



Battling with clinical submissions: War rooms and other tricks of the trade

by Julia Forjanic Klapproth

Among the gamut of documentation one works on as a medical writer, I would argue that a submission dossier is one of the most interesting – and the most challenging. The summary documentation reflects a compilation of a broad spectrum of data and information and culminates in the clinical overview (CO). In this 30-page report, the author has the task of condensing many different messages from numerous studies, and often years of research, into a single, concisely written document with a consistent take-home message. The CO is supported by two broader summary documents, the summary of clinical efficacy (SCE) and the summary of clinical safety (SCS). These provide a comprehensive summary of all data that is being provided in the dossier, looking at the results both on a study-by-study basis as well as in an integrated, across-study manner (in as far as this is possible). But preparing a dossier is rarely just a writing task: it is a multifaceted activity often requiring skills in diplomacy, team management and project planning.

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A writer working on a submission project is frequently faced with project teams of individuals from different functions and departments, each with a slightly different agenda. Although it would seem obvious that everyone is working towards a common goal, in the midst of the game, one often wonders if these individuals are all on the same team! And as the writer your job is to cull the necessary information and messages from each of these functions and prepare a document with a unified message. More often than not it falls to the medical writer to mediate and bring the people together in some way – to find agreement on what needs to be communicated.

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As someone who basically goes from one submission dossier to the next, and on more than one occasion has a couple of submission projects running in parallel, I've developed a few survival techniques for making a smooth ride out of what could otherwise be a bumpy one. It isn't really magic to figure these things out. It is more a matter of learning from experience and understanding human nature. The first hurdle to overcome often presents itself at the

very first meeting with a project team, and comes in the form of the project plan. Every team I've ever worked with has always started by plunking down a perfectly designed time line for preparing the dossier in question, and they sit about and stare at it somewhat like a mother at her newborn infant. It is a holy thing, and they are incapable of even imagining that there might be any kind of slippage in that preciously formed plan! But there will be. There is always slippage in every plan. And as the person who is going to be expected to meet deadlines at the end of that plan when it starts jumping around like a cat on hot coals, you'll be doing yourself a favour to point this out to the team right at the beginning. Now don't get me wrong. Don't get all holier-than-thou about the issue or be too dogmatic. Just make it a point to gently suggest to the team that there should be contingency plans in place for adjustments to the plan when things start slipping. Be ready to smooth down ruffled feathers and wipe away some of the spittle as

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people have a knee-jerk reaction to your suggestions, but hold your ground. The team will respect you for it later when the slippage sets in.

So, now that you've managed to develop a plan that is still wildly unrealistic, but with a little more breathing room, it's time to get writing.

Where do you start? Generally it makes good sense to begin by developing the framework of the SCE and SCS before preparing the CO. This may seem obvious to some of you, but you would be surprised how many teams I have encountered who actually think I should finalise (yes, finish!) the CO before starting with the SCE and SCS. The rationale for doing it as I suggest is that the CO not only condenses the story, it is the place where we're meant to discuss and highlight points of contention in the data or clinical programme. And it is very frequently in the course of writing the SCE and SCS that these points come to light. In the process of comparing data across studies, patterns arise or discrepancies become apparent (which of course is exactly the purpose of looking at the data this way). It is only then, as the team debates how to present these data in the SCE or SCS and what exactly they need to communicate about them, that the foundation is laid for what will be presented and discussed in the CO. So do yourself a favour. To save yourself from having to rewrite the CO, advise the

team that they should begin with the SCE and SCS and then distill the CO from those documents afterward.

OK, so you've put all your data together into your summaries and it's time to start crafting the CO. One of the first things you should do is find out if there are any guidelines from the authorities to whom you will be submitting the dossier on your particular indication or treatment regimen. Just go to the website of the agency in question and do a search for your therapy and the indication. If there are any guidelines, these need to be addressed in the CO, referring to how the clinical programme either did (or did not) comply with these. Then, make a bulleted list of the risks and the benefits of your compound or device. This will help you to make decisions on what data need to be presented in the CO directly, and how to present it all as a succinct, cohesive story. Remember, this is where you pull the information together to tell the story. Each of the pieces needs to fit together to make a complete picture. By taking the time to define up front what pieces you have, you can more effectively slot them into place as you develop the story.

Lastly, make sure you have a copy of the most recent version of the product label that the company is intending to submit. All claims and statements in the label need to be supported by statements in the CO. Now, don't misunderstand this to mean you need to have all the data itself in the CO. This is one of the few fights I do choose to pick (I pick them carefully) with a project team. Don't be surprised if you encounter a member of the team from pharmacovigilance or regulatory departments who insist that it is a requirement to list all adverse events in the CO because these are given in the label. This is not a requirement. As long as the main statement supporting the claim in the label is made in the CO with a cross-reference to where the complete data can be found in the SCE or SCS, nothing more is needed. And to be quite honest, there isn't space in the CO for more than that.

Right, so now you have pretty well-developed drafts of the different parts of your dossier. It's time to finalise them and get that puppy off to the agency. To do that, however, you will need buy-in from each different function on the team. Have you ever tried getting a bunch of people to review a document and come to agreement on the final wording by email? It can be at worst a nightmare, and at best a long, drawn-out procedure. Enter the "war room" strategy, a concept taken from US President Bill Clinton's election campaign "rapid-reaction centre".

Basically, you bring the key decision makers from each function on your team and you lock them in a room until they come to agreement on every line in the file. Rule Number one is that once they agree on what is final, there is no changing their minds after they leave the room. This

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sounds more gruelling than it is. Essentially, this boils down to human nature. The most efficient way to resolve points of contention is to have the people involved discuss it face-to-face. By bringing the team together, everyone has the opportunity to present their perspective on any outstanding issues and the group can come to a decision together. The primary advantage of this is that you as the writer are not left with a collection of conflicting opinions and having to find a way to implement them while making everyone happy. As the team is responsible for the final content and message of these documents, they need to agree among themselves on how to resolve these conflicts. And sitting around a table together is the best way to make it happen.

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So there you have it: a few key things to keep in mind when preparing a clinical submission dossier. Obviously when you get deeper into the nuts and bolts of these documents there are numerous possible pitfalls. But in general it all boils down to keeping your head, standing your ground and being pragmatic. Only pick the fights that matter, so think about what it would mean if you don't get your way on a given point before you dig in your heels. And don't forget to have fun.

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