23rd Annual
Princeton Workshop

Saturday, May 4, 2019
8:00 AM – 5:00 PM

Princeton Marriott at Forrestal
100 College Road East
Princeton, NJ 08540
609-452-7800

Conference Chairs
Dan Benau, PhD
Katherine Molnar-Kimber, PhD
AMWA-DVC is pleased to announce the 23rd Annual Princeton Conference on Saturday, May 4, 2019, at the Princeton Marriott at Forrestal. This year's conference offers programming in an all open session format that include sessions in:

- **AMWA-DVC's Medical Writing Essentials**
- **Hot Topics in Medical Communications and Scientific Writing.**

These dual tracks allow participants to pick-and-choose relevant sessions for their individual needs.

**Registration and Logistics**

<table>
<thead>
<tr>
<th>Category</th>
<th>Fee</th>
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<tbody>
<tr>
<td>AMWA Members</td>
<td>$190</td>
</tr>
<tr>
<td>Non-members</td>
<td>$215</td>
</tr>
<tr>
<td>Full-time Students</td>
<td>$180    (must provide official ID to register)</td>
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</tbody>
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*The registration fee includes breakfast, lunch, and morning and afternoon beverages and snacks.*

**Location**

**Princeton Marriott at Forrestal**

100 College Road East  
Princeton, NJ 08540  
609-452-7800

**Discount Hotel Rooms**

Attendees of the Princeton Forum can reserve a room at the *Princeton Marriott at Forrestal* at the discounted rate of $149/night (+ 14.625% tax) for May 3, 2019 to May 4, 2019.

To make an overnight room reservation, call Marriott Reservations at 1(800) 228-9290 or (609) 452-7800 **on or before Friday, April 12, 2019**, (the “Cutoff Date”).

Please identify yourself as an attendee of the American Medical Writers Group staying at the Princeton Marriott at Forrestal, located at 100 College Road East, Princeton, NJ 08540. All overnight reservations must be guaranteed with a major credit card.

**AMWA-DVC Networking Dinner on May 3, 2019**

Join us for an informal networking dinner, to be held at a local restaurant on Friday, May 3, 2019 (details to follow). Each person will pay his/her own dinner and beverages.

To sign up, email Kathy Molnar-Kimber at molnarkimber@verizon.net and insert “AMWA-DVC Princeton May 3rd Dinner” in the subject line. We will be in touch with details in mid-April.

**Questions**

Contact Katherine Molnar-Kimber at molnarkimber@verizon.net or contact Darryl L’Heureux at Membercommunications@amwa-dvc.org
## Workshop Schedule

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<th>Regulatory Writing Essentials</th>
<th>Hot Topics in Medical Writing</th>
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<td>8:00 AM - 9:00 AM</td>
<td>Registration/Breakfast/Networking</td>
<td></td>
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<tr>
<td>9:00 AM - 10:30 AM</td>
<td>Essentials of Real World Evidence: What Medical Writers Need to Know <em>Nancy Connolly and Chris Pericone</em></td>
<td>Patient Centricity: Going from Availability to Engagement <em>Dan Benau</em></td>
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<tr>
<td>10:30 AM-10:45 AM</td>
<td>Morning Break</td>
<td></td>
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<tr>
<td>10:45 AM - 12:15 PM</td>
<td>Clinical Pharmacology in Drug Development: What Medical Writers Need to Know <em>Linda LaMarre</em></td>
<td>Overview of Editing, Proofreading, Fact Checking, and Annotating <em>Melissa Bogan</em></td>
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<td>12:15 PM - 1:45 PM</td>
<td>Lunch and Networking</td>
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<td>1:45 PM - 3:15 PM</td>
<td>Introduction to Clinical Study Report Narrative Writing <em>Denise Coffey</em></td>
<td>Preventing Deaths on a Train: Writing to Target Audience <em>Kelleen Flaherty</em></td>
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<tr>
<td>3:15 PM - 3:30 PM</td>
<td>Afternoon Break</td>
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<td>3:30 PM - 5:00 PM</td>
<td>Regulatory Submissions <em>Mark Bowlby</em></td>
<td>Introduction to CME Writing <em>Don Harting</em></td>
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REGULATORY WRITING ESSENTIALS

Introduction to Real World Evidence: What Medical Writers Need to Know
Nancy Connolly MPH and Chris Perricone PhD
In contrast to tightly-controlled randomized clinical trials (RCTs), “real world” studies use large observational databases created from electronic health records, medical/pharmacy insurance claims, and other secondary data sources to examine how patients and health professionals use medicines in the more diverse “real world" setting. Attendees will understand the growing importance to the pharma industry of real world evidence (RWE) generation and how it complements RCTs with insights not otherwise available. In the workshop, participants will explore the elements of a well-designed real-world study and examine the medical writing similarities and differences between RWE and traditional interventional studies. Learning Objectives:

- Become familiar with the different types of databases and observational study designs used to generate RWE, and how they differ from those of RCTs
- Understand why RWE is growing in importance in the pharma industry and how various stakeholders use RWE at different stages of the drug development life cycle
- Learn about challenges and best practices in successfully communicating RWE study design and results

Clinical Pharmacology in Drug Development: What Medical Writers Need to Know
Linda LaMarre BS, MS, Principal Documentation Director, Bristol-Myers Squib
Clinical pharmacology is the study of medicines and drugs, including their action, their use, and their effects on the human body. Clinical pharmacology is an important component of the investigation of new drugs. During this session, we will review key principles of pharmacokinetics and pharmacodynamics. We will discuss the timing and types of clinical pharmacology studies in drug development, as well as the key clinical pharmacology documents that support a new drug application and how they relate to the Common Technical Document (CTD) and label. Learning Objectives:

- Overview of pharmacology: pharmacokinetics + pharmacodynamics
- Review of key pharmacokinetick variables
- Identify key clinical pharmacology documents.

Introduction to Clinical Study Report Narrative Writing: What Medical Writers Need to Know
Denise Coffey MSN, RN, Associate Director of Safety Narrative Operations, Bristol-Myers Squib
Patient safety narratives are a regulatory requirement for clinical study reports. Patient safety narrative serves as a comprehensive compilation of individual patient safety data for reviewers at regulatory agencies. Depending on the indication, patient safety narratives can range from being straightforward to incredibly complex documents. During the session, we will review the International Council on Harmonization Guidelines (ICH E3) reporting requirements, with a comparison to the structure and content of CIOMS safety reporting. Additionally, we will identify the organization and need for a sound medical strategy before putting pen to paper. Best practices narrative writing will be presented and sample narratives will be shared with the class. Learning Objectives:

- Review ICH E3 safety reporting requirements
- Learn to create sound medical strategy prior to authoring safety narratives
- Identify best practices when authoring safety narratives

Regulatory Submissions
Mark Bowlby PhD, Principal Regulatory Writer, Synchrogenix
Regulatory submissions represent key milestones in the development of new drugs, and medical writers are critical contributors to successful submissions. Regulatory submissions to FDA, EMA, and other agencies involve coordination of hundreds of documents and thousands of pages of content across all the disciplines involved in clinical drug development. Although most submissions are structured according to ICH guidelines, document requirements differ depending on the agency, class of drug, and type of application. This session will present an overview of the documents comprising a submission with an emphasis on the role of the medical writer. Learning Objectives:

- Understand the components and structure of a submission and how they fit together.
- Understand the disciplines involved with writing summary documents in a submission.
- Learn about the role of medical writers who are integral to a submission.
HOT TOPICS IN MEDICAL WRITING

Patient Centricity: Going from Availability to Engagement
Dan Benau, PhD, MSOD, Professor, Director of Biomedical Writing Programs, University of the Sciences
The healthcare industry is moving from paying lip service to the patient to actually including the patient in the information stream of clinical trial results, drug development details, and other important data. The industry has made strides in the creation of documents readable by a general audience rather than those only directed at healthcare professionals and the clinically literate. Plain language summaries of clinical trial results are being offered to participants of those trials, and these are being made available to a broader audience. What seems to be lacking, however, is going from making available summaries to using engaging information strategies to try and get that general audience to want to gain the information rather than just making it available. Learning Objectives:
• Gain understanding of the continuum of medical communication
• Learn to identify least damaging assumptions
• Discuss the myth of nonpromotional summaries
• Gain an understanding of engagement techniques that can be used to attract a general audience

Overview of Editing, Proofreading, Fact Checking, and Annotating
Melissa L. Bogen, ELS
In her presentation, Melissa will discuss differences between editing and proofreading, and she will clarify what tasks are involved in various levels of editing (light, medium, & heavy). She will also explain what’s entailed in fact checking and annotating/highlighting references for medical-legal review. Learning Objectives:
• Describe the differences between editing and proofreading
• Compare the various levels of editing (light, medium, & heavy)
• Explain how to fact check and annotate projects for medical-legal review

Preventing Deaths on a Train: Writing to Target Audience
Kelleen Flaherty, MWC, CMPP, Adjunct Assistant Professor, Graduate Biomedical Writing Programs, University of the Sciences
Writing to target is, bottom line, the most critical skill you can possess as a writer—any kind of writer. It is important to understand your audience and how you can communicate with them with regard to sophistication and voice, as well as with regard to what they want and need to know (and keeping in mind what they already know). It’s not as easy as it seems, and if you have the kind of job where you write to multiple targets (common in freelance), it’s important to be aware of the fundamentals. You can be a flawless writer, but if what you write is not to target, it’s worthless. It’s easy to fix transient lapses in grammar or style, but near-impossible to fix an off-target piece without rewriting it. The presentation will give you the basic undergirding for accurate assessment of target audience. Learning objectives:
• Assess target audience carefully
• Determine audience “needs and wants”
• Communicate at an appropriate level of sophistication using the most effective voice
• Ensure accuracy of delivery through peer review

Introduction to CME Writing
Donald Harting MA, MS, ELS, CHCP, Harting Communications
The subject of research into best practices in developing medical writing materials came up in a recent teleconference that included members of AMWA, EMWA, and other organizations involved in medical writing. This in turn brought up the subject of what indeed differentiates a job, career, and profession. This talk will concentrate on the perspective of an educator and practitioner in the field and will cover aspects of education, training, certification, and other pillars of a profession. Some of these topics will also form the basis of a panel discussion at the end of the conference. Learning objectives:
• Describe the role of key organizations within the U.S. system for accredited continuing medical education
• Identify four different types of documents that are commonly purchased by CME providers
• Discuss the current medical writing needs of half a dozen medical education companies.
PRESENTER BIOGRAPHIES

Dan Benau, PhD, MSOD is Professor of Biomedical Writing and, for 10 years, Director of the Biomedical Writing Programs at the University of the Sciences. Over the years he has presented talks on the profession of medical writing, medical writing technology, and other relevant topics. His current interests continue to be the above plus the topic of today’s talk.

Melissa Bogen ELS has been a full-time freelance editor since 1997. Her expertise is in editing, fact checking, and proofreading a wide range of therapeutic areas. Melissa has in-depth knowledge of AMA style, FDA guidelines, & editorial production processes. She has presented open sessions at AMWA conferences on Microsoft Word tips.

Mark Bowlby PhD has over 22 years of experience in drug development, publication writing, and clinical research, and for the last 7 years has been a full-time regulatory writer. Mark has written clinical study protocols and reports, investigator brochures, briefing documents for regulatory agencies, and clinical summaries and overviews for new drug submissions. He currently is employed as a Submission lead and Principal Regulatory Writer at Synchrogenix Information Strategies, Inc. Mark has a Bachelor’s degree in Biology from SUNY Stony Brook and a Masters and PhD in Biological Sciences from UC Santa Barbara.

Denise Coffey MSN, RN works at Bristol-Myers Squib as Associate Director of Safety Narrative Operations and has over 10 years of experience in the pharmaceutical industry. During her time in industry, Denise has worked in global pharmacovigilance and epidemiology to support drug safety surveillance and has authored different regulatory documents, such as PRERS, DSURs and Risk Management Plans. In her current role, Ms. Coffey reviews safety narratives for medical soundness and oversees clinical study report narratives across all stages of drug development and therapeutic areas. Previously, she worked as a registered nurse in critical care for 15 years and taught in both the classroom and clinic as an Associate Professor of Nursing for 6 years. Denise is currently co-authoring a paper on causality assessment in drug-induced liver injury, as part of the International Consortium for Innovation and Quality in Pharmaceutical Development. When not working as a writer or mother of three, Denise enjoys spending time in her garden and taking walks with her dogs (and sometimes, her husband).

Nancy Connolly MPH, a writer in Janssen Scientific Affairs, Real World Analytics, works with health economics and commercial strategy functions to frame RWE research questions and communicate findings in the increasingly value-based US healthcare system. Prior, Nancy supported Phase 3 clinical development and communications to health authorities. She holds a MPH from Rutgers University.

Kelleen Flaherty, MWC, CMPP has been a professional medical writer for over 25 years, working as both a freelance and full-time employee, and has worked in several therapeutic areas, in several different media (eg, live, online, print, etc), for several different subfields of medical writing (eg, CME, promotional, publications, and regulatory writing). She has been a full-time or adjunct professor in the graduate Biomedical Writing Program at the University of the Sciences for 20 years.

Donald Harting MA, MS, ELS, CHCP is president of Harting Communications LLC in Downingtown, Pennsylvania. Don broke into CME writing in 2009 with help from AMWA workshops led by Karen Overstreet and Eve Wilson. As a certified healthcare CPD professional (CHCP), Don has been working since 2014 as principal investigator of an annual survey research project aimed at identifying best practices for writing needs assessments.

Linda LaMarre BS, MS works at Bristol-Myers Squib as Principal Documentation Director and has over 17 years of experience in the pharmaceutical industry. During her time in industry, Linda worked as a research formulation scientist, developing formulations for small molecule drug candidates from early discovery through Phase I clinical studies. Transitioning out of the lab into the writing group, Linda authored early phase Clinical Study Reports and other regulatory submission documents. In her current role, she drives Clinical Pharmacology storyboarding /prototyping activities, guides and mentors summary document and report writers, liaises with colleagues across many functions and regions, and authors high-level Clinical Pharmacology submission documents across therapeutic areas. When not working at BMS or mother of three teenage girls, Linda enjoys volunteering with Res-Q-Pets and traveling.

Chris Pericone PhD is a scientific writer in Janssen Scientific Affairs, Real World Analytics. He oversees protocol writing and reporting for RWE clinical/economic studies, in collaboration with health economics and medical affairs colleagues. Previously, Chris worked in regulatory medical writing and publication planning. He holds a PhD from the University of Pennsylvania School of Medicine.