A REVIEW OF PROCESSES AND SOME BEST PRACTICES FOR NARRATIVE WRITING

Speaker
Karen L. Campbell, MS
Manager, Medical Writer & Consultant, Whitsell Innovations, Inc., Chapel Hill, NC

In the world of clinical regulatory documents, there are 2 kinds of nonfiction stories to tell: that of the drug and its path to approval (or abandonment) and that of the subject. For most documents (protocols, investigator brochures, clinical study reports), the story of the drug takes center stage. Narratives, however, tell the story of individual subjects. They are informative documents that can provide Health Authority reviewers with the necessary details to understand an adverse event or other predefined situation within the context of the subject’s study participation.

In addition to understanding the overall scope of work, including narrative criteria for the project, number of narratives needed, and project timelines, key components of a successful narrative writing project include:

- Understanding the nuances of the source data (eg, final data or a data cutoff, listings or patient profiles, availability of safety data)
- Creating a detailed and thoughtful process (eg, assessing and customizing the narrative template, understanding the review process, ensuring compliance with the style guide)

The variety of data sources can add complexity. Typically, source data for narrative writing include data from a clinical database (eg, listings, patient profiles) and data from a safety database (eg, CIOMS, MedWatch). Determination of the appropriate source in case of a discrepancy between the source data ensures consistency of the narratives.

Creating a template allows for consistency between narratives in the study as well as across studies within the same overall project. Whether a template is provided by the sponsor or one is developed for a specific project, annotating the template provides several advantages: it (1) confirms that all source data have been provided to complete the narrative, (2) allows sponsor preferences and style guide requirements to be built in, (3) ensures consistency with the data used (especially if there are multiple writers on the project), and (4) helps the quality-control (QC) reviewer know where to find the data used.

Once the writing has started, tracking the progress of each narrative supports the successful on-time completion of the project. A spreadsheet noting the author and the dates of completion of the draft, medical review, QC review, and finalization helps ensure that the project has been completed and can be modified to become a table of contents for the narratives in the project. Additionally, with multiple narrative projects, spreadsheets can be used to generate metrics on “average time to complete.” Similar organization of email or computer folders can facilitate tracking of a narrative project.

Narratives can provide a sole source of information about specific subjects’ events. They represent a consolidation of information from various sources to provide details about an event of importance—whether serious adverse events or other types of events. Understanding the scope of the project, using an annotated template, and following a process will lead to the successful completion of the narrative project.

Author contact: karen.campbell@whitsellinnovations.com

FREELANCE MEDICAL EDITING, WRITING, OR BOTH: WHICH PATH IS RIGHT FOR ME?

Speakers
Julie Munden
Medical Editor & Copywriter, Blue Ink Communications, Souderton, PA
Lori De Milto, MJ
Writer for Rent LLC, Sicklerville, NJ

By Mia DeFino, MS

Both medical editors and medical writers have many interesting freelance opportunities. But choosing whether to be an editor, writer, or both can be challenging. This session focused on helping freelances decide whether they should market themselves as a medical editor, a medical writer, or both. Even if attendees were not currently freelances, the session was intended to be helpful for thinking through how to decide what you can do or would enjoy doing the most. Both Julie Munden and Lori De Milto presented their own paths to deciding what type of work best suited them and their freelance business.

Munden tried editing first and enjoyed it, then had some experience with copywriting, and ultimately found she liked medical editing much more. Today, she is a senior medical editor and content manager with one of her favorite long-time freelance clients. She is happy with her focus on editing because she likes to use her strengths of being detail-oriented, factual, and consistency-based.

De Milto has been a writer since she was a kid and has completed a master’s degree in journalism. She started out by writing for a physician newsletter and then happened to do some medical editing work when she started her freelance business, which led to multiple connections and long-term clients. Today, her business is all medical writing. When clients are looking for a freelance editor, she refers them to a colleague who is an editor because she enjoys writing more.
Both speakers emphasized that it is important for branding and marketing of your freelance business to decide which type of work you enjoy the most and what you are good at (i.e., do you have the skills and qualifications to do the type of work you enjoy?).

The types of clients and projects that medical editors and writers work for and on are very similar, and the targeted audiences are the same as well, said Munden (Table 1). However, said De Milto, there are 2 skills that writers need that editors do not: the ability to analyze vast amounts of data and information and the ability to write.

De Milto helped the audience understand the money-making potential of both paths: “Both medical editing and writing are well-paid careers. Editing tends to pay slightly less, but it is important not to choose writing just because it pays more.” It is important to do the work that is a better fit for you because you will be happier and more satisfied in your career choice.

Ultimately, there are some freelances who do well as both writers and editors, and there are other freelances who are satisfied to focus their efforts on one path, both speakers concluded. “It is important to think about how clients perceive you. They want to hire a specialist, and sometimes if you do both they may not think that you’re good enough at one or the other,” warned De Milto. She also cautioned that doing both makes it harder to attract great clients, because effective marketing focuses on what clients need and how you can meet their needs.

As an example, De Milto said that if the prospective client is looking for a particular skill set, they may be more interested in you if you do only what they are looking for, rather than if you do both. However, if existing clients only know you as an editor, for example, sometimes they will ask if you are interested in writing. If you are, this is an opportunity to do both. But if you are not interested, it is okay to say so and direct your client to writers you may know who can help, suggested De Milto. Often, even if we brand ourselves one way, we can sometimes be open to trying new types of projects to see if we like other types of writing or editing, she concluded.

Munden finished the session by providing criteria on which attendees could base their career path decisions: preferences, skills, credentials, and experience. Please see the handout from this session on the next page to help you determine the best path for you.

For a copy of the slides and all handouts, email Munden at julie@blueinkcommunications.net or De Milto at loriwriter@comcast.net.

Mia DeFino, MS, is a freelance medical writer in Chicago, IL.

Author contact: mia@mdefino.com

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<thead>
<tr>
<th>Table 1. Choosing Your Path: Skills, Credentials, and Experience</th>
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<tbody>
<tr>
<td><strong>Skills</strong></td>
</tr>
<tr>
<td>Editing</td>
</tr>
<tr>
<td>Knowledge of style guides</td>
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<tr>
<td>Literature searching and fact-checking</td>
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<tr>
<td>Knowledge of instructional design</td>
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<tr>
<td>Analyze data and information</td>
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<tr>
<td>Writing</td>
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<tr>
<td>Software proficiency</td>
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<tr>
<td>Organization</td>
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<td>Time management</td>
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<tr>
<td>Communication</td>
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<tr>
<th><strong>Education level</strong></th>
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<th><strong>Freelance Writers</strong></th>
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<tr>
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<td>Minimum</td>
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<tr>
<td>Advanced degree</td>
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<td>English</td>
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<td>Likely</td>
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<tr>
<td>Public health</td>
<td>Possible</td>
<td>Likely</td>
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<tr>
<th><strong>Certification</strong></th>
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<th><strong>Freelance Writers</strong></th>
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<tr>
<td>MWC®</td>
<td>Not applicable</td>
<td>Possible</td>
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Checklist For Choosing Your Path: Freelance Medical Editing, Writing, or Both

Use this checklist to help decide whether freelance medical editing, writing, or both is right for you. The checklist, however, is a guideline. Many successful freelance medical editors and writers might not seem more clearly suited to one career path over the other.

My Preferences and Skills

☒ I like editing more than writing. (E)
☒ I like writing more than editing. (W)
☒ I enjoy fact-checking content. (E)
☒ I know style guides. (E)
☒ I can’t resist the urge to correct mistakes and always notice illogical arguments, inaccurate statistics, inconsistent writing, and poorly constructed sentences. (E)
☒ I have an extreme passion for details, accuracy, and correct grammar. (E)
☒ I’m detailed-oriented and focus on accuracy but prefer for someone else to make sure everything is consistent and grammatically perfect. (W)
☒ I love to learn about new topics in medicine, health, and health care. (W)
☒ I love to organize data and information into clear and interesting writing. (W)
☒ I can analyze large amounts of data and information. (W)

My Credentials

☒ I have a bachelor’s degree. (E, most likely)
☒ I have an advanced degree. (W, most likely)
☒ My degree is in English, journalism, or communications. (E, most likely)
☒ My degree is in science, medicine, or public health. (W, most likely)

My Experience

☒ I have experience in editing and/or medical editing. (E)
☒ I have experience in writing and/or medical writing. (W)

Calculate Your Path

Count up the number of Es andWs.

Number of Es: ___________
Number of Ws: ___________

If you have:

Many more Es than Ws: Freelance medical editing is the best path for you.

Many more Ws than Es: Freelance medical writing is the best path for you.

About an equal number of Es and Ws:

Both freelance medical editing and writing, or writing and editing, is a good path for you.

More Es than Ws: Editing should probably be your primary work.

More Ws than Es: Writing should probably be your primary work.

My choice is:
____________________________________________