Preface

2018 Postconference Issue: Online–Only Supplement

By Jim Cozzarin, ELS, MWC® / AMWA Journal Editor

Each year ~900 members, nonmembers, presenters, volunteers, awardees, exhibitors, and staff take time from their busy lives to come together for the AMWA Medical Writing & Communication Conference. This 4-day meeting is the flagship event of the year for AMWA members and provides an opportunity to attend open sessions and for-credit workshops, listen to presentations from our esteemed award winners, meet and greet exhibitors, view posters, and network with hundreds of colleagues. Yet, most of our members are unable to attend and therefore miss out on this amazing wealth of information and opportunity.

This is why I chose again to devote this issue of the AMWA Journal to showcasing our conference content. First, let me thank our volunteer reporters who attended and have provided brief reports of many of the open sessions presented this past November in Washington, DC. These brief reports are designed to share some basic information from each session so that those who could not attend might nevertheless be informed of topics and trends of interest among our colleagues in the industry. If you see something particularly interesting, please feel free to reach out to the individual presenter. If you are on the fence about whether to spend your time and money in attending the 2019 conference, perhaps this glimpse into what you’re missing may help clarify your decision!

This online-only supplement continues to share additional postconference coverage that we just couldn’t fit into the print issue, including a presentation by Stacy Robison, MPH, MCHES, recipient of the John P. McGovern Award; additional Open Session reports; information from several of our exhibitors; and reproductions of our conference posters.

I hope you find this insight into the annual Medical Writing & Communication Conference to be of value. As you can see, if you missed it, you missed a lot! I hope to see you at the next conference in San Diego, California, later this year!

Yours in AMWA,

~Jim
You’ve all probably considered the question of whether medical writing is art or science, or both. Rather than rehashing that debate, I’m going to talk about the heart and science of medical writing. About 5 years ago, some CommunicateHealth employees dreamed up an idea to help spread the word about health literacy. It would be a weekly email and we would keep it short, sweet, nice, and conversational so it wouldn’t take up too much of our readers’ time. We would include some fun pictures so people would look forward to it every week, and We Heart Health Literacy was born. Today we have over 2,500 enthusiastic followers and growing. Adam, our creative director who does the doodles that everyone loves, is who you surely meant to give the award to. Thank you, Adam. I can take no credit for those.

We also had another purpose with We Heart Health Literacy. We wanted to bring more heart into medical writing. In a culture that values self-control and bodily perfection, being sick or even just being old can lead to feelings of shame and inadequacy. We wanted to encourage our leaders to use everyday words to interact with their audience, to normalize embarrassing questions and reduce shame and stigma.

When I say “heart,” I’m mostly talking about empathy. It turns out empathy is incredibly powerful. Empathy in health care has been shown to improve patients’ emotional health, symptoms, and psychological responses and to increase medication adherence and increase patient satisfaction. In other words, feeling seen and heard makes patients more likely to listen to and follow the recommended course of action.

Why is this happening? One of the main reasons is that empathy builds trust. And because you are all science nerds like me, here’s the basic science from the Harvard Center for Neuroeconomics. There’s a correlation between the amount of oxytocin a person’s brain produces and the level of trust they feel in any given situation. Researchers found a direct link between oxytocin levels and empathy, which is essential for creating trust. The higher the oxytocin, the higher the empathy—the deeper the trust.

What does empathy have to do with health literacy? A lot! One of the main ways we empathize is in our language. To create meaningful communications—whether they’re health websites, patient handouts, or journal articles—we need to know our readers and care about their lives. How do we show empathy in our writing? Can we make people feel seen and heard just with our words? Yes, we can.

I want to share with you 6 things we can do to build empathy in our writing.

First, write clearly and use familiar terms. You have to reach patients intellectually if you’re going to engage them emotionally. This means using familiar language, defining technical terms, and breaking information into short chunks that can be easily digested. We know that stress and illness compromise our ability to understand and retain health information.

The second thing we can do is normalize it. People who are sick or uncomfortable are often scared. Making an experience seem more common can help. For example, “Some people with herpes find that they experience ‘X.’” Or, “Many people who have been abused by a partner have done ‘Y.’” Normalizing.

Third, put yourself in the patient’s shoes. Consider for a minute: What would it be like to live with a health issue you don’t fully understand? What type of information would ease your concerns and even improve your condition?
Fourth, acknowledge emotions. Negative emotions like fear and shame can get in the way of clear thinking and healthy choices. You can make it a little easier for your readers by acknowledging their feelings. You could say, “It may be hard to talk to your doctor about your concerns, but it’s important.”

Fifth, be encouraging. Pay attention to your tone. If you’re writing about a sensitive topic, keep things positive. Consider including a message of hope. Like, “It’s normal to feel overwhelmed at first, but lots of people have learned to live with a catheter and you can too.”

And finally, be credible and be explicit. Explain research results plainly and precisely. It’s one of our greatest challenges as medical writers. But it’s essential to building trust. Many of your readers will compare multiple sources as they seek to understand their diagnosis and treatment, so it’s essential that we’re credible.

I’m going to give you an extreme example here of what I’m talking about when I talk about empathy, or lack of empathy, in our writing. This is from a denial letter from a health insurance company. You may have actually seen this—it made the rounds in the news. I’ll just read you the first few lines here. It says, “You requested man-made arms. Your arms were amputated. This claim is denied.”

It turns out the claim was denied because the doctor was out of network, but that’s not what comes across in this letter. We worked with them on some revised language, which led to increased levels of consumer satisfaction overall with the brand. The company’s JD Power consumer ratings were up 18 points after this project. So, there’s also a very strong business case for using plain language in our writing.

Empathy is critical to business too. There’s a direct link between empathy and commercial success. Businesses are more profitable and productive when they act ethically, treat their staff well, and communicate with their customers. We found this to be true at CommunicateHealth. My wife and I started the company 10 years ago in our attic. It’s true that I was 30 years old at the time—you can do the math. We now have 65 employees! Our goal was to make a difference in the world but also in the lives of our employees. We do this by offering flexible schedules, paid parental leave, and unlimited paid time off, and we’ll all get next Tuesday off to get out and vote. We’re creating a different kind of company and business. Plato is credited as saying, “Be kind, for everyone you meet is fighting a hard battle.” We could change this quote to read, “Be kind, for every one of your readers is fighting a hard battle.” And by empathizing with your readers, by not talking down to them, but instead meeting them where they are, using their language, putting yourself in their shoes, you’re putting the heart in medical writing.

At a time when our government is trying to erase entire groups of people—transgender people, undocumented people, people with disabilities, gay people, people with preexisting conditions, women—Your Words Matter. By rejecting the stereotype of the noncompliant patient, by sharing a personal story, by choosing a patient-centered term, by simply changing a pronoun in your writing, you are sending a powerful message to your reader. That message is, “I see you.” And that is the heart of medical writing.

Thank you so much for this award. It really touches my heart. And I can think of no higher honor than being recognized by my peers in this way. Thank you so much.

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References
GRANT EDITING BASICS: APPEALING TO REVIEWERS

Speaker
Meagan Ramsey, PhD, Manager, Proposal Development Unit, Center for Integrative Research in Critical Care, University of Michigan Medical School, Ann Arbor, MI

By Karen Potvin Klein, MA, ELS, GPC, MWC®

In this session, Meagan Ramsey suggested concrete ways in which medical editors can help investigators submit more competitive research grant applications. Because the National Institutes of Health (NIH) is the nation’s primary funder of biomedical research and has the most complex structure, this session focused on its process and structure—although many recommendations could apply to other funders.

At some institutes within the NIH, fewer than 10% of all applications are funded. In addition, strict page limits make the crafting of a convincing narrative a challenge. Thus, all proposals, in addition to proposing innovative and important work, must be well written and carefully prepared to have any chance for funding. As Ramsey stated, this situation is a golden opportunity for editors to play a key role in facilitating applicants’ success.

Ramsey began by noting that medical editors seeking to document their value could start with the fact that on its own website, the NIH recommends that grant applicants seek out medical editors clearly also provide value by helping to educate grant applicants—especially non-scientists and early-stage faculty members—about the process of submitting NIH applications. This is important because understanding the audience (in this case, grant reviewers) and what the funder wants are 2 essential components of any successful application, regardless of the science it proposes.

Editors are well positioned to provide value to investigators in other ways as well. For example, prospective applicants must be up to date regarding forms, instructions, and deadlines—all of which change, sometimes without much advance notice. So, the editor can be a reliable source for accurate information and suggestions on how to address new requirements. One example Ramsey gave is the NIH’s recent announcement about a change in wording of the “Scientific Premise” section; because this is new to investigators and they may have questions, editors can help interpret the NIH’s announcement and suggest ways to respond to it.

As Ramsey explained in her overview of the NIH’s structure, its 182 review panels (called “standing study sections”) will reflect the priorities of the NIH’s different institutes, and the perspectives of reviewers. She noted that medical editors could be “ideal middlemen” because they know how to meet an audience’s needs for information and understand the need to stay up to date about details of proposal submission and review.

After reviewing the steps of proposal submission, initial review by the NIH, and scientific review by the study section, Ramsey then provided a list of issues she most frequently encounters in 4 major sections of an NIH application.

• Introduction: Applicants who submit revised applications summarize the changes in a 1-page introduction. Ramsey noted that an editor is especially well equipped to organize this response and improve the tone (ie, alter subjective or defensive statements) of this critically important section.

• Specific Aims: This 1-page precis is a “snapshot” of the proposal and needs to appeal to reviewers for them to score it favorably. Ramsey said the biggest issue she sees is an overly ambitious plan (too many specific aims).

• Significance and Innovation: These sections should be separate in focus, but Ramsey noted that she often reorganizes text and suggests clarifications to better fit the NIH requirements and meet reviewers’ expectations.

• Approach: In this section, applicants describe the planned experiments. Yet as Ramsey noted, some proposals lack key details to convince reviewers of feasibility. For example, reviewers expect to see a section explaining potential issues and alternative approaches if a hypothesis falls short or if technical problems arise. She also noted that some applications do not directly address the scientific hypotheses.

This session provided an entrée to the NIH proposal submission process for those unfamiliar with it and illustrated the strategic value medical editors can add to applicants’ teams. The slides from this session (accessible to AMWA members at https://www.amwa.org/page/2018sessions) also included helpful advice about the formatting and visual appeal of text.

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THE MISCOMMUNICATION EPIDEMIC: HOW CLOSE ARE WE TO FINDING A CURE?

Speaker
Cynthia L. Kryder, MS, CCC-SP, Medical Communication Consultant, Phoenixville, PA

By Jacqueline M. Mahon, MA

Although we’ve moved beyond our childhood tin-can-and-string attempts at communication, opportunities for misconstruing messages are still plentiful. As medical communicators, we find that these crossed lines can lead to project delays, lost prospects, frustration, conflict, and even the demise of relationships. Individual perceptions—what is “said” versus what is “heard”—are everything. Can we allow miscommunication
to infect the estimated 70% of each day we spend communicating (ie, writing, reading, talking, listening)? Cyndy Kryder presented communication principles, causes of and remedies for miscommunication, and preventive medicine to help us improve and protect the health of this valuable time and effort.

**Ideal Communication**
In a perfect world, you send a message, the receiver hears and responds, you clarify, and the receiver confirms. In reality, however, multiple factors can intervene and disorder this seemingly straightforward pathway. You may be surprised to learn that 55% of an in-person message is delivered via nonverbal cues/body language and that only 7% is delivered by your actual words (Figure). Therefore, carefully consider your posture, facial expression, clothing, and other nonverbal cues when communicating face to face.

Additional causes of miscommunication include
- Being implicit (“When you get a chance, send me the estimate”) rather than explicit (“Send me the estimate this morning”)
- Using the wrong communication channel for your message
  - Synchronous or immediate: phone or live chat
  - Asynchronous or nonimmediate: voicemail, email, text, social media
- Voice or personal: phone, voicemail, or live chat
- Words or impersonal: email, text, social media
- Making assumptions, usually with a negative bias
- Rushing
- Choosing words haphazardly, without concern for clarity
- Poor listening skills
- Multitasking

**Listening** can be considered to occur at 7 levels, with 1 representing the highest risk of misunderstanding and 7 representing the lowest risk:
1. Not listening
2. Pretend listening
3. Partially listening
4. Focused listening
5. Interpretive listening
6. Interactive listening
7. Engaged listening

The biggest communication problem is that we do not listen to understand. We listen to reply.

**Multitasking** is seductive because we hear quickly, and distractions compete for our attention. Therefore, effort is required to attain the higher levels of listening. Communicators can assist in this effort (Box). According to Earl K. Miller, PhD, Professor of Neuroscience, The Picower Institute for Learning and Memory at the Massachusetts Institute of Technology, the concept of “super-power” multitasking is a myth. In fact, we are toggling among tasks, and there is a “switch cost”—time required to realign—as we repeatedly refocus our attention. Multitasking has a place in our frenetic society, but only with an understanding of its true characteristics, which include surges in the reward hormone dopamine and the stress hormone cortisol, as well as slower or reduced performance.

**Engaging in the Present**
The most successful communication occurs when all involved are fully present and cognizant of effective methods. If you are listening, and the topic, relevance, and next steps are not clear, then ask for these specifics. If you are communicating and
unsure of accurate reception, then be explicit, align your nonverbal cues with your message, and repeat the must-know information at the end.

We can all improve as communicators and listeners. The cure for the miscommunication epidemic is attention. Healthy communication increases the likelihood of successful projects, smoother and more pleasant workdays, and strong professional relationships.

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The CSR Simplification Project: Creating a Clear, Compliant, and Concise CSR

Speakers
Mitzi Allred, PhD, Director Clinical Operations, Merck, Philadelphia, PA
Diane Petrovich, PhD, Medical Writer, Clinical Operations, Merck, Philadelphia, PA
on behalf of the Merck CSR Simplification Team

By Madison Hedrick, MA
At Merck, the clinical study report (CSR) process and structure have been retooled and revised to ensure that the company’s CSRs not only facilitate the job of the Heath Authority Reviewer (reviewer) but also fully leverage the efforts and expertise of the reviewers and authors that Merck employs.

The CSR Simplification Project is a part of the movement within Merck to simplify documentation for clinical studies. The revised CSR template and process utilize focused authoring principles, leverage the electronic environment, address disclosure concerns, and build on structural authoring initiatives.

Overview of the Project
The Merck team used a logical and well-informed path to make the change from the dense CSRs to the new, Simplified CSRs (Table, Figure). As part of the project, a team of cross-therapeutic specialists collected cross-functional input, conducted benchmarking within the industry, and critically analyzed the CSR template and procedures.

Principles of Focused Author Writing Style
According to Elizabeth Brown, MS, PMP, and Kimberly Jochman, PhD, in their AMWA conference presentation,¹ the benefits of focused authoring include that it
- Allows key messages to be identified easily
- Reduces writing, review, and quality control time
- Reduces redundancy to increase quality

This style is in contrast to that usually seen in CSRs, and even manuscripts, in that every word in the document should serve a grammatical purpose or move the document forward. Simplification of a CSR means that the document is no longer comprehensive, containing all study information; rather, it is

<table>
<thead>
<tr>
<th>Build on Industry &amp; Our Best Practices</th>
<th>Leverage Electronic Environment</th>
<th>Leverage the CPT</th>
<th>Team Benefits</th>
<th>Agency Reviewer Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embrace Focused Authoring Principles</td>
<td></td>
<td></td>
<td></td>
<td>Concise/focused document to help reviewer “see” the results &amp; key messages</td>
</tr>
<tr>
<td>No distracting redundancies or unnecessary descriptions</td>
<td>Build on structured authoring initiatives</td>
<td>Protocol is only 1 click away!</td>
<td>ICH E3, FDA, CFR, CORE Reference</td>
<td>Reduce author time</td>
</tr>
<tr>
<td>Reuse reviewed &amp; approved text from protocol</td>
<td>Maximize immutable text</td>
<td>Reduce reviewer time</td>
<td>Build on existing initiatives to simplify documentation</td>
<td></td>
</tr>
<tr>
<td>Minimize customization</td>
<td>Reduce QC time</td>
<td>Applicable for most studies</td>
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</table>

CFR, Code of Federal Regulations; CORE, Clarity and Openness in Reporting; CPT, core protocol template; CSR, clinical study report; FDA, US Food and Drug Administration; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; QC, quality control.
a clear and concise document that reports results and key messages.

**Comparison of Original CSR to Simplified CSR**

The simplification of the CSR reduced the number of pages within the CSR from 27 to 4. The original CSR has lots of white space, whereas the new Simplified CSR is reformatted. The original CSR has 14 tables, whereas the new CSR has just 1 adverse event (AE) table. The original has repetitive text that restates the information already included within the tables, whereas the new CSR briefly summarizes the key methods and analyses. The original has a combined section describing both the methods and the results, whereas the new CSR has the key messaging for efficacy and safety information. The original has detailed descriptions of additional endpoints, whereas the new CSR includes only primary and secondary endpoints. The old CSR has paragraphs, whereas the new CSR has bulleted lists.

Detailed tables and slides indicating all changes to the CSR, providing a useful template, are provided by the speakers for reference on the AMWA website. For example, the Project Results section for the new Simplified CSR template now utilizes CORE for section 9, a streamlined version of sections 4 to 9 (linked to protocol), a focused-author-style revision for sections 10 to 12, and a clarified section 13. To see the other sections in their updated form, reference the slides available via AMWA.

Implementation of these changes requires communication, training, and reinforcement to achieve the best outcomes.

*Madison Hedrick, MA, is a Senior Medical Writer at Wilson Carroll Research Services, LLC, in Little Rock, Arkansas.*

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**Reference**

1. Brown E, Jochman K. Using a focused authoring strategy to create a message driven deliverable. Presented at: AMWA Medical Writing & Communication Conference; November 1-3, 2018; Washington, DC.

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**CANCER IMMUNOTHERAPY—OVERVIEW OF THE CURRENT LANDSCAPE**

**Speaker**

**Petra Volna, PhD, RPh,** Senior Regulatory Documentation Scientist, Genentech, Inc, South San Francisco, CA

**By Paul C. Dolber, PhD**

Cancer immunotherapy may seem to have sprung from nowhere in the past decade, yet its development was the result of more than a century’s intense study of immunology. Dr Volna covered both the immunologic advances and resulting immunotherapeutic modalities in this wide-ranging presentation.

Four steps are required for an effective immune response, whether the targets are conventional pathogens or cancer cells. (1) The foreign antigens must be recognized and presented to cytotoxic T cells to cause their activation. Antigen-presenting cells of the innate immune system, particularly dendritic cells, carry out this step. (2) Activated T cells must then travel to the site of the targets and (3) kill the targets. (4) Finally, memory T cells must develop to complete the eradication of the targets and maintain control against further incursions.

Because the same rules apply to cancer cells and pathogens, it is puzzling that the immune system does not prevent cancer. In fact, the immune system does detect and suppress tumor formation, a process known as immune surveillance. In
the long run, however, this surveillance may act as an evolutionary force to promote the development of more problematic cancer cells, which can avoid T cells or induce changes in the tumor microenvironment that inhibit both T-cell infiltration and T-cell activity. Several immunotherapies are being developed to deal with these problems.

**Checkpoint Blockade**

Activation of T cells requires binding of antigen to the T-cell receptor and costimulation through the cluster of differentiation 28 (CD28) receptor. The activated T cell soon expresses the checkpoint protein cytotoxic T lymphocyte–associated protein 4 (CTLA-4), which prevents further costimulation by competing with CD28 and markedly reduces T-cell activity. Similarly, maintained T-cell production of the checkpoint protein programmed death 1 (PD-1), as well as PD-1 binding to programmed death ligand 1 (PD-L1) expressed by tumor cells, reduces T-cell activity. Delivery of antibodies against these checkpoint inhibitors often rescues T cells from exhaustion, restores T-cell antitumor activity, and cures cancers.

**Preventative Vaccination**

This therapy is now used for one virally induced cancer. After it was shown that human papillomaviruses (HPVs) can cause cervical and other cancers, vaccines were developed and are now used to prevent the initial HPV infections. HPV vaccination is already reducing cervical cancer incidence.

Whether as scientists or as potential patients, it is gratifying to be witness to the fruition of over a century of hard immunologic work in the form of increasingly effective cancer immunotherapies.

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**LARGE, COMPLEX FREELANCE MEDICAL WRITING PROJECTS: BEST PRACTICES**

**Speakers**

Debby Berlyne, PhD, Freelance Medical Writer and Editor, Rockville, MD

Tom Drake, MA, CMPP, Director, Global Outcomes Group Inc, Reston, VA

**By Margaret M. Burke, PharmD**

Increasingly, freelance medical writers are being hired to work on complex medical writing projects that previously were the purview of in-house writing staff. This trend is being driven by downsizing of medical affairs and writing departments within the biopharmaceutical industry and advancing technology that improves Internet connectivity allowing for global collaboration. “The majority, probably 80%, of medical writing is no longer performed in house,” said Tom Drake, yet the need for creating large, complex documents still exists. Managing large writing projects among several individuals and over long distances presents many challenges. This presentation explored the roles of project team members, discussed key challenges in the process, and offered best practices to successfully deliver such projects.

There is no standard definition for a complex freelance medical writing project. The speakers provided their working definition and several examples of what they consider a complex freelance project (Table 1). The Academy of Managed Care Pharmacy dossier example was then used to illustrate challenges and possible solutions in the case studies that followed. The speakers discussed aspects of building a team of qualified freelances from both an agency and a freelance perspective. An agency’s job is to build the right team, which requires assessing the nature of the project and selecting freelances who are not only skilled but also a good match for the project. Team members may include a team lead, project manager, lead
writer, support writers, editors, graphic designers, and a client liaison. Debby Berlyne explained, “Each project is unique and requires its own configuration. You have to think in advance what it will be. Some of these were roles we didn’t think of in advance. That’s why we want you to know about it so you don’t repeat our mistakes.” Freelances should confirm the parameters of their participation early on, including deliverable requirements, payment schedule, and a clear delivery schedule for all drafts.

The responsibilities and desired characteristics of each team member’s role were discussed in depth. Particular attention was given to how the team lead, project manager, and lead writer roles differ (Table 2).

Potential problems during a project and possible solutions for each were illustrated using several case studies. The speakers emphasized that with large, complex documents, it is particularly important to present a single voice and a consistent format. The problems addressed included document version control, having too many source documents, and team members not meeting deadlines or turning in poor-quality work. An example of one case study is shown (Table 3).

The speakers closed by providing a summary of best practices developed from their experience in successfully managing teams of freelances in delivering complex documents (Table 4).

Margaret M. Burke, PharmD, is a medical writer with Precision Medical Writing, LLC, near Hartford, CT.

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**Table 1. Complex Freelance Medical Writing Project**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Examples</th>
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</thead>
<tbody>
<tr>
<td>More than 2 freelance writers</td>
<td>AMCP dossier</td>
</tr>
<tr>
<td>A primary editor, possibly more</td>
<td>GVD</td>
</tr>
<tr>
<td>At least 1 additional team member</td>
<td>HTA</td>
</tr>
<tr>
<td>A need for research writing, editing, and formatting</td>
<td>Publication plans for products with multiple indications</td>
</tr>
<tr>
<td>100 or more pages</td>
<td>Master slide decks</td>
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<tr>
<td>3 or more months to complete</td>
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<tr>
<td>Multiple sections needing different writing skills</td>
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**Table 2. Key Team Members Roles**

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<tr>
<th>Team Lead</th>
<th>Project Manager</th>
<th>Lead Writer</th>
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</thead>
<tbody>
<tr>
<td>Identifies and hires freelances</td>
<td>Needs to understand project content</td>
<td>Responsible for document consistency and quality</td>
</tr>
<tr>
<td>Manages budget and payments</td>
<td>Needs to know team members</td>
<td>Creates any needed templates</td>
</tr>
<tr>
<td>Communicates with client</td>
<td>Assigns tasks to team members</td>
<td>Answers content-related questions</td>
</tr>
<tr>
<td>Assigns tasks</td>
<td>Monitors progress and communicates with team lead</td>
<td>Reviews work of other writers</td>
</tr>
<tr>
<td>Oversees project timelines</td>
<td>Finds needed resources</td>
<td>Manages version control</td>
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**Table 3. Case Study—Version Control**

<table>
<thead>
<tr>
<th>Problems Encountered</th>
<th>Possible Solutions</th>
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<tbody>
<tr>
<td>Outdated version of document online</td>
<td>Agree on file name rules during initial call</td>
</tr>
<tr>
<td>2 team members working on different versions</td>
<td>Assign a single keeper of each file</td>
</tr>
<tr>
<td>Wrong version submitted to client</td>
<td>Single shared online folder of current version with subfolders for older versions</td>
</tr>
<tr>
<td></td>
<td>Use online document management tools</td>
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**Table 4. Best Practices**

<table>
<thead>
<tr>
<th>Do</th>
<th>Don’t</th>
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<tbody>
<tr>
<td>Schedule internal kickoff meeting with team members</td>
<td>Let client communication lapse</td>
</tr>
<tr>
<td>Schedule separate kickoff call with client and all team members (record it!)</td>
<td>Let delays escalate</td>
</tr>
<tr>
<td>Appoint project manager and lead writer</td>
<td>Submit sloppy work to meet deadlines</td>
</tr>
<tr>
<td>Assign only 1 writer to each section</td>
<td>Deliver subpar work early or on time if excellent work can be delivered a bit later</td>
</tr>
<tr>
<td>Keep all team members up to date on project status</td>
<td>Admit problems to client</td>
</tr>
<tr>
<td>Track status of all project elements</td>
<td>Forget ongoing communication with all internal team members</td>
</tr>
<tr>
<td>Verify abilities of all freelances</td>
<td></td>
</tr>
<tr>
<td>Use multiple reviews of all work</td>
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<tr>
<td>Have backup activities for each team member</td>
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<tr>
<td>Make contingency plans for potential problems</td>
<td></td>
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<tr>
<td>Negotiate reasonable deadlines with client</td>
<td></td>
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<tr>
<td>Keep client informed of unexpected issues</td>
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</table>
By Katherine Molnar-Kimber, PhD

Humans have been learning about life from stories for millennia. Conveying complex information as stories can help the general public and medical professionals not only grasp key health information but also absorb how that information affects them and their world on an emotional level, which can enhance its recall. Cynthia Lollar and James Mathews emphasized the differences in tone, structure, and aim between presenting the evidence-based facts in a report and presenting the information in a story.

They explained that “Informational content is designed primarily to help the audience DO or UNDERSTAND something, quickly and easily.” The facts needed for finding a clinical trial or applying for a grant can be presented in a straightforward manner, like a path. Lollar and Mathews described the parts of the informational content as

- **Lead:** Includes the most important information, including who, what, when, where, and why.
- **Body:** Expands on the details, such as other background information and quotes.
- **Last information:** Has the least importance.

In comparison, a story presents many of the facts in a winding, human-centered journey, so that you feel something such as tension, humor, suspense, curiosity, fear, wonder, or impending change. The speakers explained that “The human brain is wired to focus on, respond to, and remember stimuli that evoke our emotions.” The brain’s limbic system processes the data from our 5 senses and activates our bodies to respond physically (eg, muscle relaxation or higher heart rate), emotionally (eg, change in mood), and intellectually (eg, better memory).

Thus, stories are a vital complement to the evidence-based facts in reports to illustrate important health and scientific concepts. But most patient materials and scientific documents do not use storytelling formats, thereby missing out on connecting people to the health and scientific information on an emotional level that often makes it easier to remember.

Mathews described the basic elements of story:

- Sensory details
- Characters who want something
- A plot that poses obstacles to that desire as the story moves toward a climax or resolution

He provided an example, breaking it up into multiple parts to enhance the suspense of following the adventures of his characters throughout the interactive presentation. Some unintended, short-lived IT challenges during the presentation added to the suspense, and Mathews and Lollar demonstrated resourceful strategies as they kept the story rolling.

Mathews included quotes to punctuate the essential points for storytelling. For example, Alfred Hitchcock’s quote, “a good story is real life … with all the boring parts taken out,” emphasizes that each bit of information in the narrative nonfiction story needs to fulfill a dramatic purpose. Thus, planning involves not only choosing and organizing true facts along the narrative path to readily engage the attention of the audience, but also choosing which aspects are unessential and left out. A story has a

- Compelling character with a defined goal
- Journey through conflict/complications toward that goal
- Character altered by a dramatic series of events that culminate in a climax or emotionally significant resolution

Further, the character is an individual (not a stereotype) described with sensory detail. She or he wants something intensely but faces obstacles. As challenges are overcome (or not), the character changes with time. The storyline encompasses the journey and its relationships to past events and potential future happenings. The essential conflict is identified and agitated or enlarged. Stories often embrace nonresolution. The ending can be a resolution or a change with a surprising nonresolution.

Lollar discussed the work of the science communicator Randy Olson, author of Houston: We Have a Narrative, which boils down the classic story structure into “And/But/Therefore.”

- **And:** Introduces the protagonist and the scene, describing their normal or ordinary world.
- **But:** Describes the inciting event and the moment of change or transformation. Often, the story involves multiple challenges, and each requires action.
- **Therefore:** Describes the changes, partial resolutions, transformations, and final resolution due to the challenges and conflict.

Lollar and Mathews provided many insights on writing narratives in their presentation. Lollar also examined examples from several different digital communication platforms, including YouTube (#IAmHHS Deb Cotter, https://www.youtube.com/watch?v=uaBiWMHdM), Twitter, and Facebook for the And/But/Therefore storytelling.
In summary, if you are writing patient materials, consider structuring the information in a storytelling narrative using Lollar’s and Mathews’ insights and techniques. The And/But/Therefore technique may also be incorporated into the writing of slide presentations, abstracts, posters, and scientific manuscripts formatted in the classic IMRAD (Introduction, Methods, Results, and Discussion) structure.

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NETWORKING FOR INTROVERTED FREELANCERS: HOW TO GET BETTER RESULTS WITH LESS STRESS

Speakers
Lori De Milto, MJ, Lori De Milto Writer for Rent LLC, Sicklerville, NJ
Genevieve J. Long, PhD, Genevieve J. Long, PhD, PC, Hood River, OR

By Jennifer Fricker, BA

Many freelances choose to work for themselves and by themselves because doing so fits well with their introverted personality. However, one part of the freelance lifestyle is not a natural fit for introverts—the need to network.

Networking is essential for finding new clients, learning about the field, getting inside information, and avoiding the mistakes of others. Other freelances understand you and your challenges and can inspire you, support and validate you, and help you combat isolation. Lori De Milto and Genevieve Long can both attest to the power and value of these connections—they even met one another at an AMWA Annual Conference!

So how can an introvert best approach the challenge of networking? The most important first step, according to De Milto and Long, is to have the right attitude. When asked what words they associate with networking, the audience at this open session gave such answers as “stress,” “awkward,” “dread,” and “insincere.” Much of this negative view stems from the perception of networking as self-marketing. But Long says the goal of networking is not selling yourself—that is obnoxious and feels uncomfortable. Instead, as De Milto advises, your goal in networking should be to give more than you take: “Collaboration always beats competition.”

For an introvert, meeting and talking with new people can be draining. Focus your networking efforts strategically so that your investment of energy is well spent. Target people who are looking to hire your type of freelance by joining specific professional associations, like AMWA. Try volunteering for your local AMWA chapter; having a task to focus on, like setting up chairs or handing out badges, can make attending an event less intimidating.

In-person networking is the most effective. The right preparation can help: practice your “elevator speech,” which should include how you benefit clients, what you do, and who you work with. This short blurb is not to sell yourself, but rather to give the other person some context to interact with you. Bring business cards and dress professionally. If possible, reach out to a few attendees ahead of time whom you want to meet, and set up a specific time and place to get together, such as during a beverage break between sessions.

When you’re at the event, smile and be confident and approachable, don’t talk too much about yourself, and end each conversation well. Focus on the other person, by saying, “I know there are lots of people here, and I don’t want to keep you!” Jot down notes on the back of their business card so that you can remember the context of how you met when you follow up later. Keep in mind there are likely lots of other introverts around you who are reluctant to make the first move themselves and would welcome your opening comment or question. Chat with the people who sit next to you in a session or who are standing in line with you to reach the buffet. And when attending a multiday event, schedule frequent breaks for “alone time” to rest and recharge.

After the event, review the business cards you received and reach out to people you think could be helpful to you (and you to them) with a LinkedIn invite and/or an email saying it was nice to meet.

What about networking online? Social media, such as LinkedIn, can be effective, but you must rank high in search results to be found by clients. This takes engagement—sharing useful, relevant content (news and tips, not self-promotion) with your connections in posts and comments.

Whether in person or online, once you’ve made connections, keep them strong by sharing resources, connecting people, and giving referrals. The more you give, the more you will receive: focusing on others, rather than yourself, is the secret to networking without stress.

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YOU CAN’T POSSIBLY UNDERSTAND HOW I FEEL (BECAUSE I WON’T TELL YOU): THE RIDDLE OF FEEDBACK

Speaker
Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc, Chapel Hill, NC

By Jennifer Fricker, BA
In this open session, Robin Whitsell shared that survey results have found that most employees appreciate both positive and negative feedback but that most do not receive valuable feedback, or any feedback at all. Lack of feedback leads to disengagement and withdrawal, so how can we improve at providing effective feedback to our colleagues? And how can we seek out and act on constructive feedback for ourselves?

First, Whitsell reviewed common pitfalls to avoid when giving feedback:
• **The “good news sandwich.”** Believe it or not, many managers are actually taught this terrible technique of sandwiching bad news between 2 pieces of positivity. However, it is much better to be straightforward and avoid mixed messages.
• **Making a molehill out of a mountain.** This is another method of “softening the blow,” but when managers overly qualify and minimize negative feedback, the employee is left with the mistaken impression that what happened was not a big deal.
• **Not giving any feedback.** Managers may hesitate to give feedback because they aren’t sure how to say something, are too busy, or are waiting for the perfect time—these all lead to avoidance of giving feedback at all.
• **They/everyone/the team.** Feedback characterized as coming from “them” or “everyone” or “the team” makes the recipient feel ganged up on, paranoid, and betrayed.
• **Drive-by.** Feedback delivered in a “drive-by” leaves the recipient with no chance to respond or ask questions, meaning they are not prepared to address the problem.
• **Disneyland feedback.** Nonspecific, all-positive feedback doesn’t contain anything constructive to take forward and work on.

Whitsell then reviewed the trifecta of effective feedback (Figure). The best feedback exhibits those 3 elements and is followed by an invitation providing the opportunity for clarification: “Do you want to talk about this more?”

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Face-to-face and in-person delivery of feedback is best. The next best option, for those interacting remotely, is a video call. If video is not an option, then a phone call or an IM chat provides a better opportunity for back and forth than an email. If feedback must be delivered via email, remember, “Don’t type angry!” It’s better to cool off first. Also, don’t wait forever for exactly the right time or to come up with exactly the right words—better to open the conversation in an imperfect way than never to have it at all.

What about receiving feedback? If no one has said otherwise, we might assume that everything is fine; in reality, however, that might not be the case. How do we solicit constructive feedback and then act on it?

Here are some ways to ask for feedback
• “I’m working on X; have you noticed anything that might help me?”
• “In the past I’ve been told X; have you seen this?”
• “Do you have any observations that would help me improve?”

To then act on the responses you receive, you need to overcome any initial defensive reaction. Don’t deflect with excuses or justifications—really listen, instead. Three magic words may help you listen and absorb feedback: “Tell me more.”

Don’t ask for feedback when you are not ready to hear it, such as when you’ve just finished a stressful project or are feeling emotionally drained. It also helps to ask for feedback from peers with whom you have an established, trusting relationship.

Whitsell concluded the session with a little bit of homework. Try it yourself! Make 2 lists of names: (1) For whom do you have feedback? (2) From whom do you need feedback? Then, ask a trusted colleague to ask you in 3 weeks if you have reached out to those people.

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THINK AND COMMUNICATE VISUALLY

Speakers
Cynthia L. Kryder, MS, Medical Communicator, Phoenixville, PA
Lori Alexander, MTPW, ELS, MWC®, President, Editorial Rx, Inc, Fort Myers, FL
Jia You, Interactive Graphics Editor, Science Magazine, Washington, DC

By Brian Bass, MWC®
Medical writers are story tellers, and stories are told best when we combine words and visuals. For this reason alone, this session was an invaluable opportunity for attendees at the 2018 Medical Writing & Communication Conference.

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**Timely.** Given as the behavior occurs, ongoing, rather than after the fact or only once a year

**Specific.** Exactly which things need to be changed

**Actionable.** How to go about making the change

**Figure.** The trifecta of effective feedback.
Cyndy Kryder explained that the mind processes visuals much faster than words. She demonstrated this point by challenging the audience to identify the most memorable aspects of several examples. Research dating to the 1980s shows that visuals boost learning and comprehension, but it’s taken decades for us to think about how visuals impact what we write. According to Kryder, visuals are also more persuasive. Studies show that people only read 20% to 28% of the words on a page, but that visuals can break through the scanning.

She outlined several strategies for selecting the appropriate visual to support your content:

- Pie charts are an effective way to express parts of a whole
- Bar graphs are a clear means of presenting values in categories
- Tables are ideal for communicating comparisons and highlighting specific values
- Line graphs are an efficient means of tracking trends over time

Kryder urged the audience to think outside the box by considering other types of visuals beyond simple charts, graphs, and tables. She suggested isotype arrays to help readers visualize risks and rankings, word clouds to visualize commonalities and diversities, visual scales such as the Faces Pain Scale, and infographics to communicate a central story. It’s important for writers to use the right tools for the right audience, and to keep visuals simple and digestible.

Lori Alexander impressed the audience with data on the degree of information overload to which we are all exposed, noting that infographics can help us process that information more efficiently. Today we’re exposed to 5 times more information than in 1986. We consume more than 100,000 words in an average day, yet as Kryder pointed out earlier, we only read up to 28% of them. Alexander explained that the challenge is especially great when it comes to the amount of medical information to which the average person is exposed. It is estimated that the amount of available medical information will double every 73 days by 2020, which is now just 1 year away.

According to Alexander, data visualization as discussed by Kryder enables medical writers to present data with clarity and objectivity. In contrast, infographics enable us to tell a complete story that not only includes data but also leads the reader to a conclusion. As a result, infographics have an inherent degree of subjectivity to them.

Of particular relevance to medical writers, Alexander pointed out that today infographics are gaining traction in the clinical setting with health care professionals. They’re easy to digest, fun to share, and extremely engaging. She pointed to the popularity of visual abstracts and video abstracts as examples of this growing trend. The trick to creating an effective infographic is that you must be able to think visually. In her opinion, medical writers need to start thinking beyond words—thinking of themselves as medical communicators and embracing the use of images to bring greater communicative power to their work.

Jia You discussed the process of visualizing data in science and medicine. She explained that the key element of effective visual communication in medical communications is design—the combination of concise wording, clear graphics, logical color and contrast choices, and ensuring those elements tell the story accurately and completely. She presented a framework that graphically represented the wide range of visuals that may be used in communicating science and medicine. Visuals can range from being precise to general, and from explanatory to exploratory.

Through a number of examples, You showed how line graphs facilitate precise reading of data points while the use of angles, areas, and color intensity are suitable for depicting general trends in the data rather than providing precise readings. Color hue is an effective way to categorize information but is ineffective when it comes to representing quantities. However, she warned attendees that when using color they must keep in mind that approximately 5% of the US population is color blind.

Similar to the strategies Kryder provided earlier for selecting visuals that are appropriate to support your content, You outlined the several options for depicting different types of data visually:

<table>
<thead>
<tr>
<th>Depict</th>
<th>Visual Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change over time</td>
<td>- Line graph</td>
</tr>
<tr>
<td></td>
<td>- Column graph</td>
</tr>
<tr>
<td></td>
<td>- Calendar heat map</td>
</tr>
<tr>
<td></td>
<td>- Circle timeline</td>
</tr>
<tr>
<td>Comparison</td>
<td>- Paired column graph</td>
</tr>
<tr>
<td></td>
<td>- Proportional symbol</td>
</tr>
<tr>
<td></td>
<td>- Radar graph</td>
</tr>
<tr>
<td></td>
<td>- Parallel coordinates</td>
</tr>
<tr>
<td>Part-to-whole relation</td>
<td>- Pie chart</td>
</tr>
<tr>
<td></td>
<td>- Stacked column graph</td>
</tr>
<tr>
<td></td>
<td>- Grid plot</td>
</tr>
<tr>
<td></td>
<td>- Tree map</td>
</tr>
<tr>
<td>Correlation</td>
<td>- Scatter plot</td>
</tr>
<tr>
<td></td>
<td>- Line + column graph</td>
</tr>
<tr>
<td></td>
<td>- Bubble chart</td>
</tr>
</tbody>
</table>

Throughout their presentations, the speakers provided a wealth of resources, which they have also made available online. You can access their resources here.

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Identifying Experience and Expertise to Succeed as a Medical Writer

Speakers

Damiana Chiavolini, MS, PhD, Instructor, UT Southwestern Medical Center, Dallas, TX
J. Kelly Byram, MS, MBA, ELS, CEO, Scientific and Medical Communications Lead, Duke City Consulting, LLC, Albuquerque, NM
Anne Murray, PhD, Scientific Research Writer, UT Southwestern Medical Center, Dallas, TX

By Vicki VanArsdale, MS

This interactive session focused on career development for both freelances and those who work in house in academia, although the lessons learned are broadly applicable. Attendees heard 3 different perspectives on how to leverage their expertise and background to enter or advance in medical writing and editing and received actionable advice on job-seeking practices, transferable skills, and continuing education.

Becoming a Medical Writer

The panelists work in the medical writing field in different capacities, and each had a different point of entry. Murray had no experience in medical writing but was able to get her foot in the door as an in-house professional by leveraging her science background. She was in the right place at the right time; they needed a medical writer, and she was able to cross over after demonstrating her writing skills. Chiavolini worked as a biomedical researcher who left the bench for a career in academia. Byram is a freelance who runs her own company; she is only taking clients by referral now. She started in publishing but got interested in science and medical writing.

Although their paths differ, the panelists agree that networking and continuing education are keys to developing a medical writing career. Byram said it’s important for medical writers to grow their skill set, to expand into other areas, and to mentor and help each other. She said someone once told her “network or don’t work,” so introductions and network building are essential. Chiavolini suggests networking at AMWA’s Annual Conference and following up with new contacts to nurture relationships and have access to new opportunities. AMWA Engage is another good way to connect with peers.

Tips on Entering Medical Writing as a Freelance

• Research potential employers (benefits, job satisfaction)
• Modify your CV or resume to fit each job posting
  – A potential boss may be more interested in scientific expertise and may allow for writing skills to develop over time
  – Highlight writing/editing experience gained during school or at prior jobs
• Clarify uncertainties about the job posting, tasks, salary potential, and professional development during the interview
• Salary negotiations
  – Read AMWA’s latest Salary Survey
  – Academia notoriously pays less but has better benefits
  – Offer a salary range acceptable for personal needs

Tips on Entering Medical Writing as an In-House Professional

• Salary negotiations
  – Read AMWA’s latest Salary Survey
  – Academia notoriously pays less but has better benefits
  – Offer a salary range acceptable for personal needs

Tips on Entering Medical Writing as a Freelance

• Freelances are hired to provide expertise and solve problems, so experience and expertise are essential
• Understand total (direct and indirect) financial requirements and have clients with the potential for ongoing work before leaving a paying job
• Define your value proposition (what makes you stand out)
• Have a business philosophy and a set of guiding principles
• Clients are the boss
• Learn how to negotiate and manage expectations; contracts
• List goals
  – Full-time or part-time?
  – Consistent or intermittent?
  – Retirement
• Considerations: Self-motivation, problem-solving ability, organization skills, working alone
• Assess possible distractions: Children, household chores
• Comfort level with uncertainty: Cash flow management, benefits

Byram said, “If you’re risk averse, [freelancing] may not be the path for you.” Freelancing is a full-time business, and it’s up to the freelance to make things happen. She recommends consulting with an accountant to determine what tax filing status is better: for example, sole proprietor or LLC.

Surviving Versus Thriving as a Medical Writer

Networking, nurturing relationships, mentoring, and continuing education are keys for thriving as a medical writer. Murray said she attends AMWA conferences to expand her education via workshops and open sessions. In house, she broadens her rapport with scientists by eating lunch with them periodically and stays in touch through email.

In her role as an in-house instructor, Chiavolini introduces herself to new faculty and sets up an in-person meeting; she also uses email and encourages them to attend sessions on various aspects of scientific and medical writing. She also encourages faculty to reach out to her very early in the grant application process to allow time to improve grantsmanship and quality of writing. Chiavolini said AMWA is an invaluable resource and said to find allies on the job who support professional development and conference attendance.

As a freelance, Byram maintains her relationships with clients via open communication. She vets clients before working with them to assure a good fit but knows when to let a difficult client go. She said AMWA and peer mentoring are essential; she belongs to a group in New Mexico that...
meets quarterly. All freelances should revise their business plans yearly and include a budget for professional development and continuing education. Byram offered this advice: “There’s enough work for everyone, but find a niche where you can flourish.”

A session handout, with extra tips and advice, can be found here.

Vicki VanArsdale, MS, is freelance writer and health care marketing communications specialist near Washington, DC.

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### INTRODUCTION TO HEALTH ECONOMICS AND OUTCOMES RESEARCH (HEOR) FOR WRITERS

**Speakers**

Beth Lesher, PharmD, BCPS, Pharmerit International, Bethesda, MD

Catherine Mirvis, BA, Pharmerit International, Bethesda, MD

By Valerie Sjoberg, MAc, MWC®

Health economics and outcomes research (HEOR) exists across a variety of sectors in the health care industry and can provide ample opportunities for medical writers who are interested in the field. In this session, Beth Lesher and Catherine Mirvis presented an overview of HEOR, ways that health sectors use HEOR, and how writers with science and nonscience backgrounds can break into HEOR writing and editing.

**Overview of HEOR**

According to Lesher, HEOR focuses on the economic, clinical, and humanistic outcomes of various health care interventions and can play an important role in demonstrating the value of a product. Evidence for HEOR can be gathered from a variety of sources, including studies, registries, chart reviews, and patient-reported outcomes. HEOR is used by academic institutions, pharmaceutical companies, health plans, health care professionals, and others to

- Identify unmet needs
- Supplement randomized controlled trials with real-world evidence
- Address evidence gaps
- Promote patient-centered research
- Help develop and evaluate cost-containment strategies
- Adapt data to different populations
- Respond to changes in market environments
- Comply with health technology assessment submissions

In the United States, HEOR evidence is most commonly used by pharmaceutical companies, and it can be applied throughout the product lifecycle (Table 1).

<table>
<thead>
<tr>
<th>Trial Phase</th>
<th>HEOR Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical</td>
<td>Exploratory research, gap analysis, very early modeling, market assessment, key opinion leader research</td>
</tr>
<tr>
<td>1 and 2</td>
<td>Market assessment, early modeling, piggyback studies, gap analysis, burden-of-illness studies, patient-reported outcomes development/testing/validation</td>
</tr>
<tr>
<td>3 and 3b</td>
<td>Payor assessment, registries, pricing and reimbursement, model development and validation, comparative effectiveness research, Academy of Managed Care Pharmacy dossier, piggyback studies, value message development, global value dossier</td>
</tr>
<tr>
<td>Post-launch</td>
<td>Phase 4 studies, comparative effectiveness research, retrospective studies, Academy of Managed Care Pharmacy dossier, model refinement, database analyses, global value dossier, piggyback studies, prospective observational studies, chart reviews, health technology assessment, safety surveillance, registries</td>
</tr>
<tr>
<td>Loss of exclusivity</td>
<td>Safety surveillance, comparative effectiveness research, health technology assessment, real-world studies, global value dossier</td>
</tr>
</tbody>
</table>

HEOR, Health Economics and Outcomes Research.

Health care decision-makers, such as pharmacy and therapeutics (P&T) committees within a hospital or insurance company, also frequently use HEOR evidence to influence their choices. Lesher described how P&T committees (often composed of clinicians, a lawyer, quality assurance personnel, and a lay member) determine which of 2 drugs will be offered at their hospital by weighing the clinical and economical outcomes associated with each drug (Table 2).

**Table 2. Sample Drugs Reviewed by Pharmacy and Therapeutics Committee**

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cost per Tablet</th>
<th>Efficacy</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>1 tablet daily</td>
<td>$1.25</td>
<td>77%-80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nausea, vomiting, irreversible hepatotoxicity (5%)</td>
</tr>
<tr>
<td>Drug B</td>
<td>1 tablet daily</td>
<td>$1.50</td>
<td>78%-80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Nausea, headache</td>
</tr>
</tbody>
</table>

**The Writer’s Role in HEOR**

The field of HEOR offers opportunities for writers (Table 3) who come from a variety of backgrounds. Whereas Lesher arrived to HEOR by receiving her PharmD, working as a pharmacist, and completing a medical writing fellowship, Mirvis arrived by completing an English degree and gaining exposure to science as an intern at the National Cancer Institute.
Writers with a medical background can leverage their existing skills to break into the field, and writers without a medical background can also bring valuable assets to the HEOR space, including expertise with Microsoft Word, insight into nonexpert audiences, strong writing mechanics, and an ability to organize ideas. Mirvis recommended that these writers enhance their medical knowledge by brushing up on statistics, learning about different health audiences, and taking workshops through the American Medical Writers Association.

Educational resources exist that can help those interested in HEOR professional development. The Professional Society for Health Economics and Outcomes Research offers short courses in HEOR. The Academy of Managed Care Pharmacy holds 2 national meetings annually that involve education in the pharmacy space. Finally, HealthEconomics.com provides education and research related to HEOR. These resources, in addition to leveraging existing writing skills, may help writers who are interested in HEOR find opportunities in the field.

Note: The slides for this presentation are available on the AMWA website here.

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Table 3. Opportunities for Writers in HEOR

<table>
<thead>
<tr>
<th>Writing</th>
<th>Editing</th>
<th>Project Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dossiers</td>
<td>Dossiers</td>
<td>Dossiers</td>
</tr>
<tr>
<td>Publications</td>
<td>Publications</td>
<td>Publications</td>
</tr>
<tr>
<td>Value messaging</td>
<td>Slide decks</td>
<td>Reports</td>
</tr>
<tr>
<td>Objection handlers</td>
<td>Reports</td>
<td></td>
</tr>
<tr>
<td>Study reports</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Modeling reports</td>
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</tbody>
</table>

Instructional design is the practice of creating content that ensures efficient and effective learning. For medical writers, this means that—before beginning the writing process—they must think about the goals of education, the needs of the learners, and what the end product will look like.

- **Goals of education:**
  Large educational programs are usually broken down into smaller educational activities, each with its own learning objectives and tasks. These learning objectives should specifically describe what the audience will better be able to know or do after the completion of each activity. The medical writer should strive to understand what each activity aims to achieve and how all of the educational activities will work together to meet the goals of the entire program. Tasks and postactivity assessments are often used to determine whether educational activities were successful in helping the learners achieve the learning objectives.

- **Learners’ needs:**
  The medical writer should learn as much as possible about the learners. Who is the audience? What is their level of knowledge and education? What are their educational needs? How will this educational activity contribute to their work or everyday life? Are there any language barriers or cultural differences to consider? All of these factors greatly impact how the medical writer should construct the content.

- **End product:**
  The medical writer should also ask in which format the audience will receive the content. Will the activity be presented electronically or in print? Will it be viewed on a laptop, tablet, phone, or something else? Which technology and programming capabilities will be used to build the activity? Will the medical writer be assisted by graphic designers and software programmers? Will interactivity with the audience (e.g., live surveys) be feasible and to what extent? Does the activity need to be monitored? All of these factors must be taken into consideration to ensure that content is developed and presented to the learners properly.

**Microlearning**

With the rush of today’s life, learning trends have shifted toward shorter and faster educational formats. Microlearning is a type of educational product that includes 3- to 5-minute bursts of content presented to learners via the written word, graphics, or videos. To be effective, microlearning activities must be

- **Bite sized:**
  Content should be focused, take no more than 3 to 5 minutes to view, and stand alone without other educational pieces.

- **Content focused:**
  The activity should provide just the right amount of
information the learners need to achieve the learning objective (note that “objective” is singular; microlearning is specific to learning 1 objective).

• Learner centric:
  Content should be delivered with a platform that allows the learners to become engaged and immersed in the activity to drive the learning process.

• Accessible:
  The activity should be immediately available when needed by the learners, as well as having the flexibility to be delivered to whatever device the learner is using.

• Relatable:
  Content that evokes strong feelings and emotions is more likely to leave an impact on the learners.

• Easy to retain:
  Content should be relevant to the learners’ lives, which makes it easier to remember.

Examples of microlearning videos include powerful snippets that teach viewers—in a just a few minutes—very specific information about a topic, such as how to switch a phone to low-battery mode, how to fill out a consent form, what the structure of the heart valves is, how a diabetes drug works, and how a pulmonary embolism is formed. (These are just a sampling of the video snippets used to drive home content to learners during Dr Anderson’s presentation.)

Communicating highly complex medical content to a professional audience in 1 or 2 microlearning videos is not a replacement for a full-fledged learning program, but it can be an effective way to explain difficult topics or provide an alternative method to achieving learning objectives. As microlearning is able to disseminate quick, effective, and powerful messages to large audiences, it may also be used by clinicians to help explain a specific disease, therapy, or clinical trial to patients or the general public.

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WHAT’S NEW IN THE AMA MANUAL OF STYLE

Speakers
Stacy Christiansen, MA, Managing Editor, JAMA, and Co-Chair, AMA Manual of Style, JAMA Network, Chicago, IL
Annette Flanagin, RN, MA, Executive Managing Editor, JAMA Network, and AMA Manual of Style Committee, Chicago, IL
Cheryl Iverson, MA, Co-Chair, AMA Manual of Style, JAMA Network, Chicago, IL

By Laurie Anne Walden, DVM, ELS

The AMA Manual of Style is updated between editions to reflect changes in policy and style. Stacy Christiansen, Annette Flanagin, and Cheryl Iverson discussed revisions that have already been implemented and upcoming changes for the 11th edition, scheduled for publication in 2019.

Manuscript Preparation
Iverson discussed reasons for upcoming changes in reference styling (Table 1). For example, omitting periods after DOIs and URLs in reference entries facilitates accurate link copying.

All elements within tables and figures (column headings, axis labels, etc) will be set in sentence-style instead of title-style capitalization. Table titles will continue to use title-style capitalization.

| Table 1. Reference Updates in the 11th Edition of the AMA Manual of Style |
|------------------|---------------------------------------------------------------------|
| • Publishers’ locations no longer included |
| • Online references: URLs moved to ends of reference entries and not followed by a period (style already implemented for DOIs) |
| • Examples added for social media and digital references: tweets, blog posts, databases, etc |

Style and Terminology
The 11th edition will include numerous style updates (Table 2). Christiansen said that allowing they to be used as a gender-neutral singular pronoun helps preserve patient confidentiality and has been implemented by other style guides.

The new edition will include grammar guidelines for social media. For clarity, posts about scientific content should use standard capitalization and punctuation and avoid potentially confusing shorthand (such as U for you).

Further, the new edition will update guidelines for describing socioeconomic status and people with addiction. These

<table>
<thead>
<tr>
<th>Table 2. Selected Style and Terminology Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Use of they as a singular pronoun allowed in certain circumstances (sentence rewrite preferred)</td>
</tr>
<tr>
<td>• New entries added to list of nonhyphenated terms (eg, open access journal)</td>
</tr>
<tr>
<td>• New entries added to abbreviation list: ACL (anterior cruciate ligament), LGBTQ (lesbian, gay, bisexual, transgender, and queer), MERS (Middle East respiratory syndrome), and more</td>
</tr>
<tr>
<td>• All fellowship designations, including non-US fellowship designations like FRCP, no longer included in bylines</td>
</tr>
<tr>
<td>• Health care: still 2 words</td>
</tr>
<tr>
<td>• Space added between the number and the degree symbol in temperatures (“37.5 °C,” not “37.5° C” or “37.5°C”) per SI notation</td>
</tr>
</tbody>
</table>
recommendations avoid assigning labels (e.g., low income instead of the poor). Other terms, such as nauseated/nauseous, will be added to the Usage section. Spelling and spacing variations will be added, with JAMA Network preferences indicated in bold (e.g., data set/dataset).

The Genetics section will specify using italicized gene symbols or gene descriptions instead of gene aliases: write “TP53” or “tumor protein p53 (Li-Fraumeni syndrome) gene,” not the gene alias “p53.” Whether gene symbols need expansion depends on context, said Christiansen. The stylebook will follow the Human Genome Variation Society recommendation to avoid the terms mutation and polymorphism, preferring terms such as sequence variation and allelic variant.

Measurement
The Statistics and Mathematical Composition sections will add terms (e.g., multivariable/multivariate) and new examples. New to the 11th edition will be the SI convention of inserting a space between the number and the degree symbol in measures of temperature, such as in “temperature of 37.5 °C” (not “37.5°C”).

Technical Information
Information on typography, tagging, and display will be combined into a single chapter. The new edition will also include discussions of XML and the JAMA Network single-source workflow.

Guidelines such as those of the Committee on Publication Ethics and the International Committee of Medical Journal Editors (ICMJE) will be added to the Resources section. In the publishing glossary, terms such as CD-ROM and fax will be removed; cloud, IP address, and others will be added.

Editorial Assessment
Corrections
Retraction and replacement is a new option for correcting some published articles. Twenty-one percent of retractions occur because of errors, not misconduct, said Flanagin. Pervasive errors are mistakes (such as coding errors) that occur before the data are analyzed, propagating incorrect numbers throughout the manuscript. Retraction and replacement, which does not carry the stigma of full retraction, is available for articles with pervasive errors that change the findings. In these cases, journals can publish an author’s letter of explanation; replace the article, retaining the original DOI but not adding a retraction watermark; and publish a PDF with corrections highlighted.

Authorship
The new edition will update authorship roles (Table 3). JAMA Network journals have begun to accept some requests for shared first authorship. Two corresponding authors can be listed in some cases.

| Contributors | Everyone who worked on a project (authors, collaborators, writers, assistants, etc) |
| Authors | Contributors who meet all 4 authorship criteria of the International Committee of Medical Journal Editors |
| | Byline authors: listed in byline |
| | Nonbyline authors: listed at end of article |
| Collaborators | Members of a formal group who contribute significantly to the work but are not authors |
| Group Authors | Individuals who work together on boards, committees, working groups, etc, and use a group name for authorship |

Data Sharing and Access
The ICMJE now requires data sharing statements for articles reporting clinical trial results, as outlined in the AMA Manual of Style. The new edition will also include discussions of public access models (no author fee, journal holds copyright), open access models (article processing charge, author holds copyright), and predatory journals.

Finding Style Updates
Updates are posted on the AMA Manual of Style website. Readers can ask style questions on Twitter (@AMAManual) and read about scientific communication topics at the AMA Style Insider blog.

For more details from the conference presentation, see the session slides on the AMWA website (https://www.amwa.org/page/2018sessions).

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REGULATORY COMPLIANCE FUNDAMENTALS FOR PROMOTIONAL AND EDUCATIONAL WRITING IN LIFE SCIENCES

Speaker
Ilyssa Levins, President, Center for Communication Compliance (CCC), New York, NY

By Ilyssa Levins
The US regulatory environment affects the development of materials prepared and submitted by medical communicators. That’s why an understanding of the fundamental regulatory requirements for promotional content is imperative.

Government regulators like the US Food and Drug Administration (FDA) expect companies and their agents
(which include medical writers paid by a company) to adhere to regulations for promoting drugs and medical devices. Under FDA rules, companies are not permitted to make promotional claims that are not consistent with the labeling or that suggest that a drug or device is safe and effective for a specific use that is not in the approved labeling.

This means that anyone communicating about a prescription health care product must understand the definition of product labeling and how to make compliant claims supported by the product labeling. This includes the use of market research, competitor information, patient quality-of-life data, and disclaimers, among other areas.

Moreover, the number 1 reason companies receive enforcement letters is failure to adequately disclose risk information. There must be an accurate and nonmisleading impression of both the product’s benefits and risks.

Do you know the basic regulations? Test yourself on a few fundamentals here.

The FDA has a well-established enforcement program against companies and individuals who violate the law and regulations governing promotion.

For medical writers specifically focused on data communications, the FDA recognizes that scientists must share information, and that the public and investors are entitled to scientific information as it is evolving, before the product is approved. To address this, the FDA permits “scientific exchange”—a regulation that permits companies to discuss scientific data regarding a prescription product before approval, if that information is objective, fairly balanced, and includes balancing risk information. However, at no point until FDA approval may the company claim that the drug or device is safe and effective. When this exchange is nonpromotional in nature, it is regarded as acceptable from an enforcement standpoint and is known unofficially as a “safe harbor”; that is, these are the circumstances when the FDA is not likely to take enforcement action.

For a free mobile application that makes it easier to search warning letters, send an email to ilevins@communicationcompliance.com.

Evaluate your professional development opportunities here.

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REGULATORY WRITING FOR THE DIGITAL ERA—A PARADIGM SHIFT

Speaker
Becky Nuttall, Lead Medical Writer, EMD Serono Research and Development Institute, Inc, Rockland, MA

By Leslie Kowitz, MA, ELS

Regulatory Climate Today
Today’s regulatory climate sees the pharmaceutical industry’s push to accelerate time to market along with new Health Authority (HA) requirements for succinct, fully electronic submissions. Beginning in 2019, both the US Food and Drug Administration (FDA) and European Medicines Agency will only accept electronic submissions—no more paper. What does this climate mean for regulatory writers?

Becky Nuttall believes regulatory writers have a unique opportunity to influence the design and message of regulatory documents, which may ultimately help to get important medicines to patients faster by alleviating unnecessary burdens on HA reviewers.

Since the Prescription Drug User Fee Act (PDUFA) passed in 1992, FDA approval times for New Drug Applications and Biologics License Applications have decreased significantly, from more than 2 years (prior to PDUFA) to approximately 11 months (in 2017). Although approval time has decreased, the percentage of applications approved on the first cycle has changed little, and although companies and patients appreciate shorter approval times, reviewers are under pressure to assess more applications in less time. Enter the skilled regulatory writer, equipped with a toolkit for the digital age.

Writing for the Regulatory Reviewer
Many of us learned to “tell the story” when writing for regulatory agencies, which implies the reviewer will read a document in a linear fashion. However, in today’s ever-changing world of smartphones, apps, online media, and more, regulatory writers must design documents to account for the way busy HA reviewers actually read on screens. That means using keywords, scannable subheadings, navigational links, strategically placed white space, paragraph chunking, and ultimately less focus on dense text.

Leveraging Research From Other Disciplines
Researchers from fields such as Web design and library science have compiled a rich body of knowledge from studies on subjects ranging from eye-tracking and reading patterns to information architecture and the effect of layout on comprehension. Some of the important findings show that people who read on screens tend to

- Read in a zig-zag pattern on screen (following an F-pattern)
- Read by skimming rather than word by word
- Spend 80% of reading time on the left half of the screen
Nuttall shared some ways regulatory writers can use these findings to better design documents to adapt to reviewers’ needs:

• Split up long paragraphs (1 idea per paragraph)
• Put important information and key messages first, followed by supportive information
• Link to exhaustive analyses instead of reproducing them in the document
• Use short, active-voice sentences
• Use tables and figures to summarize complicated data
• Place links strategically to allow reviewers to focus on key messages

Putting Key Messages First
Nuttall recommends starting with the key message at the beginning of a paragraph, followed by supporting details that back up that main point (deductive reasoning model). Starting with the key message is the most direct approach and ensures the reviewer focuses on that message first without getting bogged down in the details, which can cause reviewers to skip key information.

Designing documents for the way reviewers read on screen (not on paper) should guide our writing and development decisions, such as strategically placing hyperlinks and using the left side of the screen for focused keywords and subheadings. Nuttall suggests that rather than putting links to tables or other sections up front, we should focus the reviewer’s attention on the key message first, then offer links to supporting details. For example, does it make sense to write “Tables X, Y, and Z may be found in Section 15.2.3” at the very beginning of a section in the clinical study report? Or does it make more sense to put that last—allowing the reviewer to focus on key messages first?”

Too much information can be damaging. Beware if one of your experts says, “Go ahead and keep it in—it couldn’t hurt.” More times than not, this indicates ancillary details that can detract from key information you are trying to impart.

Reimagining Document Development
Common complaints in regulatory writing groups include

• “Documents are written without a plan.”
• “There is never enough time.”
• “There are too many reviews and reviewers.”
• “People rewrite what has already been wordsmithed.”

How can we avoid these pitfalls?

Nuttall shared her positive experiences working with teams to craft key messages outside of the final document using Microsoft PowerPoint slides. This technique allows teams to think differently about content when seeing it outside of a “document” format. Teams usually have an idea about desired study outcomes even before database lock or the end of a stability study, so craft your key statements using base-case scenarios and fill in the data later.

Engaging Your Team
As the regulatory writer, you can educate and guide your team in this systematic approach to developing regulatory documents that fit the current climate.

1. Use a “shell” PowerPoint slide to align on key messages (provide examples and instructions to team members to fill in). Use bullet points for supporting messages to be used as new topic sentences.

Example of a key message: WonderDrug 10 mg, given orally twice daily in subjects with Disease who are on standard of care, significantly reduced Symptoms, with no increased safety risk, compared with placebo/active.

2. Transfer bullet points as-is to the shell. Determine strategic placement. Flesh out paragraphs and check for text density. Aim for ≥3 to 4 paragraphs per page.

3. Determine logical architecture. Can you put some details into tables? Do all the results need to be up front, or can they be placed later in the document?

4. Review the document for searchable words that would be of interest for a regulatory reviewer. Do your key statements begin with the keyword (active voice)? Can you rearrange the sentence to bring the keyword(s) to the left of the screen?

Example of a “safety” keyword: Cardiac toxicity (including pericardial effusion, hypotension, and cardiac ischemia/infarction) was balanced across treatment arms.

5. Ensure navigation is optimized. Do titles of tables and figures reflect what is actually in them? Are they succinct, or do they contain too much detail? Do subheadings give navigation prompts on the left side as to what information is contained in the document?

6. Conduct a final key message search. Cut and paste the key messages from your document (which should be the first sentence in each paragraph) into another blank document. Compare it to the original PowerPoint file. Is everything you wanted to say there? Is there any information loss or additional information creep?

Nuttall presented a case study, in which her team developed a briefing package for the FDA using this technique and emphasized that reviewer feedback was extremely positive. These steps present a practical approach to help you guide your team toward an improved process for developing regulatory information for today’s digital landscape. HA reviewers thank you in advance.

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MAKING A CAREER OUT OF MEDICAL WRITING

Speaker
Madison Hedrick, MA, Senior Medical Writer III, Wilson Carroll Research Services; President-Elect, AMWA Southeast Chapter

By Vicki VanArsdale, MS
Madison Hedrick used her presentation as a platform to offer her perspective on medical writing and to provide practical advice for those just starting in the field (targeted level of experience: <3 years). At the time of this presentation, she worked full-time for an academic medical institution and performed freelance work on the side—she now has a new role as a senior medical writer for a large research support firm.

From Pre-Med Student to Medical Writer
Hedrick wanted to be a doctor, so she took a lot of pre-med classes and had a double major in biology and technical writing. But as she gained hands-on experience working with patients, she realized that she didn’t enjoy it. She started looking for other career options and eventually realized medical writing was the perfect fit for her interests and skills.

She started applying for jobs even if she didn’t have the qualifications—hoping she’d get lucky and that something would pan out. She finally got a call back from someone who saw her potential. Although she wasn’t qualified for the position, she was offered $25 an hour to write grants. She jumped at the chance and learned everything she could as she went along. The grants she worked on were eventually funded for more than $100 million, which increased her value as a grant writer and enabled her to get more work writing grants and manuscripts.

Use AMWA to Increase the Chances of Success
Hedrick became very active in AMWA early on. She offered these tips on making the most of an AMWA membership:

• Create a LinkedIn profile and keep it up to date and full of content
• Check the job boards daily and apply
• Join a local AMWA chapter and get involved
• Go to the conferences to learn and to network with peers
• Use AMWA’s Engage to connect and collaborate with others
• Refer to AMWA’s Salary Survey to set appropriate rates

She recommends reading the posts on AMWA’s Engage daily and joining the conversation, whether to ask questions or respond to others. She said the more you connect with people, the more they get to know you, and you never know where that can take you. Networking has helped her tremendously: she’s President-Elect of the AMWA Southeast Chapter and is on the AMWA National Membership Committee.

Practical Advice for Those New to the Field
“Know your worth and don’t take things below your value,” Hedrick said.

Those new to medical writing face a challenge: how to get a job in the field and gain experience when many job postings call for 2 years of experience. Hedrick suggested getting mentors to guide the way, using Google to conduct research to learn new types of medical writing skills, and learning by doing. When working as a freelance, full-time or on the side, she thinks it is okay to keep rates slightly lower if you are benefiting by gaining experience, but be sure to increase those rates as knowledge increases and skills improve. Working for free or for deeply discounted rates is not recommended. She also reminds those who do offer discounted rates that it may be difficult to increase the rate with that client in the future, which could be costly.

Refer to AMWA’s Salary Survey to get an idea about appropriate rates because rates vary by sector (eg, pharmaceuticals), service (eg, editing versus writing), location, and level of experience. Hedrick said, “Never put the rate under $40 an hour even when you’re starting out.” One audience member said working for extremely cheap rates hurts the entire industry and makes it harder on everyone to make a living. Hedrick agreed.

Other ways to gain experience:

• Volunteer to write grants or other medically focused documents for nonprofit organizations or AMWA
• Browse FoundationCenter.org for grant-writing opportunities
• Write articles for the AMWA Journal or other publications
• Leverage any undergraduate, graduate, or doctoral work involving scientific writing
• Apply for entry-level jobs in the field and work in house (for a university, for example)
• Don’t be afraid to apply for jobs—even those you may not feel qualified for or that may not be perfect for you
• Take notice of writing errors on websites that are relevant to the field; you could offer to copy edit to get your foot in the door of a nonprofit research organization, for example.

Marketing is also important. Networking and word of mouth go a long way toward growing a medical writing career. It’s also important to have a current LinkedIn profile and to make a point to engage and actively use it to connect with peers, industry leaders, recruiters, and possible clients. If freelancing, it’s extremely important to have a website that conveys your expertise and experience. Hedrick uses a simple website builder called Wix; another audience member uses Squarespace. Everyone should keep an updated curriculum vitae or resume on a laptop or smartphone to send out at a moment’s notice. Also, be sure to always use a professional email address.

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ELEVATING THE PATIENT VOICE: OPPORTUNITIES AND CHALLENGES FOR MEDICAL COMMUNICATORS

Speakers
Samir Shaikh, MBA, Deputy Director of Patient Affairs, US Food and Drug Administration, Washington, DC
Catina O’Leary, PhD, LMSW, President and CEO, Health Literacy Media, St. Louis, MO
LaTasha Lee, PhD, MPH, Senior Manager of Partnership Engagement, Sickle Cell Disease Clinical Trials Network at the American Society of Hematology, Washington, DC

Moderator
Monique Pond, PhD, AAAS Science & Technology Policy Fellow, Bethesda, MD

By Wendy Kluender, PT
Medical communicators have a unique opportunity to assimilate information and the results of medical research and share it over a variety of platforms with professionals, study participants, and their caregivers. The panelists at this session came from a variety of backgrounds and were able to share with the medical communicators in attendance some ideas for improving patient engagement in research studies and drug development.

The session focused on 3 main areas that are integral to the process of patient involvement in clinical studies:
• Engaging patients in their care and decision-making
• Enrolling, engaging, and keeping patients in clinical trials
• Collaborating with patients at all phases of the trial

Engaging Patients in Their Care and Decision-Making
All panelists agreed that there can be barriers to patient engagement in health care and decision-making. Much of this can be attributed to a lack of understanding of the process and a lack of effective communication from the professionals working with the patients in clinical trials. Catina O’Leary shared with the group that we need to consider that medical testing can be unpleasant and may affect participation. Samir Shaikh also pointed out that patients may be tapped multiple times for each segment of the investigation and that this can be a negative experience if they don’t understand the process.

Medical communicators need to provide information in understandable terms to these patients. The value and importance of the study participants should be made clear as well, to improve engagement.

According to LaTasha Lee, the American Society of Hematology provides some clinicians with pocket guides that help them discuss treatment options with patients. Care is taken to make sure educational materials are patient focused. They are trying to look holistically at the barriers participants in clinical trials experience in order to give them a voice in the clinical trial process.

Enrolling, Engaging, and Keeping Participants in Clinical Trials
Patients with rare conditions can be difficult to find for enrollment in studies and drug trials. Once these patients are found, they tend to be tapped for multiple studies, which can be a hardship on them. To find new participants, researchers may reach out to clinicians, emergency medical services, clergy, psychologists, and other professionals in the community.

One surprising resource for this dilemma has been the use of social media. Dr O’Leary reported that they have used social media successfully to find new patients, understand their unique issues, and discover how they are comfortable talking about and trying to manage their conditions. Once patients have enrolled in a study, researchers must continue to understand and address participation barriers to keep participants engaged and make them feel valued by researchers.

Collaborating With Patients
Participant collaboration during all phases of trials and studies is another way to improve engagement. Mr Shaikh pointed out that patient councils can collaborate with researchers and drug developers to come up with data collection plans that work for each unique population. Dr Lee shared that by pulling in the patient voice, participants can begin to feel like part of the team, and the research then becomes more meaningful to them.

What about study results? Participants in these studies and drug trials want to know and understand the results. According to Dr O’Leary, researchers don’t hold up their end of the deal if they fail to share study results effectively. This can negatively affect future participation in studies and marginalizes the participants. Trial summaries have been best received by participants when results are presented first in a thorough but simple and relevant way. Audience testing ensures the effectiveness of materials.

Additional information on patient-focused drug development can be found on the US Food and Drug Administration website at www.fda.gov by typing “voice of the patient reports” in the search bar.

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MEDICAL WRITING PROFESSIONALISM: COMPETENCY MODELING, APPLICATION, AND EXAMINATION

Speaker
David B. Clemow, PhD, MWC®, Advisor, Scientific Communications Information Strategy, Eli Lilly and Company, Indianapolis, IN

By Vicki VanArsdale, MS
This session provided an overview of the 2017 DIA Medical Writing Competency Model and how medical writers and their supervisors can use the model for professional development and competency testing. Also, the AMWA Medical Writer Certified (MWC®) credentialing program was discussed.

DIA Medical Writing Competency Model
Developed by the DIA Medical Writing Community Working Group, the DIA Medical Writing Competency Model defines what knowledge, skills, abilities, and behaviors (KSABs) a competent medical writer should possess. It was created in 2009 but updated in 2017 to reflect current trends. Clemow was an integral part of the revision process, along with a team of industry professionals with 419 cumulative years of combined medical writing experience across sectors, companies, and geographic locations.

The Competency Model covers the scope and breadth of the medical writing profession and is broken into sections: KSABs, work functions (tasks/activities), and additional information (general abilities, certifications). Each section contains information for all medical writers as well as for those in a particular niche. For example, all medical writers would have similar KSABs, but more specific KSABs are noted for publication writers versus regulatory writers (Table 1).

Application of the DIA Competency Model
The Competency Model is a resource that can be used to create or revise job descriptions and create checklists and screening tools to assess the skills and abilities of prospective employees. Additionally, managers can use the assessments to set goals and to explain how medical writers will be measured against expectations in their professional development plans. Medical writers can use the Competency Model to perform a self-assessment, so they are better prepared for discussions with their managers and their performance reviews. Career paths can also be explored, and a technical ladder can be created. Clemow offered an example (Table 2).

Clemow said it’s important to retain good employees, so the Competency Model can also be used to base assignments on a medical writer’s competencies and interests, to provide resources and training, and to facilitate knowledge sharing. For example, a list of internal subject matter experts can be maintained so that if someone needs help writing protocols, they can quickly reach out to someone with that expertise.

Aspiring medical writers and those already working in the field should know what makes a good medical writer. Clemow said, “You have to be able to write and communicate, but what’s also really important is knowing your science, knowing how to be a project manager, and having quality soft skills, meaning how you interact with people.” Soft skills relate to the behaviors in the KSABs, such as conflict resolution and how to respond to review comments.

AMWA Medical Writer Certified Examination and Credentialing
Designations such as Medical Writer Certified (MWC®), Board of Editors in the Life Sciences (BELS), or Certified Medical Publication Professional™ (CMPP), to name a few, can help medical writers and editors stand out from the competition.

The Medical Writing Certification Commission oversees the MWC® program and is responsible for everything from setting eligibility requirements to developing examination content.

### Table 1.

<table>
<thead>
<tr>
<th>Who</th>
<th>Knowledge, Skills, Abilities, and Behaviors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Medical Writers</strong></td>
<td><em>(K, S)</em> Industry guidelines, project management skills, science, communications techniques</td>
</tr>
<tr>
<td></td>
<td><em>(A)</em> Deliver written/visual communications that tell a scientific narrative, author content for cascade-level messaging</td>
</tr>
<tr>
<td></td>
<td><em>(B)</em> Act with the highest ethical standard, demonstrate judgment-based thinking</td>
</tr>
<tr>
<td><strong>Regulatory Writers</strong></td>
<td><em>(K, S)</em> Standardization initiatives (eg, ICH), regulatory authority regulations and guidance</td>
</tr>
<tr>
<td></td>
<td><em>(A)</em> Prepare regulatory submission communication strategy, prepare documents for e–publishing</td>
</tr>
<tr>
<td><strong>Publication Writers</strong></td>
<td><em>(K, S)</em> Publication guidelines (eg, GPP3), reporting guidelines (CONSORT)</td>
</tr>
<tr>
<td></td>
<td><em>(A)</em> Prepare publication plan strategy, prepare publication documents</td>
</tr>
</tbody>
</table>

*A, ability; B, behavior; CONSORT, Consolidated Standards of Reporting Trials; GPP3, Good Publication Practice; ICH, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; K, knowledge; S, skill.*

### Table 2.

<table>
<thead>
<tr>
<th>Role</th>
<th>Abilities</th>
</tr>
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<tbody>
<tr>
<td><strong>Medical Writer</strong></td>
<td>Write documents within a team environment</td>
</tr>
<tr>
<td><strong>Senior Medical Writer</strong></td>
<td>Evaluate, analyze, and interpret medical literature with minimal supervision</td>
</tr>
<tr>
<td><strong>Principal Medical Writer</strong></td>
<td>Serve as a medical writing lead for submission–related documents</td>
</tr>
</tbody>
</table>
and addressing appeals. Since its inception in 2015, 75 people have earned the MWC® credential, and that number continues to increase yearly.

The DIA Competency Model is the backbone of the MWC® examination. The Competency Model’s domains are represented by questions covering presenting, interpreting, organizing, evaluating, and gathering information. There are also questions about ethics. Therefore, learning the Competency Model’s content is helpful in preparing for the examination, Clemow said. Other tips he provided were to attend AMWA workshops and review notes, to set up a self-study syllabus based on the content outline, and to review the recommended resources. Sample topics on the examination include epidemiology, writing mechanics, patient education, project management, statistics, and regulatory submissions.

How to Earn the MWC®
Certain criteria must be met to apply for the MWC® exam. Some of the requirements are having a bachelor’s degree and a minimum of 2 years of paid, full-time work experience in the field. Activities that constitute 2 years of relevant experience include the preparation of

- Patient education brochures, news articles, Web content, and books
- Journal articles for health care professionals and biomedical researchers
- Continuing education monographs for health care professionals
- Regulatory documents for government agencies
- Grant proposals for research scientists and institutions
- Sales training and marketing materials for the pharmaceutical industry

A PDF version of the presentation slides can be found at amwa.org/2018sessions. The Competency Model is available to DIA members through its Medical Writing Community. The Competency Model is also published:


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FROM PROTOCOL TO PACKAGE INSERT: A DATA JOURNEY

Speakers
Alex Rohall, BA, Senior Manager, Medical Writing, PROMETRIKA, LLC, Cambridge, MA
Christine Quagan, BA, Senior Medical Writer, PROMETRIKA, LLC, Cambridge, MA

By Dawn Hayward, BS
The information on a package insert (PI) for a New Drug Application (NDA) or Biologics Licensure Application (BLA) contains critical information health care professionals (HCPs) and patients need to assess the usage, risk, and safety of a drug. This session covered 3 key sections of the PI:

- Indication and Usage
- Adverse Reactions and Adverse Events
- Clinical Studies

These sections come from the data, the speakers explained, which journey from clinical investigators to databases to statisticians to medical writers who convey the message in the submission document. In 1966, the Fair Packaging and Labeling Act required detailed descriptions on the label, now called the PI, to determine efficacy and risk. Throughout this process, medical writers refer to the “guidance,” which contains suggestions on how to frame the content on the insert, and the physicians labeling rule, which summarizes content for HCPs.

Indication and Usage
Alex Rohall spoke about the Indications and Usage section of the PI, which must answer 3 major questions:

- What is the drug used for?
  - Treatment, cure, or prevention of a “recognized disease or condition”
- Who is the drug intended for?
  - Population, including age group
- What are other parameters the population must have?
  - The drug could be concomitant therapy for another medication

A Limitations of Use section describes the consequences, risks, or fatal adverse events (AEs) associated with a drug. Rohall then gave an example that addresses both: “Drug X is indicated for the treatment of hypertension in adults and pediatric patients 1 year of age or older. In patients younger than 1 year of age, Drug X can adversely affect kidney development.”

Adverse Reactions and Adverse Events
Christine Quagan spoke about the Adverse Reactions section of the PI. An adverse reaction (AR) is an effect reasonably associated with the drug, whereas an AE is an effect that may or may not be associated with the drug. The sponsor, who oversees the clinical studies, will look at how many people experienced an
effect, whether it occurs at a higher rate than with placebo, and whether the medical literature on that drug class gives similar effects. The guidance suggests that incidences greater than or equal to 10% of the treatment group with twice the rate of placebo may be reasonably associated with the drug.

The introductory sections include a disclaimer stating that AR rates may vary from trial to trial, a database description giving the number of patients on drug and placebo, timing and type of study (randomized, single, or double blind), dosage, and criteria for inclusion, which gives the rate of incidence for the particular AR used as a cutoff. Next, data from the Integrated Summary of Safety (ISS) are provided for ARs in the following manner, in which examples from pooled studies were shown:

1. The most common ARs are listed first and grouped by body section.
2. The numbers of patients having the ARs are listed with the percentages in both drug-treatment and placebo groups.
3. The ISS, although itself not included in the PI, contains information from all trials associated with the drug.

Although individual studies may have a high rate of a particular AR, if the rate does not meet the cutoff, it will not appear in the ISS.

Quagan lastly explained that the study protocol determines when to collect, follow-up, and how to assess the severity of an AE, its relationship to the study drug, and reporting serious AEs.

Clinical Studies Section
Rohall spoke about the clinical studies included in the PI; although not every study makes it into the PI, the US Food and Drug Administration (FDA) has seen all the data. Those studies included best represent how a drug is used properly, how the drug is effective for the indication, and the conditions for which the drug cannot be used. The Clinical Studies Section contains 3 important subsections:

- **Study Design**
  - Gives the number of patients taking drug and placebo and type of study
- **Population**
  - Describes percentages of patients who participated in the study, including age, sex, and ethnicity
- **Endpoints**
  - Describes the parameters tested to determine the effectiveness of a drug

Tables that follow this detail statistics of the endpoints used in the study. All endpoint data are given during submission in the Integrated Summary of Effectiveness. Rohall explained that endpoint selection is based on current medical literature, data from the clinical program itself, and suggestions from the FDA, which may have “input from experts in the field.” The study protocol will detail how endpoints are collected and analyzed for the trial.

Last, the speakers emphasized that the draft label is not the final product. The draft labeling is submitted and finalized through discussions with the FDA during the NDA/BLA review of all the clinical data. Changes are made from new data, new formulations, new indications, and new medical findings.

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**WHAT SHOULD A MEDICAL WRITER KNOW ABOUT GENE THERAPY AND GENE EDITING?**

**Speaker**
Elise Eller, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, Lafayette, CO

**By Shara Pantry, PhD**
The central dogma dictates that genetic information flows from deoxyribonucleic acid (DNA) to ribonucleic acid (RNA) to protein. DNA, which contains genes, is packaged into chromosomes that are located in the nucleus. DNA in the nucleus is copied to RNA (transcribed) and processed into messenger RNA (mRNA). The mRNA is transported to the cytoplasm, where it is interpreted (translated) into amino acids that are linked together to make a final product (protein). Proteins direct a variety of biological functions in the human body.

When the original, template DNA is mutated, problems with the transcription or translation processes can occur. The potential ultimate result of the mutation is a nonfunctional or dysfunctional protein and, in turn, a genetic disease or disorder. To correct genetic disorders, the majority of currently available drugs target the faulty protein. However, genetic disorders may potentially be corrected by targeting the mRNA or the template DNA itself. Two technologies have emerged that have the potential to treat or cure human genetic disorders by introducing new DNA to the cells (gene therapy) or fixing the faulty DNA (gene editing).

The use of both gene therapy and gene editing is on the rise, and it is important for the medical writer community to understand the science of gene therapy and editing, the ethical concerns for the use of these tools, and the regulations governing the two.

**Gene Therapy**
The goal of gene therapy is to treat or cure a genetic disorder by introducing DNA or RNA into the cell to augment the defective gene without modifying the organism's DNA. The therapy gene, which codes for a functional protein, is put into a viral vector and delivered to the target cells. The most commonly used viral vectors are adenoviral- or retroviral-based.
Gene therapy vector delivery can occur in vivo or ex vivo. For in vivo gene therapy, a viral vector containing the therapy gene is injected directly into the organism. For ex vivo gene therapy, the patient’s cells are removed, the therapy gene is introduced into the cells, and then the cells are transplanted back into the patient’s body. Ex vivo gene therapy is favorable because it is more efficient and less likely to elicit an immune response; however, it cannot be used for all cell types.

Potential Pitfalls and Problems With Gene Therapy

• **Delivery:** Highly efficient and cell type–specific delivery is often difficult to achieve.
• **Immune response:** Gene therapy vectors are viewed as foreign by the patient’s immune system and may elicit an immune response that results in severe disease. This can be avoided with ex vivo delivery.
• **Integration site:** Integration sites are random and may disrupt the function of critical genes, such as tumor suppressor genes.
• **Commercial viability:** Gene therapy is expensive and often used for rare disorders that affect only a small population.

**Gene Therapy Regulation in the United States**

In the United States, gene therapy is regulated by the Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER). CBER oversees biological and related products, including vaccines, cellular and gene therapies, and devices related to cellular and gene therapy products. New gene therapy products are approved using the Biologics License Application process.

**History of Gene Therapy Trials and Approvals**

The first gene therapy trial, aimed at treating adenosine deaminase deficiency, occurred in the United States in 1990. However, a gene therapy trial–related death in 1999 drastically slowed the progress of the field. After this incident, increased measures for monitoring gene therapy trials were implemented in the United States; consequently, the United States did not approve its first gene therapy product until 2017. China and the European Union, however, saw their first gene therapy approvals as early as 2004.

Two of the new US-approved gene therapy products, KYMRIAH and YESCARTA, are chimeric antigen receptor (CAR) T-cell therapies. This technology, currently being used to treat cancers, engineers the patient’s immune cells to treat his or her cancer. As a part of the process, a patient’s T lymphocytes are removed and altered to express a CAR on their cell surface that specifically recognizes cancer cells. The CAR T cells, once reintroduced into the patient’s body, help to identify and attack cancer cells throughout the body.

**Gene Editing**

Gene editing alters an organism’s DNA sequence, rather than augmenting gene expression. Common gene editing systems include:

• Zinc Finger Nucleases
• Transcription activator–like effector nucleases
• CRISPR-Cas9

Currently, the most popular gene editing system is the CRISPR-Cas9 system (another enzyme, CPEF1 [CRISPR from *Prevotella* and *Francisella*] is also being investigated). CRISPR (clustered regularly interspaced short palindromic repeats) was originally identified in bacteria in the 1980s and serves as a form of acquired immunity in bacteria. CRISPR is a family of short, repetitive DNA sequences in a bacterium’s genome that read the same forward and backward. In between the repetitive DNA sequences are DNA spacers derived from viruses that previously infected the bacterium. The pieces of nonbacterial DNA maintained in the bacterial genome help the bacterium to identify new infecting viruses that are similar. The CRISPR DNA serves as a guide for the Cas9 (CRISPR-associated protein 9) enzyme, which cuts the DNA in a sequence-specific manner.

For research purposes, the CRISPR-Cas9 machinery can be delivered in vivo or ex vivo and can be used to precisely edit target DNA sequences. To accomplish this, a synthetic CRISPR guide RNA specific to the target DNA sequence is coupled to the Cas9 enzyme. Once the DNA is cleaved, the dysfunctional gene can be removed, replaced, or revised.

Potential Pitfalls and Problems With Gene Editing

• **Delivery:** Guide RNA–Cas9 machinery may be too large to be packaged into viral vectors. Lipid nanoparticles and other methods are being explored as an alternative for delivery.
• **Efficiency:** For gene editing treatment to work, knockout efficiency of 60% to 95% is needed, which can be difficult to achieve.
• **Off-target effects:**Editing specificity is dependent on the design of the guide RNA, and other areas of the organism’s genome may be edited at areas other than the target site. *In vitro* and cell-based assays will likely be needed to demonstrate minimum off-target effects before approving gene editing products. Research is currently being performed to find alternatives to Cas9 or ways to improve Cas9 efficiency.
Ethical Concerns With Gene Editing

So far, most clinical applications for gene editing target somatic cells for the treatment of various medical conditions. However, the field of gene editing is moving toward gene editing of germline (reproductive) cells, which would affect an individual as well as any offspring. Most researchers have stayed clear of germline editing. However, in 2015, China announced the successful editing of human zygotes that were not intended for pregnancy and drew concern from the research community worldwide.

Later in 2015, an International Summit on Human Gene Editing was held in Washington, DC, to address the scientific and ethical concerns surrounding human gene editing. The overall consensus was that germline editing should not be used to modify human embryos that are intended to establish a pregnancy and that technical issues should be addressed before germline editing is used in clinical settings. However, the summit did not call for a ban on germline editing for research purposes (Table).

**Table. Overview of International Guidelines on Human Germline Editing**

<table>
<thead>
<tr>
<th>European Union</th>
<th>Germline editing/eugenics banned</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>Germline editing may be permitted in the future with strict oversight</td>
</tr>
<tr>
<td></td>
<td>Research grants involving germline editing will not be reviewed by the National Institutes of Health</td>
</tr>
<tr>
<td>United Kingdom/ Sweden</td>
<td>Gene editing of human embryos is permitted for research purposes only</td>
</tr>
<tr>
<td>Japan</td>
<td>Draft guidance permits gene editing of human embryos with restrictions (not for genetic enhancement)</td>
</tr>
</tbody>
</table>

Thus far, there are no gene editing products approved for human use. However, there are 17 active/recruiting preclinical trials. The majority of these trials are being performed in China. However, there is currently 1 actively recruiting gene editing trial in the United States.

Gene editing can be controversial, but it has the potential to greatly alter the medical landscape of the world.

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CAN YOU TEACH AN OLD REVIEWER NEW TRICKS?

**Speaker**

Robin Whitsell, BA, BPh, President, Whitsell Innovations, Inc, Chapel Hill, NC

“Nothing’s going to change if you don’t change it,” Robin Whitsell said, closing out “Can You Teach an Old Reviewer New Tricks?” The presentation centered around ways to alleviate many of the common issues medical communicators have in working with reviewers. From simple annoyances like being late to meetings to more serious things like breaking timelines. Whitsell offered three basic steps to help train reviewers to be better team players: prepare, explore, and engage.

**Prepare**

Often, thorough and intelligent planning can ease many of the potential issues that arise with reviewers throughout a project. Whitsell noted that proper planning and preparation before the project kickoff meeting is an excellent place to start, giving the following tips:

- Obtain a list of meeting attendees and identify their roles—especially note the decision makers;
- Obtain or build a timeline;
- Look over the team calendar to identify any “showstopper” days that might create delays in the timeline (ie, holidays, planned vacations);
- Lay out a plan for escalation; and
- Highlight portions of the project that require the most reviewer attention.

Whitsell also emphasized anticipating issues that may arise with particular reviewers. By directing the reviewer’s attention to sections that need addressing—such as the data—and away from sections that have already been finalized, valuable time can be saved in the review process.

**Explore**

Whitsell suggested 2 main exploratory techniques that can be used to keep reviewers on schedule and cooperative: finding a champion and establishing a process. A champion is “a mentor—someone who can offer advice when you need it” and potentially lobby for you. It was noted, however, that “the goal of the champion is to have somebody who can help you without changing your team dynamic.” Additionally, it is important to set up a process for reviewers; it increases consistency and reduces redundancy. Whitsell noted that it was also crucial to establish a process of support for reviewers, which may help improve the relationship between writer and reviewer.
Engage
To have a successful working relationship with a challenging reviewer, we have to reframe our thinking...we’re not in conflict with a problem child, we’re engaging a problem child. To do so, communication is essential. When there are misunderstandings, questions, or conflicts, it is important to address them with reviewers. According to Whitsell, this can be done all throughout the process, including preemptively. The opportunities for reviewer engagement can come

- Right after the kickoff meeting with a follow-up email reaffirming timelines and commitments made in the session;
- When there are miscommunications;
- When deadlines or portions of work are missed; and
- When you’ve lost the audience and message in the narrative.

Particularly when reviewers miss deadlines, it is important to do what Whitsell calls The Circle Back: “when you reach back to any specific team member and talk to them about what’s missing, what you needed from them, or what they didn’t do.”

Ultimately, a difficult reviewer can be retrained to participate effectively on a project. Whitsell noted that by being clear, respecting your part in the problem, having a plan, and knowing when to escalate, you can help a reviewer become a helpful resource, enriching both the product and the experience. “Be well with what you’ve done,” Whitsell said, “and be well in your commitment to yourself to train your reviewers to treat you the way you deserve to be treated.”

QC DETOURS: IMPROVING THE QUALITY CONTROL PROCESS

Speakers
Amanda Pennington, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc, Downingtown, PA
Pamela Fioritto, Quality Reviewer and Medical Editor, Whitsell Innovations, Inc, Cleveland, OH

By Shannon Hach, MD, ELS
In the development of clear and accurate medical and scientific documents, the quality control (QC) team is responsible for maintaining the integrity of materials while adhering to allotted timelines and budgetary constraints. This process requires documents to move along a course that is sometimes fraught with roadblocks. Toward the end of the journey, the QC specialist (“QCer”) is in the driver’s seat and is often faced with the challenge of hitting a bump (or multiple bumps) in the road. In this session, Mandy Pennington and Pam Fioritto sought to highlight the most common roadblocks and provide a collaborative forum to identify solutions.

Prior to the conference, Mandy and Pam surveyed 11 QCers. Initially, they sought to define QC. Respondents predominantly identified the following tasks: reviewing grammar, spelling, and punctuation; checking data; confirming adherence to format and style; and copyediting. A QCer was defined as the person who performs these roles and is often expected to complete “other duties as assigned,” thus becoming a “Jack of all trades.”

The survey also assessed the most common types of documents prepared by QCers, as well as their most common work settings. Of the respondents, 72.7% worked mostly on regulatory documents, 36.4% worked on manuscripts/peer-reviewed publications, and the remaining 27.3% worked on educational, marketing, or public relations materials. The majority of respondents worked in pharma/biotech (44.4%) or freelance businesses (33.3%). Respondents had worked in QC for an average of 3.9 years.

Asking about the likes and dislikes of working in QC, the survey was able to identify the most common issues facing QC specialists. The top frustrations or roadblocks included (1) unreasonable or limited timelines and (2) issues with source documents (ie, inconsistent annotation and writers not providing or specifying location of the materials).

The session participants were asked to participate in small groups and to brainstorm problem-solving ideas for each issue. The following tables (Table 1 and Table 2) describe the solutions suggested by the audience.

Table 1. Managing Timelines

<table>
<thead>
<tr>
<th>Timelines With Preparation Time</th>
<th>Timelines Without Preparation Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Develop a clear process in advance and train writers and QCers in that process, thus avoiding roadblocks in the first place</td>
<td>• Check document to better predict a promised deadline</td>
</tr>
<tr>
<td>• Clearly train writers in annotation style</td>
<td>• Split work with others if too complex</td>
</tr>
<tr>
<td>• Have QCers clearly communicate any changes that are made to annotations</td>
<td>• Make a priority list: identify what MUST be done vs less important issues</td>
</tr>
<tr>
<td>• Involve QCer from kick-off throughout life of the project so that they can provided input about time needed for review</td>
<td>• Manage expectations: establish what can and cannot be accomplished within the allotted time</td>
</tr>
<tr>
<td>• Use metrics to establish formulas for typical project vs more complex project timelines</td>
<td>• Use rolling comments: send document in “chunks” so that writer can address while QC continues simultaneously</td>
</tr>
<tr>
<td>• Ensure that the end client understands and adheres to their timeline for feedback, and clearly define who gives feedback to whom, and when</td>
<td>• Consider notifying client that an increase in budget may be necessary to allow for additional QCers to meet higher expectations/ expedited turnaround time</td>
</tr>
</tbody>
</table>
What Is Pharmacovigilance?

The definition of pharmacovigilance is “a set of activities relating to detection, assessment, or understanding and prevention of adverse effects or any other drug-related problem.” Various documents are written over a drug’s lifecycle to document pharmacovigilance activities, including after the drug has been approved for the market.

Writing for pharmacovigilance and for clinical development are similar in that they track many of the same data types. Both document adverse events, drug usage, patient information, authorized indications, and general safety information about a drug. Additionally, in both settings the writer is responsible for analyzing and summarizing the data.

Pharmacovigilance writing does differ from clinical development writing in a few important ways, however. Clinical development includes drug-related data before a drug’s approval for the market (therefore in a highly controlled setting), whereas pharmacovigilance also includes drug-related data after a drug has been authorized for the market. Much more patient information is available for pharmacovigilance purposes and, because these data are not gathered exclusively in a clinical setting, missing data is normal. Another difference is that pharmacovigilance documents may reach a broader audience—including external groups like the US Food and Drug Administration, patients, and ethical committees and internal audiences like outcomes research, clinical development, and medical affairs.

Pharmacovigilance Documents

Several important pharmacovigilance documents were discussed in this session:

- Development safety update report (DSUR)
- Risk management plan (RMP)
- Periodic benefit-risk evaluation report (PBRER)
- Addendum to clinical overview (ACO)
- Signal assessment report
- Safety analysis report
- Company core data sheet (CCDS)
- Benefit-risk analysis

The first 4 of these documents are periodic reports written for external regulatory agencies, and the last 4 are cumulative reports that are mostly for the benefit of the company that holds the product marketing authorization.

Welke described the reports written for external agencies as having many common sections and shared some details about each of them. The DSUR summarizes the product’s safety in clinical studies and shows whether the product is safe to continue to study in people. The RMP describes the risk management system and how the sponsor is limiting the risks to people using the product. The PBRER summarizes the benefit-risk profile and shows if the product’s benefits outweigh the risks in the marketplace. The ACO summarizes all safety data accumulated since the product’s marketing authorization or since the last renewal.

The documents written for internal use are frequently cumulative reports that primarily serve as an analysis of product-related data. The signal assessment report evaluates the safety of a single event or related group of events associated...
with validated safety signals. The safety analysis report serves the same purpose as the signal assessment report for events that are not associated with validated safety signals. The CCDS summarizes a company’s key messages to share about the product, and the benefit-risk analysis evaluates the benefits and risks of a product. All documents—whether for external or internal use—are interconnected; some even reiterate content in other reports.

Pharmacovigilance Writing
New pharmacovigilance writers should be familiar with the product, disease, and events that are the focus of their work. It is also important for new writers to familiarize themselves with the current guidance on their product, as it changes frequently and as there are many guidance sources (Figure).

Welke described the pharmacovigilance writing career as one in which you must adhere to tight work timelines, be able to accept that some data are missing, be able to analyze and provide opinions to your team, and know what the expected content is in each document. Welke also stated that “medical writer” search terms are generally not used to describe pharmacovigilance careers. The following are the search terms she suggested for a pharmacovigilance job:

- Pharmacovigilance Scientist/Analyst/Author/Writer/Manager/Specialist
- Safety Scientist/Specialist/Writer
- Periodic Report Scientist/Analyst/Manager/Officer
- Associate/Manager/Director of Pharmacovigilance

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Tools to Thrive in a Digital World

Speakers
Monica Nicosia, PhD, Independent Medical Writer, Nicosia Medical Writer, LLC, Bryn Mawr, PA
Kathy Boltz, PhD, Owner and Principal Medical Writer, On Point Scientific, LLC, Phoenix, AZ

By Ana Jakimenko, PhD

Many digital tools are created to assist small businesses in reduction of time spent on nonbillable, boring, and administrative tasks and in improvement of data security and efficiency of billable tasks. The main digital tools used by the speakers are shown (Figure).

The data generated using Microsoft Office Suite (MS Office) tools need to be stored, accessed, backed up, and shared. Data can be stored or backed up with local hardware and software or on the Cloud. The most important factors for choosing the local site versus the Cloud are:

- **Costs:** The local site has a one-time cost, whereas Cloud-based services have an annual or monthly fee.
- **Responsibility:** The owner of a local site is responsible for maintenance of hardware and data security. If the data are deposited on the Cloud, the Cloud-based service provider will take care of that.

Local data backup generally uses a network-attached storage drive and a redundant array of inexpensive disks (RAID) with software. RAID replicates copies of data across the inexpensive disks to protect against hardware failure of any individual disk.

Nicosia advised attendees to follow the 3-2-1 rule for effective backup⁴:

- Always have 3 copies of data
- Keep 2 copies on different types of storage
- Keep 1 (or more) copies of data offsite

The most commonly used Cloud-based data storage and sharing service among freelances in 2016 was Dropbox.² An alternative, Egnyte, allows clients to access password-protected files and is cheaper than Dropbox.¹ OneDrive, another alternative to Dropbox, is included in the MS Office 365 subscription.

Website Design and Hosting

Owning a website is a powerful marketing tool for freelance medical writers. The most popular website building and hosting tools among the freelances were GoDaddy, Bluehost, and Wix.³ In 2018, the best website builder for small businesses was Wix,³ whereas the best website host was HostGator.³

Travel and Data Security

To ease traveling, Boltz recommended using airline and hotel apps and an Expensify app to efficiently digitize and categorize travel expenses. Anyone can monitor Internet
traffic through public Wi-Fi networks (airport, coffee shop, etc). To protect one's privacy while traveling, Boltz recommended:
• Hard shutdown of all electronics before going through customs
• Use of a purchased virtual private network before connecting to public Wi-Fi or use of your own network (eg, cell phone)

Recent data security breaches of companies like Yahoo and Facebook make the managing of passwords and login information vital for everyone. Best practices for enhanced data security are as follows:
• Use secure passwords everywhere
• Use different passwords for every account
• Use 2-factor authentication whenever it is available

Boltz suggested using password manager software such as LastPass or Dashlane to help create unique passwords and to always keep your smartphone locked with a 6-digit PIN. The MS Office 365 subscription keeps the software updated, which makes the use of Outlook for email a compelling solution for freelances. The editor's choices for small businesses are Intermedia Exchange Email and MS Office 365 Business Premium.5

Business Software
Online accounting services offer user-friendly interfaces and navigation and allow users to keep track of accounting and time spent working, accept credit cards payments, etc.5,7 The best free time-tracking app is Toggl, and the best integrated invoicing apps are Harvest, FreshBooks, and Paydirt.8 Working remotely through screen sharing has lots of options: Join.me, Cisco Webex, Zoom, UberConference, and Google Hangouts.

The 3 most popular citation management tools are EndNote, Zotero, and Mendeley. Other useful digital tools are FreeMyPDF (PDF unlocking), Unpaywall (full text finder), PerfectIt proofreading software (proofing), and transcribe (transcribes audio file into text).

For more information, the presenter’s slides are available on the AMWA website at https://www.amwa.org/page/2018sessions.

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References

RESPONSES TO REGULATORY AUTHORITIES:
MEASURE TWICE—CUT ONCE

Speakers
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Art Gertel, Principal, MedSciCom, LLC, Lebanon, NJ

By Priyanka Ingle-Jadhav, MD, PhD, MWC®
Key interactions with regulatory authorities occur essentially at 2 stages of the drug development cycle. The first is prior to
Submission of a registration dossier to the regulatory agency, which comprises both formal and informal exchanges of information between the Sponsor and Agency. This can be in the form of Sponsor-requested meetings or responses to inquiries from the Agency. The other important interaction is in the postsubmission period of an application dossier, during which regulatory authorities pose questions to Sponsors requiring written responses.

With respect to the US Food and Drug Administration (FDA), the first kind of interaction, prior to submission of an application, is generally to get additional insights from the Agency on the sufficiency of available data and the planned clinical program. The Agency will provide recommendations for technical changes, the Clinical Development Plan, Investigational New Drug Application documentation, or a Special Protocol Assessment or will provide guidance on ways to resolve any critical issues that might affect the application approval process, going forward. These formal communications are clearly outlined in FDA guidance. A formal meeting request is made by the Sponsor to the Agency, stating clearly the meeting type requested. Depending on the type of meeting, a response on acceptance and format of the meeting is communicated by the FDA, usually between 14 and 21 calendar days after the request was made. Following this, the Sponsor is required to submit a meeting package (often referred to as a “Briefing Book”) 30 to 50 days prior to the scheduled meeting (depending on the meeting type). The pre-NDA/BLA (New Drug Application/Biologics License Application) meetings are usually held 6 to 12 months prior to the planned submission, to allow for a comprehensive review of the provided summary of relevant data generated during drug development. Thus, the meeting package should include details about any critical issues that may impact the application approval.

Postsubmission communications vary with different regulatory agencies. Although there are some significant differences in timelines for communication between the agencies, using a standardized approach to getting ready for and then writing responses to authority questions can make the process more efficient. The central theme is to be proactively prepared with a team capable of rapidly producing focused responses. This team should comprise key functions such as clinical operations; biostatistics; clinical pharmacology; preclinical operations; chemistry, manufacturing, and controls; regulatory affairs; medical writing; and document management. In order to have a well-managed and well-planned writing process, the team members should be assigned specific roles and responsibilities so that it is clear who should be doing what once the questions come in.

The team should initially get ready to address potential regulatory questions by performing a self-critical “gap-analysis” to identify the potential challenges that may be raised by the regulatory authorities. For example, these could include weaknesses of the drug or class of drug, deficiencies in the development program or data analysis, etc. This helps them identify what issues are expected so that the team can plan on likely deliverables that will be needed to support a response to each issue.

Timelines must be agreed on to manage who will deliver what pieces when, and these must be realigned, as needed, depending on the challenges that arise during the writing process. A tracking sheet for monitoring the status of responses in preparation (ie, in draft, in review, or finalized), open action items, and whether the responses will have appendices or literature is an essential tool for managing the process. The team is often writing several responses in parallel, and a tracking sheet helps keep effective oversight of each of these.

It is helpful to have a medical writer as a team coordinator who is capable of pulling the input from the contributing functions together and who is responsible for maintaining the tracking sheet. For larger teams and projects, which may require multiple medical writers assigned to subsets of responses, it is important to have a medical writer who has oversight across all the activities and who can coordinate the activities across all the areas.

Once the questions from regulators arrive, the team needs to distinguish which questions have already been addressed in preliminary work and which are new. It is important to triage the questions to identify which are more complicated and may need longer to prepare (perhaps external experts will need to be involved or fully new analyses will be needed) so that these can be prioritized by team. Questions that were not anticipated will need to have content authors assigned who can lead the discussion on response strategies. It is also important to identify issues that may require further contact with the regulator to clarify any areas of uncertainty.

Because FDA questions can arrive at any time, it is important to agree in advance on the process for action and on meeting frequencies after questions arrive, as well as to set goals for time to completion of the response. In the absence of official regulatory guidance for format and content of responses, it is advisable to keep the responses brief, well-structured, and consistent with the layouts and presentations from the dossier to make them reviewer-friendly and easy to read. References should be made to the identifying item number and location in the original briefing package to allow the reviewers to easily locate and access the initial positions. It is also imperative for the team to be strongly focused only on answering the questions asked and to not add any new data unless requested.

In the case of a Marketing Authorization Application to the European Medicines Agency, initial assessment reports at day 80 and day 150, which are sent ahead of the final consolidated list of questions at day 120 and day 180, are beneficial in helping to identify any such issues prior to the clock stop. Once an area of concern is identified in the preliminary questions, the team can begin to prepare their strategy for a response, which will then be refined after the final questions are received. If additional data analyses are required to address the anticipated queries, these can be initiated so they are ready to use if
the question remains in the final list of questions. The medical writer is ideally positioned to identify the parties responsible for supporting data and analyses that will be required to develop regulatory responses. They must have a good understanding of the development process and work closely with their team members in order to guide an efficient and effective preparation of position statements and responses to regulator questions.

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Reference

FIT FOR FREELANCE: HOME WELLNESS
HEALTH SECRETS

Speaker
Reggie Wilson, MS, Founder, Fit for Freelance, Naples, FL

By Kelly Schrank, MA, ELS
Reggie Wilson began in public health and nutrition and transitioned to medical writing as an extension of his desire to help remote workers enjoy their work-life balance. The session began with a recommendation of a TED Talk by Simon Sinek called “Start with Why” (https://youtu.be/IPYeCltXpxw). Your why drives behavior. Reggie Wilson believes quality of life is a better motivator than just improving health. For instance, you should focus on the experience of the 5-minute walk rather than just doing it to check it off your list or lose weight. As he stated, “The most enjoyable effects are likely to get you walking again.”

Health components include family history, environment, and lifestyle. A low level of exercise is a risk for a number of chronic health conditions, including diabetes, pain, obesity, constipation, heart disease, arthritis, high blood pressure, cognitive dysfunction, and stroke. Taking a break from work to stand up or walk for at least 1 minute makes a big difference in waist circumference, according to an article he cited, although he recommends a break of closer to 5 minutes. Overall, individuals should be striving to reach the Centers for Disease Control recommendations for activity levels: 150 minutes per week (22 minutes per day) of moderate exercise or 75 minutes per week of vigorous exercise.

There are immediate and long-term reasons to exercise. As Wilson said, right now (ie, sitting at the session [or reading this article]), there is less blood flow to the brain, and you have decreased focus and creativity; it takes more time and effort to stay locked in and produce mistake-free work. In the long term, a continued sedentary lifestyle will result in more cortisol, which is associated with anxiety, depression, weight gain, and heart disease at high levels.

His solution? Have the audience stand up and move around to a YouTube video called “Instant Recess” (https://youtu.be/tMuZ0_.Y7n4).

Physically active people are happier and more productive, according to a number of articles Wilson cited: participants in a 2-week exercise program also decreased their sensitivity to anxiety. Exercise can make a difference in whether you have a good day at work or a bad day at work.

Wilson created a wellness community with online tips, personal training, and support for freelances and entrepreneurs who want to confidently work better: https://fitforfreelance.com/.


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Home Wellness Recommendations:

• Take 1 Break an Hour
  – 5 minutes is optimal
  – Trade a coffee break for a walk

• Take Power Naps
  – 5–10 minutes
  – Use a timer

• Eat Healthy Snacks
  – Cut-up cucumbers
  – Almonds

• Get Regular Sleep
  – 7 hours/night

• Drink Water
  – Too little: get up to get more
  – Too much: more bathroom breaks

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37 TIPS FOR EFFICIENTLY WRITING SCIENTIFIC PUBLICATIONS

Speaker
Katherine Molnar-Kimber, PhD, President and Medical Writer, KMK Consulting Services, Kimnar Group, LLC, Worcester, PA

By Kristin A. Roynesdal, MS
Medical writers who work on scientific publications can improve their bottom line by adopting a productivity mindset and working more efficiently. During this session, Katherine Molnar-Kimber shared 37 efficiency tips for the planning, writing, and reviewing of scientific manuscripts.

Planning for Publication
Before writing, planning can save medical writers significant time and stress. At the start, you should obtain clear, specific details about the project, including timelines, your responsibilities, team members, and ultimate publication goals (Figure 1). By clearly defining tasks, determining priorities, and setting a tentative schedule, many common problems encountered during writing and revision can be avoided. Additionally, “you want to make sure you get buy-in from all stakeholders,” explained Molnar-Kimber, to avoid delays during revision due to late reviewer input.

Delays can also be avoided by consulting relevant guidelines for determining authorship (eg, International Committee of Medical Journal Editors [ICMJE] recommendations) and reporting methods (the Enhancing the QUAlity and Transparency Of health Research [EQUATOR] network for clinical trials; Animal Research: Reporting of In Vivo Experiments [ARRIVE] for animal studies). If a target journal is known, its instructions should be examined to ensure the manuscript matches the journal’s scope and to identify journal-specific requirements, such as word or figure/table limits. Journals often provide author checklists, and some, such as Radiology, even provide public access to peer review checklists. Molnar-Kimber advised consulting these checklists early and often.

Figure 1. Specific details to clarify during the publication planning stage. ©www.gograph.com / artist: get4net, figure modified by Katherine Molnar-Kimber.

Writing Your First Draft
Molnar-Kimber encouraged writers to begin with the Results section “because everything in the document is dependent on the presented results.” The Methods should only include the steps taken to obtain the results. For the Introduction, sufficient information should be provided for the reader to grasp the rationale and understand the Methods and the Results. Finally, the Discussion should focus on the significance of the study’s results to the larger field.

The Results section largely requires writing about numbers to describe comparisons or highlight differences that are statistically or clinically significant. To create clear sentences about numbers, Molnar-Kimber proposed using the “4 W’s” of writing:
- **Who**: Groups or subgroups
- **What**: Units of measurement
- **When**: Duration of analysis or year
- **Where**: Study site location or geographic population
- **How much**: Magnitude/direction of the effect or response

After the Results are complete, the Methods can be written. Here, you may question what steps must be included and what can be left out. To avoid confusion, Molnar-Kimber suggested listing the reagents used and asking 2 questions:
- Is this essential to reproducing the study?
- Would most readers need this information to understand the results?

If the answer to both questions is “yes,” this information belongs in the Methods. If the answer to the second question is “no,” the information can be placed in the supplementary file.

When working on the Introduction and Discussion, you may struggle with which section should cite contradictory data described in published articles. To minimize this deliberation, Molnar-Kimber provided a decision tree (Figure 2). Briefly, if the article spurred the investigators to alter the design or

Figure 2. Decision tree for selecting where to cite an article of contradictory data. Copyright 2018, Katherine Molnar-Kimber.
interpretation of the research in the current study, it should be cited in the Introduction. If not, it can be cited in the Discussion.

To minimize writer’s block and procrastination, Molnar-Kimber encouraged reading key references to gain context. She also cautioned against editing while writing, which can often hinder the flow of ideas. Instead, you should plan a time for editing separate from writing.

Reviewing the Manuscript

After writing is complete, you should spend time self-editing for structure, grammar, style, and consistency. Molnar-Kimber suggested using PerfectIt 3 software to save time during proofreading and help fix inconsistencies in hyphenations or abbreviations.

When multiple people review a document, version control can be difficult to maintain. Several software programs are available to help manage the review process. Some, such as PleaseReview, allow multiple reviewers to work on the same document simultaneously. However, if the program allows only a single reviewer, Molnar-Kimber recommends training the team to sign the manuscript back in when stepping away from the computer to avoid unnecessary delays between reviews.

Just like writing, implementing productivity tips into your daily work requires planning and review. To supplement this, Molnar-Kimber provided a handout for writers to list their top 6 tips and prioritize them by helpfulness. For maximum efficiency, writers should implement the highest-priority tip consistently for 1 month, then assess its advantages/disadvantages and determine whether to continue its use.

Online Resources

A document file summarizing the session slides and handout content is available online.

The Radiology checklist for peer reviewers can be found at https://pubs.rsna.org/page/radiology/reviewer-checklist. To learn more about the PleaseReview software, visit https://www.ideagen.com/products/pleasereview.

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CHALLENGES FOR BIOLOGIC AND BIOSIMILAR DEVELOPMENT: A CHEMISTRY, MANUFACTURING, AND CONTROLS (CMC) PERSPECTIVE

Speakers

Teresa Chu, PhD, Medical Writer and Consultant, Whitsell Innovations, Inc, Chapel Hill, NC
Mary Ellis Bogden, BA, Senior Writer and Manager, Whitsell Innovations, Inc, Chapel Hill, NC

By Leslie Kowitz, MA, ELS

Welcome to the world of CMC—chemistry, manufacturing, and controls. Teresa Chu and Mary Ellis Bogden took the audience on an information-packed tour of biologic drug development, analytical chemistry, and the emerging space of biosimilars. For many, this was not only an introduction into the differences between biologics and biosimilars but also an exploration of the complexities and challenges in drug development and manufacturing processes—topics often challenging for medical communicators. This report provides a general overview of the session’s focus on biosimilars. A more comprehensive article on biologic drug development and the analytical methods used to determine biosimilarity is planned for a future issue.

The Goal of CMC

To develop a new drug in the United States, a company must submit sufficient information to assure “the proper identification, quality, purity, and strength” of the product (21 CFR 312.23) in the form of an Investigational New Drug Application (IND). The CMC group is responsible for planning, driving, and overseeing studies and experiments that generate information required to write the Quality sections of the IND. In the case of biologics, Chu emphasizes that “the process is the product.” The process is as much a part of a company’s license as is the final drug product.

What Are Biologics and Biosimilars?

Before going further, we need a common lexicon to eliminate potential confusion (Table on next page).

Brief History of Biosimilars

Biosimilars are relatively new players to the US pharmaceutical industry, available only since 2015 (Zarxio from Sandoz, biosimilar to Neupogen), whereas the European Medicines Agency recorded their first biosimilar license in 2006 (Omnitrope from Sandoz, biosimilar to somatropin). Some of the early biologics approved in the 1990s saw their patents expire after 20 years in the early 2000s, making those fair game for other companies to try to create highly similar products. As of this writing, 13 biosimilars are currently available in the United States.
Developing Biosimilars Versus Biologics

So, a particular biologic product is moving off patent and you think it would be a great idea to create a biosimilar. How do you do it? Chu reminds us that the manufacturing process for biologics is proprietary, so only the original manufacturer knows how to produce their biologic product. Biosimilar companies therefore have to figure out how to make the product and show biosimilarity through analytical methods, which is not as simple as it sounds. Small-molecule drugs have well-defined chemical structures and can be analyzed to determine all their components. Known as the RLD when licensed by the originator (eg, Valium).

Biosimilar

“Follow-on” biologic that is highly similar to the RP; with an abbreviated regulatory pathway. Less expensive than the RP, manufactured by a company other than the originator (eg, Inflectra).

Small Molecule (Drug)

Created by chemical synthesis, these compounds are small (molecular weight <900 Da), have well-defined chemical structures, and can be analyzed to determine all their components. Known as the RLD when licensed by the originator (eg, Valium).

Generic

Small molecule, chemically identical to the RLD, with an abbreviated regulatory pathway. Less expensive than the brand name drug, manufactured by a company other than the originator (eg, diazepam).

The following Figure shows relative resources used and emphasizes different stages of development for biologics and biosimilars. The originator company (left) is heavily weighted on clinical studies, whereas the biosimilar company (right) focuses its efforts and resources on the analytical data to prove similarity.

Abbreviated Regulatory Pathway

One major difference between biologics and biosimilars is in regard to their regulatory approval pathways. Although biologics go through a lengthy and expensive research and development process, originator companies must also conduct 3 phases of clinical trials (healthy volunteers and target population) before submitting a Biologics Licensing Application—a significant financial investment (hence, their hefty price tag to patients).

In 2010, President Obama signed into law the Patient Protection and Affordable Care Act (which amends the Public Health Act) to create an abbreviated approval pathway for biologics products that are “highly similar” to a US Food and Drug Administration (FDA)–approved product. The pathway is referred to as the Biologics Price Competition and Innovation Act (BPCI Act) of 2009. The goal of the BPCI Act is to facilitate market competition and regulatory approval and help get these medicines to patients faster and potentially for less money than the original biologics by leveraging existing safety and efficacy data previously reviewed by the FDA.

Although the pathway may be abbreviated for biosimilars, the FDA does not make it any easier for companies to license biosimilars. Reviewers employ the same rigor as with any original product. They evaluate applications for biosimilars on a case-by-case basis and look at the “totality of evidence.” In addition to the extensive analytical data required for showing similarity to the Reference Product, phase 1 and confirmatory clinical studies are usually required to show safety and efficacy of the biosimilar in 1 or more indications for which the original product is licensed.

Time will tell what changes may occur in the marketplace as a result of biosimilars competition. The goals of the BPCI
Act are promising to patients, but the challenges are high for those seeking success with biosimilars. With so many companies already vying for position, others are pulling out of the biosimilars space because there will not be enough room for everyone.

For additional information, see the FDA’s final guidance, Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product and Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, April 2015.

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YOUR FREELANCE BRAND: HOW TO STAND OUT IN A SEA OF FREELANCES

Speakers
Lori De Milto, MJ, Freelance Medical Writer, Lori De Milto Writer for Rent, LLC, Sicklerville, NJ
Kathleen Labonge, MBA, Freelance Medical Copyeditor, Write Point Editing Solutions, Greensboro, NC
Eva Stabenow, MA, German/English Translator, Wordplay Translations, LLC, Nashville, TN

By Kelly Schrank, MA, ELS
Freelances who want to “stand out” (ie, do less marketing and make more money) need to have a brand. “To clients, most freelance medical writers or freelance medical editors seem the same or similar,” says Lori De Milto. Having a brand—a personality for your business that evokes trust and makes clients think of you first—is a differentiator in a crowded market.

Although personal and business brands overlap for freelances, they are not the same. Business branding is how clients, potential clients, and colleagues perceive you as a business based on your visual images and key messages, whereas personal branding is more about your behavior and tone of voice online and in person, especially when networking. The session’s focus was on business branding.

Elements of a Brand
The elements of a brand include a logo, a tagline, a company name, a tone of voice, and colors. A logo is an image, symbol, other design, or just your company name in a nice design used to visually represent your business. A tagline is a memorable phrase or sentence that helps your audience understand what you do. It is used with the logo on your website and in other marketing materials. A company name could be a business name or just your name and title/what you do.

Your brand’s tone of voice expresses the company’s values, personality, and way of thinking. A palette of colors associated with your business (normally a dominant and a secondary color, and sometimes an accent color) further cements the personality and professionalism of your business.

Brand Statement
The first part in developing a brand is creating a brand statement, which clearly and concisely explains
• Your services,
• Your target audience(s) or client types, and
• How you’re different from or better than other freelances.

You don’t actually have to be different from or better than other freelances; you just need to position yourself as different or better. For example, De Milto discussed how her brand focuses on delivering targeted medical content and doing this on time every time. Many freelances write content that’s targeted to the audience and meet their deadlines, so this isn’t unique. But De Milto thinks that using this in her branding makes her stand out in the minds of clients.

Base your positioning on the needs of your clients (eg, making the client’s life easier, doing the project right, and meeting deadlines) and your core values and personality traits (eg, dependable, efficient, and responsive). You need to develop your brand statement before you contact a designer for the rest of your branding.

Template for a Brand Statement
[My target audience] can count on me for [key services] delivered with [things that make me different, including core values and personality traits].

Working With a Designer
To prepare for the process, gather logos you like (those of other freelances or even other types of businesses), colors you like, your brand tone of voice, and images you like (such as icons or other images). De Milto suggests hiring a professional and avoiding sites like Fiverr.com.

Your designer will help you to choose colors that look good on the Web and in print and to develop a logo that looks great on your website, email signature, and business cards. The advice from the group for the design process was to be honest about what you like and don’t like and don’t develop “analysis paralysis.”

The session materials have more details and examples, such as the brands of Lori, Eva, Kathleen, and other freelances: https://www.dropbox.com/sh/25mlnxlwxjy49gg/AACBdD3CKgzYf-y4wGFkT_Dya?dl=0.
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DISSECTING THE CRITICAL “SPECIFIC AIMS” PAGE OF AN NIH GRANT

Speaker
Madison Hedrick, MA, Medical Writer III, Wilson Carroll Research Services, LLC, Little Rock, AR

By Chandler Wilson Carroll
The Specific Aims page of the National Institutes of Health (NIH) grant application is the most important part of any NIH grant application. It is the primary marketing document for the entire proposal and exists to define the “big picture” and provide a roadmap for the research strategy.

In a single page, you must quickly gain the reviewers’ trust and confidence while also convincing them that your work is important to fund. You must convince them that you (or your client) are the best person to complete the work you proposed. For this reason, the Specific Aims section can be the most difficult to write.

Organization of the Specific Aims Page
• Overarching problem and goal
• Context and setting for the project
• Central hypothesis
• Specific aims and experimental overview
• Expected outcomes and impact of the project

General Guidelines: Tips
The Specific Aims page is all about selling ideas! It is crucial for setting the frame of mind for the reviewers. A Specific Aims page that leaves reviewers feeling distinctly not excited will likely color how they will feel concerning the sections that follow. Deliver a clear message:
• Offer something special
• Make it similar to a good news article:
  – Concise
  – Good headlines
  – Visually appealing
  – Easy to read
  – Comprehensible to a wide audience
• Remember your audience: ALL reviewers!

General Guidelines: The Reviewer
Many reviewers will only read the Specific Aims page. Visualizing the reviewers as a group and the individual reviewer as an audience member when writing your Specific Aims page is beneficial.

Reviewers are often overworked and tired and may only spend a few hours on your grant. They are knowledgeable about research design and methods as well as NIH grant mechanisms, but they may have little in-depth knowledge in the specific area the grant focuses on.

NIH Guidelines for the Specific Aims Page
“State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.”

“List succinctly the specific objectives of the research proposed, e.g., to test a state hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.”

Specific Aims Page in Four Sections
Part 1: Introduction
• Introductory Paragraph: Convinces the reviewers of a significant problem. This will scaffold your argument for your solution that is relevant to the mission of the funding agency.
• Opening Sentence: Identifies what the proposal is about and immediately relates it to the mission of the funding agency.
• Knowns: Brings the reviewer up to speed on the “current literature” and state of the field in < 5 sentences; ALL key points need to be introduced here (this is the framework for your concept).

Figure. Used with the permission of M. Hedrick.
• Unknowns: Problem(s) that need to be addressed.
• Frame the Problem: The problem points to that critical need that serves as the driving force for the proposal. Conclude with WHY the lack of a solution is an issue for this funding agency.

Part 2: The "What, Why, Whom" Paragraph
• Long-Range Goal (broad): Principal Investigator’s career goal, which should match the funding agency.
• Objective of the Application (narrow): The purpose of the project described to meet the critical need; must have a well-defined endpoint.
• Central Hypothesis (most narrow).
• Rationale: What will be possible after completion of the aims that is not possible now? What is the underlying reason to complete the project as it relates to the agency’s mission?
• Well-Prepared: Collective basis for the competitive advantage of your group. Convince the reviewers that you and your team have the solution to this critical need.

Part 3: The Aims
• Aims Paragraphs: Provide a logical, step-by-step development of key hypotheses and activities through which you will fulfill the objectives to address the critical need or problem.
• Each paragraph should collectively address the objectives; be conceptual, but not descriptive; and avoid aims that are dependent on the outcome of other aims. A formatting suggestion is provided below:
  Specific Aim 1—Brief, focused statement
  × subtext with more details, including measurements and comparisons
  Specific Aim 2—Brief, focused statement
  × subtext with more details, including measurements and comparisons
  Specific Aim 3—Brief, focused statement
  × subtext with more details, including measurements and comparisons

Part 4: The Payoff Paragraph (the Impact)
• Innovative/Transformative Statement: Should directly follow the aims/goals/objectives and build advocacy for the project.
• Expectations: Make sure these are specific and credible.
• Impact: How these outcomes will meet the identified need.
• Inspirational: How will this "change the world?"

After completion of the entire research strategy and Specific Aims page, it may be beneficial to go back and ensure that the following questions are answered:
• What experimental outcomes (at least 1 important outcome per aim) do you expect?
• Collectively, how do they achieve the overall objective stated in the hypothesis?
• What are the impacts of your expected success—what will be the subject that was [not possible/not known] that will be [possible/known] with respect to the following:
  – Knowledge benefiting human health and disease; and
  – Advancement of your field of research?

After reviewing your answers to these questions, determine if they were well communicated in the Aims page so that the reviewer can locate these outcomes with ease.

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UP YOUR EFFICIENCY GAME (WITH PERIPHERALS)

Speaker
Kate McKiernan, MA, Medical Writer/Editor, IMPACT Clinical, San Diego, CA

By Kelly Schrank, MA, ELS
Kate McKiernan has a unique perspective on peripherals, comparing how you interact with a video game through controllers to how you interact with Word through your mouse and keyboard. Her credentials for creating this session, she explained, included 28 years of video game experience. Her big question is how can we interact with computers better? Her goals include increasing how much money she makes, getting a return on the time and energy investment, having a better quality of life, and decreasing error and interaction cost.

She sets the stage with the following picture of her work area:

Shown above are USB cables, dual monitors with monitor arms, a separate number pad, and a gaming mouse.

Five Essential Peripherals
The first peripheral is helpful for those who have multiple
A hub with USB-C cables allows you to have 1 set of peripherals connect to multiple laptops, saving space on the desktop, saving precious brain power not having to adjust to different laptops or peripherals, and saving time in not having to connect to/disconnect from different laptops. Estimated cost: $15.

The second peripheral enhances the convenience of dual monitors, something many medical communicators already have, but McKiernan takes this a couple of steps further by pivoting the monitors on monitor arms, so they can be repositioned quickly and easily as needed for different tasks. Her default mode has both monitors in portrait mode, which allows you to see more words at a time in Word documents and PDFs. Monitor arms can be clamped on the end of the desk or screwed into wood. Estimated cost: $200.

The third peripheral ensures productivity in a different way by protecting your Internet router with an uninterruptible power supply (UPS). When your power goes out, you usually lose Internet because your Internet router needs electricity, too. If you plug the router into the UPS, the router can stay on for another couple of hours. Kate McKiernan recommends not connecting everything to it, as that same UPS with “everything” on it will only last about 15 minutes. Estimated cost: not provided, as the prices can vary widely.

The fourth peripheral is a separate number pad. Her personal layout has the number pad on the left, with the keyboard in the middle and the mouse on the right. With this layout, the distance from keyboard to mouse is reduced, making you more efficient, and the numeric keypad, which has limited usability on a day-to-day basis, is out of the way unless you need it. Estimated cost: $10.

The fifth peripheral, which McKiernan says was actually her first and best change, is the gaming mouse, which “changes multibutton inputs into one button.” For example, Word lets you assign keyboard shortcuts, then the gaming mouse lets you execute multiple keystrokes with one button. She broke the process down into 3 steps: pick a common task, give the task a keyboard command (in Word), and assign the keyboard command (in the mouse). For example, assign a shortcut key to insert common symbols, apply styles, and change numbers to subscript or superscript or assign a keyboard shortcut to a macro. Estimated cost: $50.

Advice for Adapting to Gaming Mouse
- Choose tasks that are simple, done frequently, easily noticed when done, and easily undone
- Assign tasks to correct template (or Normal.dotm)
- Learn a new button 1 at a time
- Assign buttons logically
- Have the mouse controller layout on screen or printed out when getting up to speed
- Group buttons together by function, type of job, or whatever makes sense for your workflow
- EndNote has its own keyboard shortcuts; combine with the mouse

The session materials have more details on how to set up Word and the gaming mouse.

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PREDATORY PUBLISHING: ISSUES AND ADVICE

Speakers
Barbara Gastel, MD, MPH, Professor, Texas A&M University, College Station, TX
Barbara C. Good, PhD, Director, Scientific Publications, NSABP Foundation, Pittsburgh, PA
Mary Kemper, BS, Medical Writer/Yoga Instructor, Mayfield Clinic/Glia Media, Cincinnati, OH

Moderator
Kirby Snell, MFA, Copyediting Client Manager, J&J Editorial, Cary, NC

By Kirby Snell, MFA
This session on predatory publishing highlighted (1) some techniques used by predatory publishers to take advantage of authors, (2) strategies for identifying potential predators, and (3) how to respond. The panelists also touched on the larger impact and threat that predatory publishers can pose for academic and scientific publishing.

What Is Predatory Publishing?
A predatory publisher is an opportunistic venue that exploits the academic need to publish but offers little reward.
Common characteristics include the following:
• Their primary goal is to make money.
• They do not care about the quality of the work published.
• They make false claims or promises.
• They engage in unethical business practices.
• They do not follow accepted standards or best practices of scholarly publishing.

Of the approximately 28,000 scientific journals currently in existence, an estimated 8,000 to 10,000 are predatory, including potentially 1,200 to 1,500 predatory medical journals. Other predatory operations include fraudulent meetings, counterfeit impact factors, and hijacked journals (counterfeit websites stealing a real journal’s identity).

Identifying a Predator
Barbara Good walked the audience through a real-life case of identifying a potential predatory journal. Although the publisher’s website looked legitimate at first, many elements proved to be red flags, including a questionable mailing address, indexing information advertised only as “coming soon,” publication charges due at submission, journals in many disciplines all produced by the single publisher, poor use of English across the website, published articles of dubious quality, and no request for conflict-of-interest statements.

By watching for such warning signs and by asking themselves careful questions (Box), authors can guard themselves against potential predators.

Recognizing Valid Journals
Authors should take care, however, not to dismiss lesser-known but valid publications, such as small interdisciplinary journals or journals from developing countries. Barbara Gastel shared 2 cases of invitations she had received to peer-review or submit manuscripts, 1 from a questionable-sounding publication and 1 from an unfamiliar journal from overseas. Some investigating revealed that both titles were reputable, and she enjoyed rewarding experiences that would have been missed if she had disregarded the invitations too soon.

Predatory Publishing and Open Access
Mary Kemper highlighted the contributions of Jeffrey Beall, a Denver librarian who coined the term “predatory publisher” to define the threat to scholarly publishing by these deceptive journals that corrupt the gold model of open access (OA). He profiled predatory publishers on his blog Scholarly Open Access (2012-2017), which offered critical commentary on their questionable practices. Beall’s blacklist was an invaluable resource for academic authors and librarians, but it was also criticized for its shortcomings (eg, the use of the term predator) and his critique of the OA social movement. Following consistent harassment by several notorious blacklisted publishers, Beall shut down his blog in 2017.

While Beall’s list is now inactive (although archived online), other resources for fighting predatory or illegitimate publishing exist, including Cabell’s International (which maintains both a whitelist and a blacklist) and Think Check Submit. The Directory of Open Access Journals also recently delisted more than 3,000 of its approximately 11,000 journals in an effort to crack down on predatory journals.

The Impact of Predatory Publishing
Although the pressure to publish—and, increasingly, the pressure to publish in OA—is significant, writers and researchers must be cautious when selecting venues and responding to invitations from unfamiliar publications to review or submit work. Most immediately, an author’s reputation is endangered by publishing in a journal that lacks peer review, is not indexed, or that publishes bad science. More broadly, predatory publishing damages the medical literature itself: publishing research that is pseudoscience or poorly done (or falsified) can eventually erode the medical literature base to the point that “truth” is not discernible.

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Questions to Ask
• Did you receive an obsequious-sounding email from the journal?
• Do they charge a very large or very small submission fee? On submission or at acceptance? Is the fee transparent on the site?
• Is the journal indexed? Are the metrics legitimate?
• Is the website’s language awkward, with misspellings, poor grammar, etc?
• Is the journal very young?
• How quick is peer review?
• Does the publisher claim to publish many journals in varied fields?
• Are any editorial board members prominent researchers in the field, or anyone you recognize?
• Does the editorial office address seem legitimate?
• How does a sample article read?
• Was the journal or publisher on Beall’s list? Are any current Web resources evaluating them?
2018 CONFERENCE COVERAGE

OPEN SESSION REPORTS

MASTER THE DISASTER

Speakers
Brian Bass, MWC®, President, Bass Global, Inc, Fort Myers, FL
Larry Lynam, DSc, MA, SM, RM, Principal, The Lynam Group, LLC, Coral Springs, FL
Michelle Sauer, PhD, ELS, Principal Editor, RNA Editing, LLC, Cypress, TX

Moderator
Lori Alexander, MTPW, ELS, MWC®, President, Editorial Rx, Inc, Fort Myers, FL

By Larry Lynam, DSc, MA, SM, RM

With a dash of wit and a dose of practicality, this session created awareness around a variety of disasters that we each faced as freelances while attempting to keep life and business functioning. We can all agree that disasters come in many forms and fashions, and no one is really prepared for unanticipated challenges when they visit or stay for an extended time in your life. Disasters include the natural phenomena unique to our respective geographies (hurricanes, floods, blizzards) but also include the “unnatural” ones, such as health issues, caregiving for our loved ones, and travel and technologic nightmares. In the discussion of caregiving, we reframed the term “sandwich generation” (caregivers for both parents and children) to point out that not all sandwiches look alike, as “open-faced” sandwiches (caring for either parents or children) present similar issues that we have all experienced and created a work-around to overcome. We shared numerous problems related to travel and technology that we had to solve. Some of these nightmares were thrust upon us, and others were inadvertently self-inflicted. Nevertheless, in all cases, we had to think on our feet and solve the problem as best we could.

In addition to commiserating over shared woes, we outlined several goals and takeaways for our attendees. One key is to develop and use perspective—not all disasters have the same magnitude, and proper perspective can prevent exhaustion. Another theme that we all recognized was the degree to which we deployed humor as a coping mechanism and the importance of perfecting our coping skills before deployment is needed. In general, proper preparation includes improved communication tactics for both clients and family members. But there are nuanced solutions for more unusual obstacles, such as back-up equipment (and generators) to prepare for disasters.

An obvious but important skill was the development of a strong network. This theme played throughout our stories, as the importance of relationships, personal and professional, enabled us to overcome and get back on track.

Our attendees left with some actionable advice, and discussions were started for additional solutions for other possible disasters. Doors have been opened to expand this topic for the future.

Larry Lynam, DSc, MA, SM, RM, is a medical science writer and workshop facilitator with The Lynam Group, LLC, in Coral Springs, FL.

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The Medical Writing Certificate program at the University of California San Diego Extension is designed to provide graduates with the foundational knowledge and skills needed to work as a medical writer in the commercial sector, government agencies, and/or academia. The certificate will equip scientists, communication professionals, and others with a strong biomedical and/or life sciences background to write specifically for scientific, education, or regulatory audiences. Course content is delivered in a fully online format, and students can finish the 22-unit program in 18 months. The course content culminates in an applied Capstone project, which prepares students to secure professional positions as medical writers in four distinct specialty areas: Continuing Medical Education Materials, Scientific Grants, Regulatory Writing, and Journal Article and Publication Development. Program faculty are dedicated educators and nationally recognized experts in their medical writing specialties. For more information on the program and our faculty, visit: https://extension.ucsd.edu/courses-and-programs/medical-writing-courses.

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Viitai
The 2018 Medical Writing & Communication Conference in Washington, DC, was a well-organized, fun-filled event. Viitai develops and brings the best-quality applications to life science organizations. Our innovative applications are efficient, standards-aligned, regulatory filing-driven, scalable, and compliant with regulations, with intuitive UI.

Biodigital Library (BDL) is an enterprise literature lifecycle and digital knowledge management system for life science organizations.

Medical Writing Management solution (mWrite) is a document and digital resource management system dedicated to making medical writing easier:
- Documents can be classified by drug program, study number, and milestone/snapshot;
- The resource management section allows users to link resources relevant to this writing;
- Documents can be classified by type and status;
- Users can
  - add/view versions;
  - view audit history;
  - lock/unlock documents;
  - search documents;
  - copy link to the document and paste into their writing;
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PerfectIt helps find and correct consistency mistakes in hyphenation, capitalization, and italics, and ensures all abbreviations are defined. It also checks headings, lists, and tables. You can even customize it to check house style guides. PerfectIt has more than 7,000 users around the world, ranging from freelance professionals to Fortune 500 firms.

PerfectIt will help you save time on quality control of regulatory submissions, evaluations, dossiers and publications. Try it for free at www.intelligentediting.com.

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Editorial Freelancers Association
The Editorial Freelancers Association (EFA) is a national, non-profit professional organization for writers, editors, copyeditors, proofreaders, translators, researchers, indexers, and other self-employed professionals in the modern publishing and communications industries. Founded in 1970, the EFA now has more than 2,500 members, many of whom have a background in medical communications. Learn more at www.the-efa.org.

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The University of the Sciences Biomedical Writing Programs
The University of the Sciences offers 100% online programs in biomedical writing. Our current program choices are Master of Science in Biomedical Writing, Certificate in Marketing Writing, and Certificate in Regulatory Writing. The programs are
designed to accommodate working professionals, so classes are offered asynchronously, via webinar, or via other live online delivery methods in the evenings or on weekends. Courses are currently $1,000 per credit with potential additional discounts to AMWA members. All of our programs can be completed part- or full-time in 2 years or less.

USciences was the first accredited educational institution to develop and award a degree in biomedical writing. It continues to be one of the few to do so globally. All of our faculty, both full-time and adjunct, teach subjects in which they have had personal experience in industry; many continue to be currently engaged in those areas. Our industry links allow us to create experiential opportunities for our students.

The results of a recent review of our alumni indicate that approximately 80% of all graduates remain in medical writing or related areas of the pharmaceutical industry. We are proud members of the medical writing profession.

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Board of Editors in the Life Sciences
In the early 1990s, in recognition of the need for an objective test of editorial skill, a group of senior life-sciences editors developed a process for testing and evaluating proficiency in editing. The result was the creation of the Board of Editors in the Life Sciences (BELS), which administers 2 examinations that focus on the principles and practices of scientific editing in English.

BELS examinations—one for basic certification and one for diplomate status—give qualified manuscript editors in the life sciences a way to demonstrate their editorial proficiency, afford potential employers a way to identify proficient editors in the life sciences, and help to establish a standard of proficiency in editing in the life sciences.

To be eligible for the basic BELS certification examination, which is offered 5 or more times per year at sites throughout North America and abroad, an editor must usually have a bachelor’s degree or the equivalent from an accredited academic institution and at least 2 years of relevant experience. BELS has certified about 1,500 editors in over 20 countries.

The BELS examination for diplomate status consists of review of a portfolio of edited material and requires 6 years of relevant experience.

For more information, visit www.bels.org.

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Trilogy Writing & Consulting
At Trilogy, medical writing is our passion. As specialists in clinical regulatory documentation, we provide a service that is more than just writing. Our writers are integral parts of our clients’ teams: proactively planning, coordinating, and writing their clinical documents to meet timelines, with a readability that reduces the time for review and approval. We have been helping pharmaceutical companies and clinical research organizations of all sizes, worldwide, to streamline their documentation processes for over 16 years—either as support on a one-off document or the entire clinical development program.

We provide our clients with constructive advice on their projects: we guide our clients’ teams through the writing process and ask them the right questions in order to produce documents that communicate effectively. Our writers are trained to understand that our job is not to produce a data dump: it is to think about the data available and work with the team to pull out the messages and present them as clearly as possible, so that a reviewer can quickly find the information they are looking for and easily understand the story to be told.

Trilogy currently has more than 50 writers, who are located in Trilogy’s 4 offices in the US and Europe.
To view the following posters from the 2018 AMWA Medical Writing & Communication Conference click here.

Development of a Disease- and Compound-Specific Content Library
Susan Cupo, MS, and Mitzi Allred, PhD
Merck & Co, Kenilworth, NJ, USA

Creating and Evaluating an On-Demand Writing Workshop for a Large Research Institute: Reaching Out to Colleagues With Busy Schedules and Far-Flung Locations
Loretta Bohn, BA; Bill Ferris, MEd; and Julie Shogren, BA
Multimedia Communication Services, RTI International, Research Triangle Park, NC

Get to Know Your AMWA Member Benefits
Gail Flores, PhD; Madison Hedrick, MA; Haifa Kassis, MD; Al Saint Jacques, MBA; and Jin Zhang PhD
On behalf of the 2017-2018 AMWA Membership Committee

Enhancing the Authorship Experience, One Survey at a Time
Amy Kuang, Brittany Jordan, Jeri Freeman, and William Glass
Allergan plc, Irvine, CA, USA

Expedited FDA Programs and Safety Label Changes
Priyanka Ingle-Jadhav, MD, PhD, Aff.MFPM
CRC Pharma LLC Parsippany, NJ, USA

Science Communication: Strategies for Communicating Clearly and Effectively with Laypeople
Beth Knight, PhD
Whitsell Innovations, Inc, Chapel Hill, NC, USA

Developing an Editorial Team: Tools for Sustained Success
Amy Martin,1 Alyssa Dallas,1 and Margaret Mathes2
1RTI Health Solutions, Research Triangle Park, NC, USA; 2RTI Health Solutions, Manchester, UK

Supporting Drug Development Programs: Where Do Medical Writers Fit In?
Teresa McNally, PhD, and Monique A. Pond, PhD
Whitsell Innovations, Inc, Chapel Hill, NC, USA

Medical Writing and Publication in the Age of Transparency: Trends, Challenges, and Good Practices
Yanni Wang, PhD, CMPP
International Biomedical Communications, LLC, Frederick, MD

Home-Based Medical Writing: Tips and Tricks
Dwyn DeSilver, BS, and Maureen Piotrowski, MBA
Whitsell Innovations, Inc, Chapel Hill, NC, USA

Evaluation of a Medical Writing Certificate Program's Specializations, Student Information, and Workforce Data
Tim K. Mackey, MAS, PhD1,2; Robert Houghtaling, BA2; Donna Simcoe, MS, MBA, CMPP3; R. Michelle Sauer, PhD, ELD4,5; Lori Alexander, MTPW, ELS, MWC6; and Dikran Toroser, PhD, CMPP7
1Department of Anesthesiology & Division of Infectious Diseases and Global Public Health; 2UCSD Extension; 3Simcoe Consultants, Inc; 4RNAEditing, LLC; 5University of Texas Health Sciences Center; 6Editorial Rx, Inc; 7AMGEN Inc
Navigation by the Numbers: A Look at the Benefits of Protocol Navigation Management at the National Institute of Mental Health (NIMH)
Charles B. Servis, BS1; Anne Evans, MS1; and Jeanne Radcliffe, RN, MPH2
1Clinical Monitoring Research Program Directorate, Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute, Leidos Biomedical Inc; 2National Institute of Mental Health Intramural Research Program

Summarizing Safety Data for Regulatory Submission Documents
Barbara S. Orban, MS
Whitsell Innovations, Inc, Chapel Hill, NC, USA

Training and Mentoring Model to Support the Transition to a Role in Medical Writing (Narrative Medical Writer and Clinical Technical Editor)
Carolina Salazar,1 Cindy Marlene Fernández,1 Yudy Brigith Artunduaga,1 Catalina González,1 Mary E. McKenna,2 and Susan Sfarra2
1MSD Colombia; 2Merck & Co, Inc, Kenilworth, NJ, USA

Protocols and Protocol Amendments: Effective Quality Review Steps
Sharad Wankhade, PhD
Merck & Co, Kenilworth, NJ