Successfully outsourcing medical writing

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Abstract

A large proportion of medical writing activities are now outsourced. This means the need for medical writing service providers is growing, and with increased demand there comes an increased supply of providers. The challenge that arises in such a rapidly growing field is to develop a system that enables outsourcing departments to efficiently select and utilise the right vendors for their needs. This article will provide some practical advice on how to optimise outsourcing with professional medical writers and to bring their particular skill sets to bear to help clinical teams prepare their regulatory documentation more efficiently.

Keywords: Strategic outsourcing, Medical writing, Vendor management

Outsourcing activities have grown steadily over the last two decades, and the newest forecasts do not show signs of a slow-down in this trend. Recent analyses suggest the global contract research organisation (CRO) market will grow with a compound annual growth rate of 9.83% between 2014 and 2019.[1] Since medical writing activities are needed throughout a clinical programme, the demand for these services is a constant in the clinical development landscape. Medical writing activities begin as early as writing the clinical development plan, continue through the many stages of a study life cycle (Figure 1), and 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. With an increased regulatory focus on transparency in sharing clinical data and pharmacovigilance strategies during clinical development, the demand for writing services is expanding.

However, outsourcing activities to a medical writing service provider is a different beast than outsourcing activities such as monitoring or performing a clinical study. The challenge lies in finding experienced, professional medical writers and managing the outsourcing process such that clinical teams have the right support at the times needed. There are four main stages involved in outsourcing medical writing: (1) identifying what and when best to outsource, (2) finding and selecting the medical writing company, (3) managing the activities of the services provided, and (4) evaluating performance (of both the provider and the client) at the end of the project. The process should enable you to select a provider who can meet the needs of the clinical team by producing documents that communicate key messages effectively and help reviewers find the information they need. The ultimate goal should be to build a productive, long-term relationship with a core team of writers who are an integral part of your clinical team.

Box 1: The four main stages of outsourcing medical writing

1. Defining what and when to outsource
2. Finding and selecting the medical writing company
3. Managing the services provided
4. Evaluating performance at the end of the project (of both the provider and the client)

So, what's the trick to getting this right? The following is a set of guidelines and suggestions that can help make the outsourcing of medical writing activities a better experience for everyone.

Stage 1: What and when to outsource?

Once a clinical development plan is in place and the studies are planned, the timing for almost all of the documents that will be needed to support that plan can be defined fairly well (usually to within a

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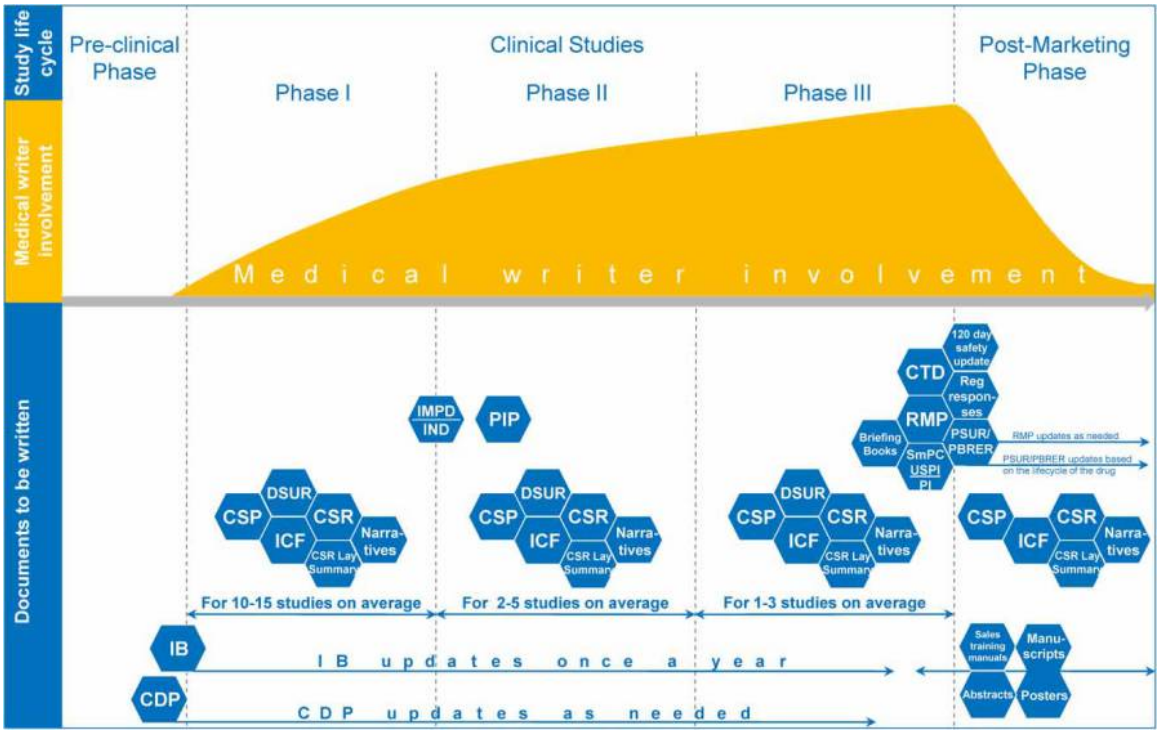

Figure 1: Medical writer involvement in clinical development. Medical writing activities begin as early as writing the clinical development plan, continue through the many stages of a study life cycle, and culminate in writing the clinical dossier of a Common Technical Document and responses to questions raised by the regulators and supporting teams at European oral hearings or FDA advisory committee meetings. With an increased regulatory focus on transparency in sharing clinical data and pharmacovigilance strategies during clinical development, the demand for writing services is expanding. Abbreviations: ASR, annual safety update report; CDP, clinical development plan; CSP, clinical study protocol; CSR, clinical study report; CTD, common technical document; IB, investigator brochure; ICF, informed consent form; IMPD, investigational medicinal product dossier; IND, investigational new drug; PIP, paediatric investigation plan; PSUR, periodic safety update report; RMP, risk management plan; SmPC, summary of product characteristics; USPI, United States Packaging Insert.

quarter of a given year). Teams know they will need a protocol for each study planned, that an Investigators Brochure will be needed from the start of the first study and will be updated annually, that Development Safety Update Reports will be needed throughout the programme, and that clinical study reports will be needed within a year of completing each study. None of the deadlines for these documents needs to come as a surprise and cause unnecessary stress on teams as they scramble to find resources and time to prepare the documents.

When a team has identified that it will need medical writing support, outsourcing of the medical writing activities should begin with a plan of what documents will be needed and when. Sit down with the clinical team and walk through the clinical development plan with them. Map out which documents will be outsourced and when they will be needed. Repeat this exercise every 6 to 12 months, and keep your vendors updated of shifts in the plan in a timely manner.

Helpful tip: Having well written documents earlier in a clinical programme improves all subsequent documents. An experienced writer who gets 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 in later documents. Having these nicely crafted in the early stages of a programme reduces the time needed for writing and reviewing of later documents. So think about ways to get medical writers involved earlier rather than later.

Stage 2: Finding and selecting a medical writing company

Ask the right questions

There are many different types of companies offering medical writing services, all promising quality documents that will be delivered on time. But on closer inspection, medical writing is often not a core competency for many of them. The core expertise of most CROs is the running of studies, data management, and/or statistical analyses; many CROs only offer medical writing because clients want the convenience of having a single vendor

run the study and provide the associated study documents.

The difficulty thus lies in determining which companies truly have writers with the skill sets and experience to meet the medical writing needs of your clinical teams. There are several things you can ask to find this out, including the following:

- **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.
- **Does the company recommend timelines for preparing the documents? How detailed are they?** An experienced medical writing group will provide a time schedule that outlines all the activities that will be involved from kick-off to delivery of the final draft. Getting this from the writer tells you how well they understand the reality of writing, reviewing, and finalising a document. It also lets you know if they understand the scope and resources expected from their side. And it will make clear whether or not the expectations from your team's side are realistic.
- **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? Do they question or point out to you the challenges they see in the request you have made (e.g. in the required timelines)? Do they make any counter-suggestions for helping the team overcome these challenges? Their questions give 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.
- **Do they recommend that their writers have direct access to the key team members?** This shows they understand that integrating the writer into the clinical team is one of the most effective ways to streamline the writing process. Removing the need for a middle-person to get explanations and clarifications on specific topics avoids the 'Chinese whispers' approach to getting information to and from the writer, which has the inherent risk that some information may get lost along the way. When the writer is a fully-fledged member of the clinical team, they are empowered to keep the project moving by proactively getting the information they need from the team when and as they need it.
- **What is their system for dealing with review comments?** Does their company have a well-defined procedure in place that outlines how to process reviewer comments? Is it practical or complicated? How will they communicate open issues with the team?

The answers to these (and 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.

Provide the right information

Part of ensuring you get a meaningful response to your request for proposal (RFP) depends on providing sufficient information for the vendors to make a fair assessment of the scope of the project and to give them enough time to prepare the bids. Make it very clear what your expectations are for the project. And be realistic: if you know the plan according to your SOPs is for two drafts and a final version, but no team in the history of your company has ever achieved this, then you cannot be surprised if the vendor comes back needing a change order when they get to the third draft. So be honest with yourself and give them a realistic description of what to expect. Tell them things like:

- How many rounds of review your company usually has (i.e. how many drafts are likely to be needed for each document).
- How many reviewers will be involved in each review round. Will their comments be consolidated before coming back to the writer, or will the writer need to consolidate them?
- Whether you want the writing company to do a quality control check or if it will be done by an internal group.
- Whether 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 (they may have some clever ideas on how to optimise some activities). Understanding exactly what you want to outsource not only helps the vendor make a realistic bid, it also helps you know what you are really buying and gives you a better chance of selecting the right company to do it.

Most problems that arise during RFPs are a direct result of too little time for the RFP process.[2] A survey performed in 2008 by Industry Standard Research Reports[3] found that most pharmaceutical companies give CROs only 10 working days and limited information to prepare their proposals. In recent years I have witnessed requests with as little as 3 to 5 days' turn-around time. 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. Giving bidders sufficient time to prepare their proposals, including time to ask, get answers to, and digest the answers to all their questions, will get you more meaningful information on which to make your choice.

Helpful tip: See the RFP process as the opportunity for both sides to get to know each other. Make time to personally meet the vendors you are interested in, including their lead writers, together with the clinical lead from the team they will be working with. Ask questions about their experience as writers, why they think they have the skills to prepare the documents you need, and how they measure their success as writers. This is an 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 to 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 communicate the right messages if companies don't integrate them into the clinical teams. Unfortunately, medical writers are often not invited to strategic meetings, e.g. with management or key opinion leaders, which leaves them 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 the data down on paper and make sure there are no spelling mistakes, you have already lost out on what they can offer your clinical teams. 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 document.[4]

Communicating well is about capturing the many nuances behind an idea. If your medical writer is never able to listen to discussions about the study or the product, they cannot have an in-depth understanding of the decisions and choices made. How then can they accurately communicate the implications behind these decisions and choices in the texts they write? Effectively explaining the rationale and strategy, and understanding how they 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 argumentation behind the thoughts, a writer can suggest how best to build the information into a coherent story that says exactly what it needs to.

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

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 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. These will address the status of timelines for all deliverables (e.g. due dates for tables, figures, and listings, input from team members, impact on upcoming drafts of the document), as well as changes in strategy or new information (e.g. recent feedback from the key investigator about a protocol).
- Team meetings include all contractors. If separate providers are involved for different services

(e.g. one company to perform the study, another to do the statistics, and another to write the documents), they should all be at the regular team meetings. It is important that all issues are discussed as a cohesive team. 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.

- 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.

Helpful tip: When you first start working with a new provider, consider starting with a small document or a well-defined series of documents as a pilot project. This gives both sides a chance to get to know each other and learn how to work together. Remember, you are building a relationship, and investing in ironing out bumps at the beginning can go a long way to solidifying the team for the long-run. It also gives you a chance to see how the writers work and if they fit well with the clinical teams they will be supporting.

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 write several, if not all, of the documents on a project because they become familiar with the background and strategy of the product. Over time, a writer better understands the dynamics of the team they are working with, which helps them establish a more efficient working rapport with that group. In addition, they accumulate knowledge from across documents and can better ensure that subsequent documents are consistent with each other. 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. Much as you would the clinical lead or the statistician.

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 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 decide how to resolve areas that were bumpy.

Listen to the feedback from the writer about areas that need improvement. Many writing projects spiral out of control because the team is unable to give the writer clear instructions. Common reasons for this are divided opinions within the company, lack of communication internally, and/or lack of leadership within the clinical team. This frequently results in the writer receiving mixed messages (about content, changes in deadline, etc.). To save face, internal groups often put the blame on external providers rather than acknowledging that the problem was really a failure in their own team dynamics. It is a shame to lose a good writer, who has already become familiar with your product and company processes, 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 is an important part of optimising the overall process of outsourcing medical writing. But don't just take my word for it. A survey conducted in 2009[5] found that the top four relationship management tools considered 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).

Helpful tip: When developing metrics to measure key performance indicators, remember to include metrics for measuring your internal group's role in the process. It is not sufficient to simply measure whether the draft of the report was delivered late. You need to look and see whether deliverables from your side (e.g. source materials, review comments, etc.) were delivered on time too. Perhaps the drafts were all late, but upon scrutinising the statistics you will find that they were all delivered within the predefined turn-around time for writing activities, and it was the source delivery date that skewed the timeline.

Box 2: Helpful tips

1. Having well written documents earlier in a clinical programme improves all subsequent documents. Think about ways to get medical writers involved earlier rather than later.
2. See the RFP process as an opportunity for both sides to get to know each other. Spend time talking to the vendor, including their lead writers, to see if it feels right at the individual level, and not just on paper.
3. Consider starting with a pilot project to help both sides get to know each other.
4. Metrics of key performance indicators should measure your internal group's role in the process as well as that of the medical writer to fully understand the source of problems.

Conclusion

Successfully outsourcing medical writing requires choosing 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 will hinge on developing a good relationship with a vendor and you should be aiming for a long-term commitment to get the most from your investment. The key to success lies in working together, communicating frequently, integrating the writers onto the clinical team, and sharing good and bad experiences to develop and maintain a relationship that is mutually beneficial. The suggestions presented here will help identify and retain a company with medical writing expertise, which will ultimately help your company save time and money at all stages of your clinical development programme.

Author information

Julia Forjanic Klapproth became a medical writer in 1997. Since then she has been president of EMWA twice and is actively involved in the medical writing community. As Senior Partner of a medical writing consultancy for the last 13 years, she is keenly aware of the challenges in successfully outsourcing medical writing.

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