

# Regulatory Matters

SECTION EDITOR



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## Calling all medical writers: Focus your writing with lean authoring

In today's medical writing environment, authors are routinely faced with expedited timelines to write documents about highly complex studies with overwhelming amounts of data. Reviewers are subsequently presented with complex content, with messages often hidden among unnecessary text and numbers. To ensure the important information within our documents is clear, medical writers must use lean authoring principles as standard practice.

### Benefits of lean authoring

Lean authoring is a way of writing that removes unnecessary words and content to focus documents on key messages. Successful incorporation of lean authoring principles leads to streamlined documents that are easy to read, straightforward to interpret, and improve the overall reader experience. Benefits of implementing lean authoring principles include: 1. easily identifiable key messages; 2. reduced writing review and quality control time; and 3. increased quality.

### The lean authoring process

There are three important questions to ask yourself when successfully using lean authoring principles to focus documents on the key messages (Figure 1).

#### 1. Is the text needed?

- Understand the needs, priorities, background, and experience of your audience; knowing this helps drive what text is needed, and the document can be tailored accordingly. For example, introductions for regulatory authorities, which are therapeutic area experts, can be minimal, whereas introductions for academic audiences may require more therapeutic area context.
- Say messages once by using cross-references, keeping content in the section where it belongs, and relying on tables to present data while avoiding numbers in text.



#### 2. Is the message clear?

- Be sure that every word is needed, either to add information or for correct grammar. Why say something in 15 words when you can say it in nine? Simpler language leads to easier comprehension. See Figure 2 for some examples highlighting the beauty of brevity.
- Use consistent terminology and a con-

sistent presentation order to allow readers to focus on the content and move more quickly through the messages. Many teams use a style guide or convention sheet to ensure consistent terminology within and across documents.

#### 3. Is the presentation effective?

- Consider bullet points or tables to present

#### Important in medical writing:

- Large documents
- Data-driven content
- Short authoring timelines

Is the text needed?

Is the presentation effective?



Is the message clear?

Figure 1. The lean authoring process

your information. Visually organised information is easier to understand. For example, is this article easier to follow because of the bullet points?

- Engage your reader by starting with the most important information and by writing precise, nonbiased comparisons. Avoid words such as “always” and “never”, and be sure to use approximate terms such as “most” consistently. Consider establishing cutoff points for when to use terms such as “most”, “more”, “similar”, and “the majority”.

## Implementing lean authoring

Lean authoring may be new, and new ways of working may be daunting to you, your teams, or your organisation. Some teams may be eager to adopt this writing strategy that is becoming our industry standard. For more hesitant organisations, successful adoption of lean authoring will depend on:

- Sponsorship and advocacy from senior leadership.
- Socialisation to gain support from authors, teams, and management.
- Effective training, then setting and reinforcing expectations across projects.
- Processing documents and templates as tools for successful implementation and execution.

**1. Over the course of the study, a total of 31 participants were randomised (21 participants were randomised in Treatment Group 1 and a total of 10 participants were randomised in Treatment Group 2).**

A total of 31 participants were randomised (21 in Treatment Group 1 and 10 in Treatment Group 2).

**2. Table 10-4 displays the demographic information collected for the participants enrolled in the trial, which shows that the mean age of participants was similar in the PJ-123 treatment group and the Hapimab treatment group.**

The mean age of participants was similar in the 2 treatment groups (Table 10-4).

**3. The safety population included all participants who were dispensed study medication in the study and were documented to have taken at least one dose of investigational treatment.**

All participants who received  $\geq 1$  dose of study medication were included in the safety population.

**4. The proportion of participants who reported serious adverse events in Treatment Group 1 was lower than the proportion of participants who reported serious adverse events in Treatment Group 2, as shown in Table 12-5.**

The proportion of participants with serious adverse events was lower in Treatment Group 1 than in Treatment Group 2 (Table 12-5).

**Figure 2. The beauty of brevity**

Instead of using the wordy sentences on the left, try using the clearer sentences on the right.



Our organisation has used lean authoring to reduce document length by 50% to 75%. However, lean authoring is not just about cutting content. It is also about improving the reader experience by efficiently using our documents to focus on the key messages and the most relevant content. Since implementing lean authoring, feedback from our document reviewers has been overwhelmingly positive. With less time needed to read the documents and with key messages easier to understand, many have expressed our documents are even “enjoyable to read” – an attainable goal for all writers and our industry.

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