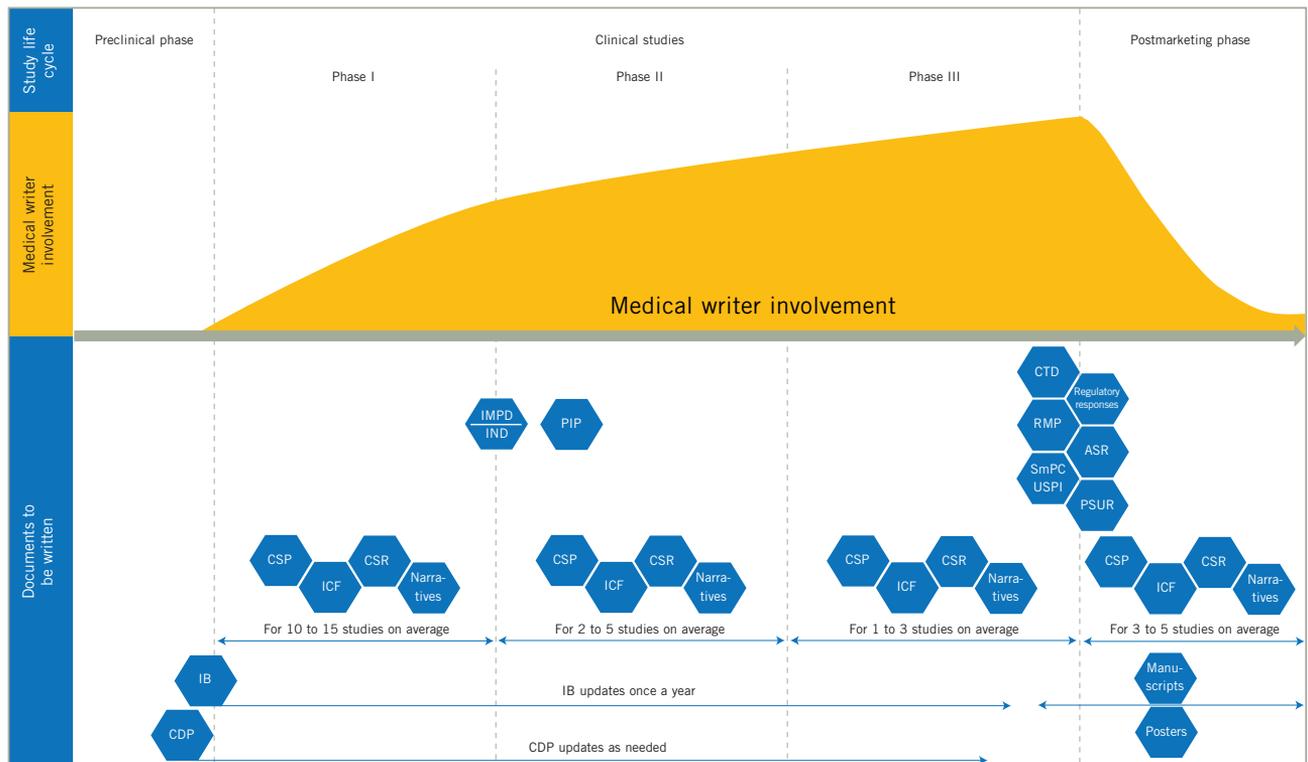
The goal is to have a process that enables you to select a provider who can meet the needs of the team by producing documents that communicate key messages effectively and help reviewers find the information they need. You also want to be sure the providers you select are not hindered by misunderstandings and a lack of communication, and you want to build a productive, long-term relationship based on trust.

STAGE 1: WHAT & WHEN TO OUTSOURCE?

The first step in outsourcing your medical writing should be to plan what documents will be needed and when to outsource them. This is critical to avoid unnecessary time crunches when the documents are required. It is a shame to have a study start late or a dossier submission delayed simply because the team did not plan for all the documents needed.

Having well-written documents earlier in a clinical programme improves all subsequent documents. An experienced writer who gets

Figure 1: Medical writer involvement in clinical development



ASR: annual safety update report
CDP: clinical development plan
CSP: clinical study protocol

CSR: clinical study report
CTD: common technical document
ICF: informed consent form

IB: investigator brochure
IMPD: investigational medicinal product dossier
IND: investigational new drug

RMP: risk management plan
SmPC: summary of product characteristics
USPI: United States packaging insert

Think about this for a minute. What does a medical writer provide? If you think they just ‘get everything down on paper’ and make sure there are no spelling mistakes, you have already lost out on what they can offer your clinical team.

involved early will ensure that the rationale, strategies and storyline of the planned development are well crafted in the early documents. Since the documents needed in a clinical programme quickly multiply, early documents serve as core resources for text and ideas and speed up the need for writing and reviewing later documents.

When initially choosing a new provider, don't be afraid to start with a small document as a pilot project. This gives both sides a chance to get to know each other, and gives you a chance to see how the writers work and if they fit well with the clinical teams they will be supporting.

STAGE 2: FINDING & SELECTING A MEDICAL WRITING COMPANY

A wide range of different types of companies offer medical writing services, all promising quality documents that will be delivered on time. But for many, medical writing is not a core competency. For example, the core expertise of many CROs is the running of studies, data management, and/or statistical analyses; many only offer medical writing because clients want the associated study documents as part of a package deal.

Clearly then, the difficulty is finding out which companies truly have the skill sets and experience to meet the medical writing needs of your clinical teams. To assess this, consider the following:

Company Expertise

Does the company offer medical writing as a true expertise, or is it a tag-on function? Ask how many years their medical writers have been writing and how many types of documents they have written. It is the breadth of experience with different types of documents and indications that gives a writer the ability to suggest creative and effective ways to communicate an idea and present your data.

Timeline Considerations

Does the company make a recommendation for timelines? If so, how detailed is it? An experienced medical writing group should provide a time schedule that outlines all of the activities that will be involved from kick-off to delivery of the final draft. This gives you an idea of how well they understand the reality of writing, reviewing and finalising a document. It also lets you know if they understand the resource needs that are expected from their side.

The Questions They Ask

What kind of questions do they ask you? Good medical writers are more than simply collators of information. Are they noticing gaps in material you provided and asking about it? Are they questioning or pointing out to you the challenges they see in the request you have made (for example in the required timelines)?

Do they make any counter suggestions for helping the team overcome these challenges? What they ask gives you some insight into not only how much experience they have, but also whether or not they seem willing and able to work with you to find pragmatic solutions to get the job done.

Their Relationship with the Team

Do they recommend that their writers have direct access to the key team members? It is important to integrate the writer into the clinical team and make sure they are not hindered by a middle-person to get explanations and clarifications on specific topics. The ‘Chinese whispers’ approach of getting information has the inherent risk that some information may get lost along the way. Plus, the writer can aid in keeping the project moving by proactively getting the information they need from the team.

Feedback

How do they plan to deal with team comments and how will they communicate open issues with the team? Do they have a system for this? Is it practical or complicated?

Getting answers to these (and perhaps other similar) questions will give you a fairly accurate idea of whether or not the provider is truly a specialist in the area of medical writing, and will give more depth to your choice than basing it purely on cost.

PREPARING COST PROPOSALS

There are things you should do to help the providers prepare the best possible cost proposal. When preparing your request for proposal (RFP), make sure you provide sufficient information and enough time to prepare the bids. Make it very clear what your expectations are for the project. Tell them things like:

- How many review rounds does your company usually have (that is, how many drafts are likely to be needed for each document)?
- Do you want the writing company to carry out a thorough quality control check or will you do that through an internal function?
- Do you want them to prepare the appendices of a report?
- Do you want them to publish the report electronically as a single, consolidated file?

An RFP that simply defines the project as ‘the writing of the clinical part of a CTD’ is like asking the provider ‘how long is a piece of string?’ Get into the habit of collecting sufficient background information about each project and giving this to the providers from the start. Clearly define each of the activities

you are requesting and be open to discuss any suggestions the writing company has about this (they may have some clever ideas on how to streamline some activities). Understanding exactly what you want to outsource not only helps the service provider make a realistic bid, but it also helps you know what you are really buying and gives you a better chance of selecting the right company to do it.

A recent article highlighting key problems of the RFP process found that most problems are a direct result of too little time for the RFP process (1). Similarly, a survey performed in 2008 by Industry Standard Research Reports found that most pharmaceutical companies give CROs only 10 working days and limited information to prepare their proposals (2). When bidders have too little time they tend to provide less information and standardised responses, which gives you less insight into the individuality of the provider. Give bidders adequate time to prepare their proposals, including time to ask questions, get answers, and digest the responses, and you will have more meaningful information on which to make your choice.

You should also see the RFP process as an opportunity for both sides to get to know each other. Make time to personally meet the service providers you are interested in together with the clinical lead from the team they will be working with. Ask questions about the experience of their writers, why they think they have the skills to prepare the documents you need and how they measure their success as writers. This is also another opportunity to answer any other open questions they may have and to see how well the two sides communicate and negotiate about the project. Begin building a relationship with the service provider at this early stage and establish an interaction based on open and transparent communication.

STAGE 3: MANAGING THE SERVICES PROVIDED

Outsourced service providers in general, and medical writers in particular, should be ‘part of the family’ and not just ‘one of the servants’. It can be very difficult for a writer to get the right messages in place if companies don’t integrate them into the clinical teams. Medical writers are often not invited to strategic meetings, for example with management or key opinion leaders, so they are out of the loop on background, decisions and strategy.

Think about this for a minute. What does a medical writer provide? If you think they just ‘get everything down on paper’ and make sure there are no spelling mistakes, you have already lost out on what they can offer your clinical team. An experienced medical writer brings a wealth of knowledge about how to structure thought, present information effectively and guide you through the documentation process. A well-written document communicates

without the reader having to work at it, which ultimately reduces the time for assessors to review the documents (3).

Communicating effectively is about capturing the many nuances behind an idea. If a medical writer is never able to listen to discussions about the study or the product, then they cannot have a true understanding of the choices made. How then can they accurately communicate many of the implications behind these decisions in the texts they write? Effectively explaining the rationale and strategy, as well as understanding how these may apply to different parts of a document, is equally important when writing a clinical study protocol as it is when writing the summaries of a clinical dossier. By understanding the rationale and arguments behind the thoughts, a writer can suggest how best to build the information into a coherent story that sets out exactly what it needs to say.

In addition, writers who have been working on your projects for some time may bring insight from other studies and documents that can be invaluable. If they are present during strategy meetings, they may see gaps in reasoning or details that can be important to making the right decisions.

So a large part of managing the ongoing medical writing services should consist of making sure the writer is an empowered member of your clinical team. This means there has to be a company culture that educates internal teams to embrace their external members. You should ensure that:

- The writer has all of the relevant information needed as soon as it becomes available. It is a shame for a writer to continue to work on a document after a decision has been made or new data are available that will change what they have written. This results in unnecessary costs and potential time delays that could have been avoided.
- There are regular team meetings. This is to discuss not only new drafts of documents, but other sources of new information (for example, recent feedback from the key investigator about a protocol).
- Team meetings include all contractors. If separate providers are involved for different services (for example, one company to perform the study, another to do the statistics and another to write the documents), these should all be at the regular team meetings. This enables the team to discuss the issues from these different areas as a group. Having meetings with each provider separately slows the process of communication and increases the risk that not all information is communicated to all involved parties.

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- Internal teams listen to and use the expertise of their external providers. There is no point in hiring someone as specialist and then not listening to them. Writers often have good suggestions for planning, coordinating and performing the writing activities and these can help teams optimise getting the job done. So listen to them and take their advice. That is what you are paying them for.

STAGE 4: EVALUATING PERFORMANCE AT THE END OF THE PROJECT

You want to avoid an outsourcing model designed to find the cheapest bidder on a one-document-at-a-time basis. Clinical teams benefit by having the same writers produce several, if not all, of the documents on a project because they become familiar with the background and strategy of the product. They know the details from across documents and can better ensure that subsequent documents are consistent with these. They also understand the dynamics of the team they are working with. So, if a writer or group of writers is good, it is in everyone's interest to keep them as part of the clinical team once they have started on a programme.

Evaluating the performance at the end of the project is therefore important to decide whether to continue with the same writing company for future projects. Once the final activities on a project are complete, take the time to meet with the key clinical team members and the medical writer(s) to share and discuss everyone's thoughts on how well the collaboration worked. Prepare a list of those things that both sides felt worked well and those things that need improvement. Then discuss these and work together to define a solution.

Listen to the feedback from the writer about areas that may need improvement internally. Many writing projects spiral out of control because the team is unable to give the writer clear instructions. This may result from divided opinions within the company or a lack of leadership within a team. To save face, internal groups often put the blame on external providers rather than acknowledging that the problem was a result of an internal communication breakdown. It is a shame to lose a good writer, who has already become familiar with your product, just because nobody took the time to identify the true source of a problem (which might have nothing to do with the writer).

Working together with your writing provider to identify and resolve problems is worth the effort and an important part of optimising the overall process of outsourcing medical writing. A survey conducted in 2009 (4), found that the top four relationship management tools considered to be moderately to highly effective were:

- Negotiating a relationship management plan with the provider
- Co-developing performance metrics with the provider
- Conducting periodic lessons learned reviews with the provider

- Allowing the provider to use its own SOPs (after the sponsor has reviewed them for adequacy)

CONCLUSION

When outsourcing medical writing, you need to select medical writers who not only understand the needs of each document, but are also proficient coordinators and who will challenge your clinical teams to present a clear, well-argued story. It takes time to develop a good relationship with a provider and you should have an expectation of a long-term commitment to get the most from your investment. Both sides need to work together, communicating frequently, integrating the writers onto the clinical team, and sharing good and bad experiences from working together to develop and maintain a relationship that is mutually beneficial. By doing this, and using the suggestions presented here to identify and retain a company with medical writing expertise, you will find that you can save time and money at all stages of your clinical development programme.

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About the author



After receiving her PhD in Developmental Neurobiology, Julia Forjanic Klapproth started her career as a medical writer in the pharmaceutical industry at Hoechst Marion Roussel (now Aventis) in 1997. Since then she has been President of the European Medical Writers Association (EMWA) twice. Julia is also an experienced trainer of medical writers, regularly running workshops for EMWA and pharmaceutical companies around the world. In 2002, Julia co-founded Trilogy Writing & Consulting, a company specialised in providing medical writing. In addition to company management activities as Senior Partner and CEO, she continues to contribute her enthusiasm to client projects, writing a wide array of clinical documents. Numerous clients have depended on and appreciated her expertise in writing and coordinating study protocols, study reports and CTD submission dossiers. Email: julia@trilogymw.com