Good Review Process – The New Panacea

Over the last 25 years, the way we write regulatory documents has evolved – from lean writing to technology that aids in populating the reports we write, things have gotten more streamlined. Which is a good thing, considering the goal of this endeavour is to get new drugs out to patients who need them as quickly as possible. Yet there is one area that has seen very little progress during that time: the review process by which teams of co-authors review and comment on drafts of a document.

The industry as a whole is striving to reduce the time needed to complete the regulatory documents we prepare. Statistics show that, on average, it takes about 8 weeks to prepare a clinical study report, ranging up to 33 weeks.[1] Many people are looking to technology to make a dent in these times. However, technology can only really help reduce time on the first step of drafting an initial draft of any document. What it cannot do is replace the cycles of review and crafting of the text that we humans do to develop the storyline and ensure the focus is on the right data. Unfortunately, that is where most of the blood, sweat, and tears are spent on preparing these reports. A survey of members of the European Medical Writers Association found that the average time spent on review cycles is about 60% of the total time required to complete a clinical study report and can be as high as 73%.[1] Although crafting a document depends on team discussion and it is an iterative process to refine the thoughts of interpreting the data, much of that 73% is due to inefficiencies.

So why is this process so inefficient? The review process has many different areas that need to work for it to run efficiently and many of these are often not done properly. There are 5 key problem areas with the review process: a lack of focus and strategic input, poor prioritisation, revisiting previously agreed sections, comments that are late or unfocused, and too many reviewers. The good news is that these are all problems of poor process and/or a lack of understanding on the part of the reviewers about how to provide meaningful feedback. Through some best practices, reviews can be streamlined considerably by helping the reviewers understand how to avoid these problems.

Like with most things in life, doing something well begins with understanding what you are meant to do. How many people who are reviewing these regulatory documents ever have any training on what a good review looks like? Very few. In the absence of a clear concept of how to do something, most humans will fall back on how they have seen something similar done elsewhere and try to mimic that. So, what kind of role models do we have for providing feedback on documents we write? Generally, these are our school teachers and our parents who corrected things we wrote while at school. What did they do when they checked our documents? They got a big red pen and circled all the spelling mistakes and corrected all the commas. So that seems like the obvious thing to do when we provide feedback on these documents.

Yet, this could not be further from the mark of what is needed. The reason we have documents reviewed by teams of people is because different people see different things and bring a different background and perspective to what we are reporting. We also want to get input from each functional area (clinical, statistics, regulatory, safety, etc) on their area of expertise. What we need from these subject matter experts is their specialised input on content related to a particular topic. Their time is precious and their insight is valuable. When we

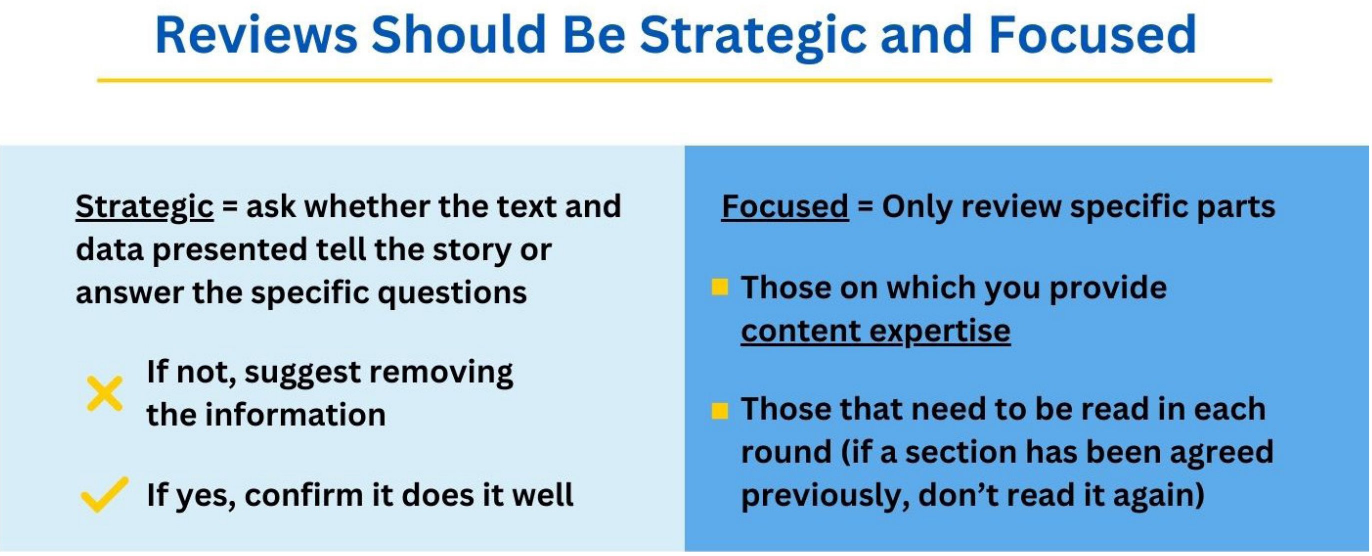


Figure 1

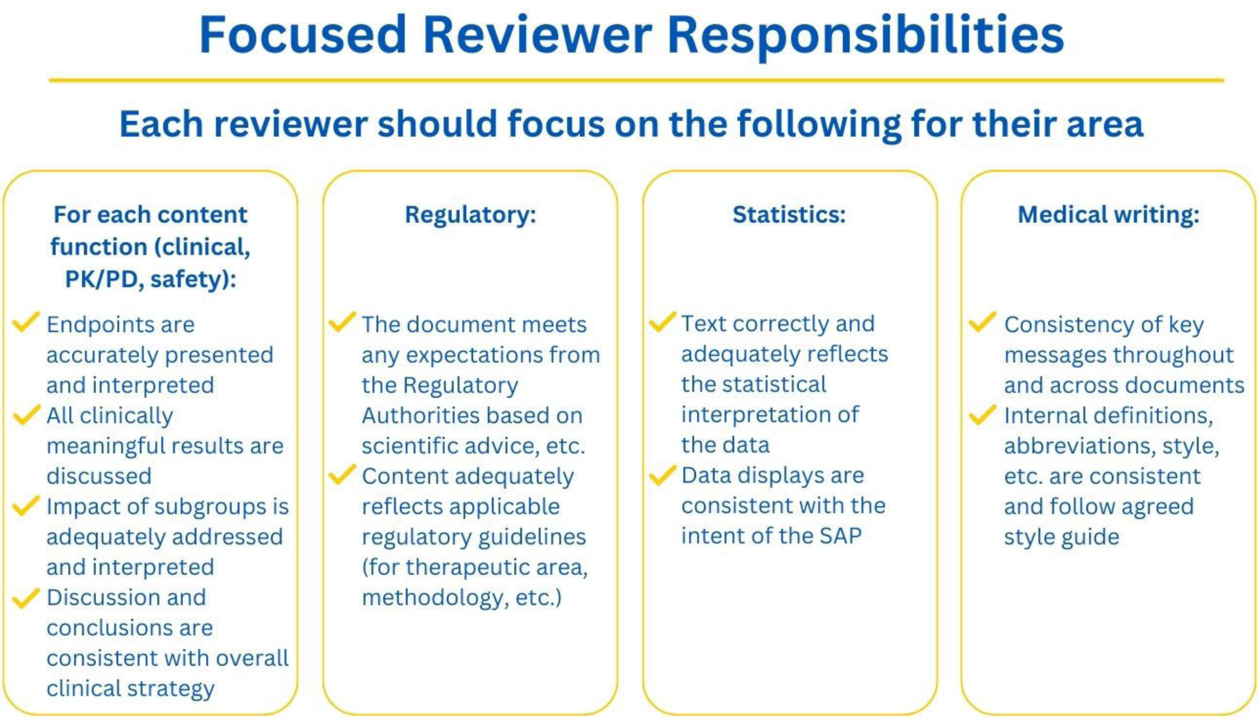


Figure 2

already have a mechanism in place to ensure grammar and spelling are corrected, these specialists should not be spending their time correcting those things, but rather the area for which only they can provide input.

Another way of looking at this is that we have compiled a team of people who all have a particular role to play. Like on any team, if someone is meant to be doing one thing but does something else, it makes the whole system unravel. A pitcher on a baseball team shouldn't be running to the outfield to catch the balls. A violinist shouldn't be grabbing the trumpet in an orchestra. A statistician shouldn't be changing the text to reflect their personal preferences on English style issues (that have been agreed in a style guide). If the functional area experts spend their time correcting 100 commas, that is time they are not spending focused on the content. Teamwork depends on trust: each reviewer needs to trust their colleagues to do the piece they are responsible for.

So what should they be doing? Every study is done for a regulatory reason – to answer a specific question about how the drug works or what its safety profile looks like. Our job when reporting on that study is to explain what that question is and what answer we got to the question. This means reviews of any document need to be strategic and focused (Figure 1).

- A strategic review asks whether the text and data presented accurately and appropriately tell the story and answer the specific questions. If not, the reviewer should suggest how to do this. If yes, the reviewer can confirm it does it well.

- A focused review means the reviewer only reads specific parts of the document: those areas the reviewer provides content expertise (see examples in Figure 2) and those that need to be read in given round of review (i.e. if a section has been agreed previously, don't read it again).

There is something called reviewer fatigue, which is the loss of concentration that sets in over the course of reviewing a document in a single sitting. Generally, a flurry of comments is made within the first 10-15 pages, after which the number of comments drops off as the reviewer begins to lose focus. Sequential review of a document (*i.e.* reading the document from page 1 like a book) leads to reviewer fatigue in later sections of the document, which can result in the need for additional review cycles because reviewers did not effectively read those sections the first time through and then need to review them again. By applying focused reviews, where the reviewer does not start on page 1 each time but goes directly to the sections for which they need to provide content expertise, reviewer fatigue is avoided and the quality of the review of those sections is better.

From a process perspective, there are a few key rules that make for a good review practice (Figure 3). The overarching goal of these rules is to help reviewers think about how to make sure their feedback aids rather than hinders the process. Will a medical writer and the rest of the team be able to do something with their comments? There is no point in making the effort to comment on something if nobody knows what you are trying to communicate.

First, all comments should provide clear directions on what the reviewer is asking or thinking. Comments must be actionable and make clear what the reviewer wants done. Unactionable comments are those that do not inform or instruct, such as the following:

- "?"
- "Bad" or "Unclear"
- "Can't you make it more convincing?"
- "Can we reword this?"
- "I think we said this better someplace else"
- "Perhaps we should be applying for a different dose"

By providing a comment that is unactionable, it will never be possible for someone to just take the comment and do something with it. They will have to come back to the reviewer to clarify exactly what should be changed. Medical writers and the rest of the authoring team should not be guessing about what the reviewer thinks the problem is. That is not an efficient means of communicating and it wastes everyone's time.

Figure 3

Similarly, efficient reviews provide comments in full sentences. Many people have the odd idea that when writing something in a comment bubble it should be in shorthand. It happens frequently that for comments made in shorthand and incomplete sentences, not only does the medical writer not know what is meant, when the reviewer is asked what they wanted to say, they no longer understand what they wrote. So, although they took the time to read the text and write a comment about it, their idea is now lost because they did not write the comment as a full thought, and they do not remember what it was about. Not only was their time wasted, and the processing of their review slowed by the need to clarify the comment, we might have lost a really important idea! So, teach reviewers to give comments that will be clear to everyone who reads them (themselves included).

Proactive revision is more effective than posing a question or just making a comment about what should be changed. If a reviewer thinks a sentence can be improved, it is much more constructive to show the team what they are thinking by rewriting it with revision marks. They should not, however, spend time changing stylistic issues or proof reading. They should stay focused on the content they are responsible for. If needed, the medical writer will top and tail the text to ensure it complies with language and style requirements.

Reviewers should help the team to triage their feedback by prioritising their comments. There is never enough time to deal with every reflection that each reviewer has. Comments should be categorised into major (critical change that needs discussion with the team – you would not sign-off if this issue is not resolved or changed) or minor (content-related but not critical), where minor edits can be ignored if needed. When time is tight, it can speed up processing the review feedback by telling the writer and rest of team which points must be dealt with and which are just nice to have.

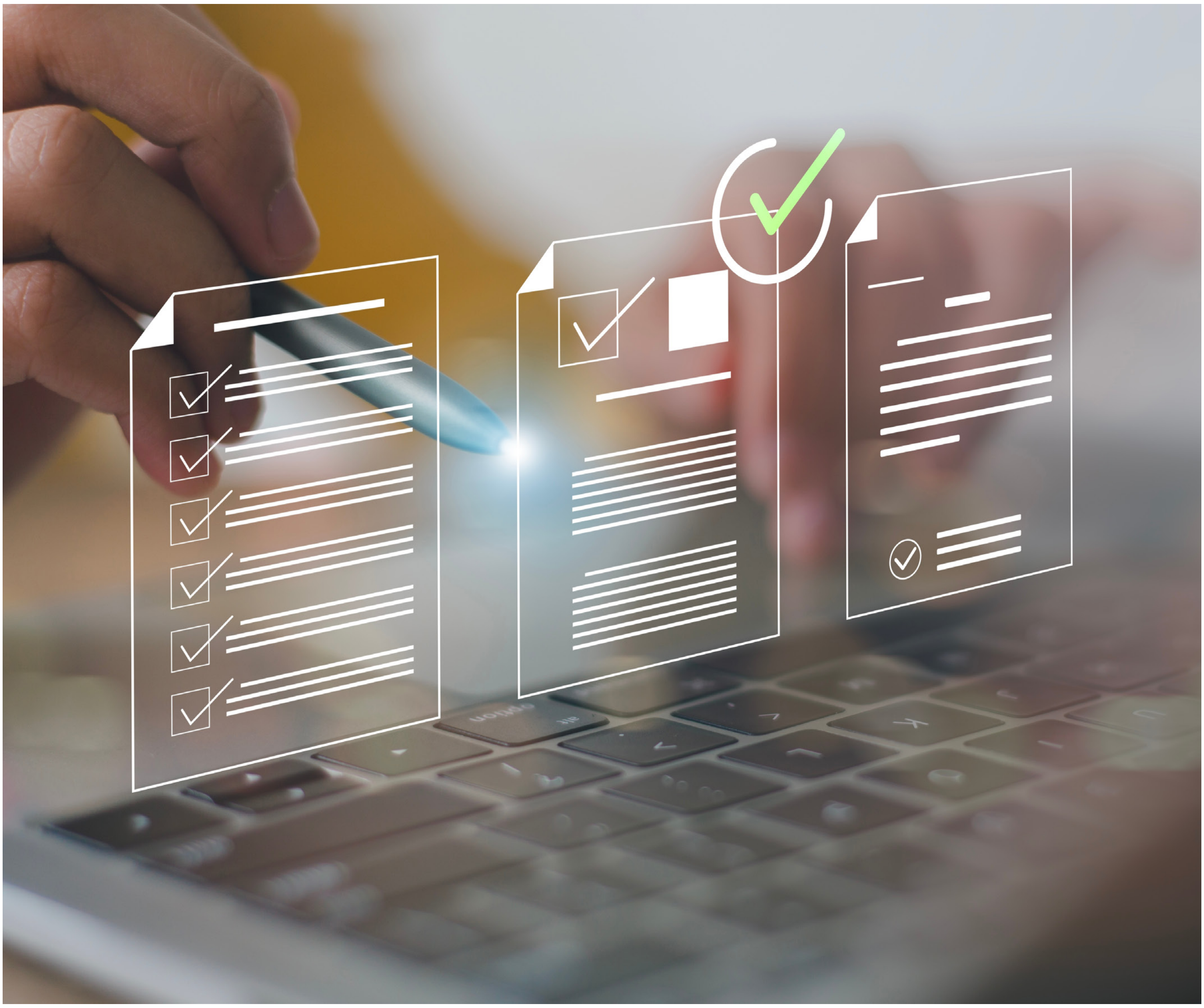
Remember that every review cycle counts. Reviewers should not think that because it is an early stage (*e.g.* Shell) they don't need to pay as much attention. The whole point of having a detailed review of early drafts is to avoid needing to make big changes once the document is fully populated with lots of content. They need to think about each section carefully, even if there is no data yet (or dummy data) and imagine how the planned order of information will flow. Giving good input early avoids the need for rewrites later that result in extra rounds of review and discussion.

Respect locked-down sections. It is essential for the process that reviewers do not revisit texts the team has already agreed on and now consider final. Their time and focus are now needed elsewhere in the document. By reviewing locked-down sections, they are inevitably going to rehash conversations that the rest of the team considers closed and this is not a good use of resources. In addition, if they spend the time allocated for a particular review reading sections they are not meant to be reading, they will need more time to complete the review. Which may delay completion of the review cycle. At a very minimum, they will be spending time on something that is not needed or effective for the process.

Although different functions perform different reviews that focus on their content expertise, there should be just ONE set of comments per functional area. Each functional area should work together to develop a consistent, cohesive position on a given topic. Reviewers should discuss things thoroughly within their function and find proper agreement before giving their comments back to the team. Not doing this results in inconsistent and often conflicting opinions on a particular topic. It is also not an efficient use of the team's time during comment resolution meetings if people from the other functions have to sit and listen to 3 people from the same function debate their stance on something. A unified functional comment saves everyone time because the writer will have a clear instruction on what needs to be done, reducing the amount of follow-up needed.

Finally, for a review process to run smoothly, all reviewers must buy into and comply with agreed timelines for providing their feedback in each round of review. Each document is a wheel in the bigger machine of everything project teams are working on. They are rarely being written in isolation and project plans are juggling the activities of many people working on multiple documents and projects. Not providing comments on time slows down the whole process, throwing out timelines of other documents and teams.

In addition, it is disrespectful to one's teammates if someone does not deliver on time. Every person on a team is working on several



projects and is up against multiple deadlines. Everyone has to plan their workload to make all their activities happen on time. Barring extenuating circumstances, if one person decides they can just take more time, they are implying that their time is more valuable than their teammates because they are, by definition, making the other people wait for them.

If comments come in late, it makes dealing with all comments less efficient. This is because the medical writer and the rest of the team need to know everyone's thoughts before making any decisions on major rewrites or changes. Concerns about timelines that seem unfeasible should be raised right at the start of a project so that all interconnected activities can be adjusted. Or, at a minimum, if someone is not going to make a deadline, they should discuss it with the whole review team and agree together on an extension. This gives everyone the opportunity to juggle their priorities to accommodate the change.

In summary, there are several aspects of reviews that could be done more efficiently in most companies. The good news is that these are frequently the result of people not clearly understanding what they should be focussing on and the impact of their actions. By providing training to reviewers, they can learn these concepts and develop better, more effective review habits. If reviewers follow a few key rules for good review practice (Figure 3), the whole process can and will be a more streamlined activity. Who knows, it might even be fun!

REFERENCES

1. Hamilton S. Effective authoring of clinical study reports: a companion guide. Medical Writing. 2014;23(2).

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