2024 Spring Conference

Friday, May 3, 2024
8:00 am to 5:00 pm
The Friday Center, Chapel Hill, NC

Navigating Changes in Medical Writing
2024 Conference Schedule

8:00 - 9:00 am Check-in, network with Platinum Sponsors
Atrium South/Wintergreen
- Light continental breakfast provided.
- Please note that no on-site registration is available.
- If you pre-registered for resume review, sign up for a slot at the registration table - resume review is from 3:30 - 5 pm in the Windflower room.
- If you do not have a preprinted parking pass, please get one from the registration table and place it on the dashboard of your vehicle.
- Please visit our Platinum Sponsor tables and Sponsor websites (see Sponsor page of this program).

Morning Educational Sessions
Attendees can attend either Track A or Track B at any time

9:00 - 10:00 am
Track A (Bellflower room)
Mastering the AI Wave: A Strategic Framework for Informed AI Tool Use
As AI tools flood the market, staying ahead can be daunting. This session presents an easy-to-follow AI integration framework, designed to make this surge manageable by breaking down the process into discrete steps that prioritize your unique needs. Discover how to systematically assess and integrate AI into your work responsibly, ensuring you’re informed, in control, and able to discriminate potential from hype. From AI literacy to critical evaluation of tools to transparent integration, this framework is your guide to implementing new AI technologies while considering and mitigating risks.
Jenni Pickett, PhD, Senior Medical Writer, Whitsell Innovations, Inc.

Track B (Windflower room)
PIPs - Initial Submission and Modifications
A Paediatric Investigation Plan (PIP) is an early opportunity and EU requirement to outline the investigation of a new drug in adolescents and children. The initial PIP is a comprehensive set of documents that defines the disease to be studied and plan for investigating the new drug in the applicable pediatric population. This presentation will lay out the components and process for the PIP life cycle, including initial PIP applications and modifying adopted PIPs.
Sam Suarez, PhD, Senior Principal Medical Writer, AbbVie

10:00 - 10:20 am Sponsor breakout session with refreshments
Atrium South/Wintergreen
2024 Conference Schedule

10:20 - 11:20 am
Track A (Bellflower room)

Lean Writing Implementation: A Success Story

This session will define lean writing and its importance when writing clinical regulatory documents. The impact of transparency requirements on clinical regulatory documents will be described. Details will be provided on how a lean writing initiative was created and implemented at a mid-size pharmaceutical company, which included an overhaul of protocol, IB, and CSR templates and process, as well as creation of "drop-in" in-text tables. Lessons learned and metrics for success will be shared.

Sarah Wilson, MS, Director, Head of Medical Writing, Alkermes

Track B (Windflower room)

Plain Language Double Feature

**Pulling It All Together – Plain Language Summary Regulations and Best Practices**

Authoring plain language summaries (PLS) to meet regulatory requirements requires multiple skill sets. These include an understanding of the ten required elements for European Union PLS. Another skill is the ability to locate relevant information in large source documents, such as clinical study reports and protocols, to author accurate results and safety sections. Finally, authors must have a knowledge of health literacy best practices to meet PLS reading level requirements. In this presentation, we will discuss how to integrate these skills to successfully author PLS.

Lee Holland, PharmD, MPH, Associate Director, RSM, Plain Language Summaries, Certara

**Lost in Translation: The Importance of Plain Language Summaries of Publications (PLSPs)**

This session will discuss what a PLSP is, why it is important, and what tools and guidelines are available when creating a PLSP. Attendees will get hands-on practice in creating a PLSP.

Chantelle Rein-Smith, PhD, CMPP, Principal Medical Writer and Consultant, Whitsell Innovations, Inc.

11:30 – 12:45 pm Lunch roundtables (see page 6)

Trillium room

Go through the buffet line and sit at the table number on the back of your badge.

HTTPS://WWW.AMWACAROLINAS.ORG/WP/2024-SPRING-CONFERENCE/
2024 Conference Schedule

12:45 – 1:00 pm President’s remarks
Trillium room
Jenni Pickett, PhD, President, AMWA Carolinas Chapter

1:00 – 2:00 pm Structured networking
Trillium room
AMWA Carolinas Conference Committee

Afternoon Educational Sessions

2:15 - 3:15 pm
Track A (Bellflower room)
Understanding The Promotional Review Process for Beginning Medical Writers
Tailored for new promotional medical writers or those seeking insights into the Promotional Review Committee (PRC) process, this session explores the vital role of PRC in reviewing and approving pharmaceutical promotional materials. The session equips participants with essential background knowledge for effective collaboration in the industry, providing a foundational understanding of promotional review intricacies and its pivotal role in crafting impactful medical writings.
Sendra Yang, PharmD, MBA, Senior Manager, Medical Information

Track B (Windflower room)
Navigating Regulatory Medical Writing in an Evolving Clinical Landscape
This presentation aims to highlight recent changes to the ICH E6 Good Clinical Practice guideline and how regulatory medical writers can leverage this information, manage the rapidly evolving drug development landscape, effectively engage stakeholders, maintain data integrity, and drive efficient and patient-centric programs.
Andrea Clark, PhD, Senior Regulatory Medical Writer, Aroga Biosciences

3:15 – 3:45 pm Sponsor breakout session with refreshments
Atrium South/Wintergreen

3:30 – 5:00 pm Resume review (preregistered attendees only)
Windflower room

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2024 Conference Schedule

3:45 – 4:45 Educational session
Bellflower room
Building Atomic Habits to Achieve Audacious Goals
Do you feel pressure to work quickly and efficiently with limited resources? "Atomic Habits" and "The Oz Principle" offer practical solutions. These books teach us to make small, consistent improvements to achieve long-lasting results and take ownership of our actions to achieve ambitious goals. Let’s discuss how to apply these principles to your career. Demetrius Carter, MBA, PMP, RAC-US, SVP, Regulatory Sciences & Medical Affairs, Certara

4:45 – 5:00 Casual networking
2024 Roundtable Sessions

11:45 am - 1:00 pm, Trillium Room

Please see your nametag for your assigned roundtable number - due to limited seats, switching roundtables is not possible.

1) Casual Networking Table I
Leader: Simone Otto, PhD, Manager Medical Writing, Propharma

2) Casual Networking Table II
Leader: Kim Jochman, PhD, RAC, Senior Director, Medical Writing, Merck

3) Helpful Tools for Editing in Medical Writing
Leader: Leslie DeCraene, Certified Medical Writer and Editor, Owner Precise Med Prose
Description: Medical Editors use different types of resources to ensure accuracy, readability, and clarity. Share your favorite editing “helper” with the table so we can discuss the resources used for assisting medical writers and editors with tasks ranging from managing project time to fact-checking, invoicing, security, etc. We will explore commonly used reference materials such as style manuals, medical dictionaries, AI resources, and software options that help editors with specific projects.

4) Taking the Lead: Leadership Strategies for All Career Levels
Leader: Chantelle Rein-Smith, PhD, CMPP, Principal Medical Writer and Consultant, Whitsell Innovations, Inc.
Description: Please visit our mobile app at https://www.amwacarolinas.org/wp/2024mobileprogram/ for an updated description.

5) Navigating Career Moves in the AI Era
Leader: Jenni Pickett, PhD, Senior Medical Writer and Consultant, Whitsell Innovations, Inc.
Description: Explore the dual importance of developing AI literacy and honing interpersonal skills as generative AI is entering the workplace. Concurrently, networking, authenticity, and adaptability are equally critical, ensuring medical writers continue to provide value through expertise, leadership, and consensus building.
2024 Roundtable Sessions

11:45 am - 1:00 pm, Trillium Room

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6) Redefining Traditional: Off the Bench and into the Medical Writing Field
Leader: Kate Pedone, PhD, Medical Writer, Whitsell Innovations, Inc.
Description: This session will be a candid conversation about my decision to return to medical writing after spending a decade at home with family. Adjusting to the transition and becoming educated on regulatory writing has offered many learning opportunities. I will talk about my experiences, describe my personal exploration of the medical writing field, and share perspectives of colleagues. I also will facilitate discussion around the challenges and successes in the constant pursuit of work/life balance.

7) Strategies for Driving Successful Reviews
Leader: Laura Bisogno, PhD, Medical Writer, Whitsell Innovations, Inc.
Description: Review is a critical component of the document writing process, but often the outcome does not meet our needs or expectations. As medical writers, how can we ensure that reviewers clearly understand their roles and responsibilities, focus only on the appropriate content and messaging, and provide actionable comments? Join this roundtable for a discussion of how to drive a successful review. We will share our successes, failures, and tips for effective communication during the review process.

8) The Art of Saying “No”
Leader: Abigail Agoglia, PhD, Medical Writer, Whitsell Innovations, Inc.
Description: If you struggle to assert yourself and say “No” when you need to, this session is for you! We'll share experiences to highlight the importance of setting boundaries at work, then discuss some of the obstacles to saying “No”. The discussion will end with suggestions for finding a personal approach to saying “No” that feels natural and comfortable. This interactive session is suitable for writers of all experience levels, including those seeking to enter the field.

9) The Ins and Outs of Breaking into Medical Writing I
Leader: Stephanie M Byrd, PhD, RAC, Senior Clinical Research Scientist, Syner-G BioPharma Group
Description: Attendees will have the opportunity to engage in a discussion with an experienced medical writer about their unique path to breaking into the medical writing field. The presenter will discuss with attendees the soft and technical skills that an individual can develop to demonstrate proficiency within the medical writing field in addition to the programs and opportunities available locally and nationally to further develop these essential skills.
2024 Roundtable Sessions

11:45 am - 1:00 pm, Trillium Room

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10) The Ins and Outs of Breaking into Medical Writing II

**Leader:** Julia DiFiore, PhD, Clinical Research Scientist II, Syner-G BioPharma Group

**Description:** Attendees will have the opportunity to engage in a discussion with an experienced medical writer about their unique path to breaking into the medical writing field. The presenter will discuss with attendees the soft and technical skills that an individual can develop to demonstrate proficiency within the medical writing field in addition to the programs and opportunities available locally and nationally to further develop these essential skills.

11) Upskilling in Preparation for AI-Enabled Writing

**Leader:** Demetrius Carter, MBA, PMP, RAC-US, SVP, Regulatory Sciences & Medical Affairs, Certara

**Description:** The world of medical writing is advancing at a rapid pace, thanks to the use of generative AI tools. In this roundtable discussion, we will explore the new skill sets that medical writers need to master to use AI technologies to their fullest potential. As AI tools revolutionize content creation, medical writers must adapt and learn new competencies to thrive in this highly competitive field. By examining the strengths and weaknesses of generative AI in medical writing, this presentation emphasizes the importance of understanding AI-generated content and its implications for scientific communication. Additionally, we will delve into the vital role that expertise, ethics, and quality control methods play in the dynamic relationship between medical writers and AI technologies. This insightful discussion will equip medical writers with the knowledge and skills they need to stay ahead of the curve in the ever-evolving medical and regulatory writing field. Join us as we cover these essential aspects and embrace the exciting possibilities of AI-powered medical writing.

12) Write Like a Pharmaceutical Boss: Drug Info Pearls Writers Need to Know

**Leader:** Mechelle Renee Akers, PharmD, RPh, CPh, Freelance Medical Writer, Lucente Medical Communications

**Description:** Get ready to master the art of writing about medications! Join our roundtable, “Write Like a Pharmaceutical Boss,” for beginning medical writers. Whether you write for consumers or professionals, grasp the essentials. Explore common medication queries, reliable information sources, and key terminology. Craft precise, reader-friendly content that excels.
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Conference Registration

8:00 - 9:00 am Check-in, network with Platinum Sponsors
Atrium South/Wintergreen

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- Please check in to get a name tag. Your roundtable number is on the back of your tag.
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Educational Sessions
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- **Track A:** Bellflower room
- **Track B:** Windflower room

Lunch Roundtables and President’s Remarks: Trillium room

Breaks: Atrium South/Wintergreen

Digital Conference Program

- Please scan the QR code for our full conference program!
- For convenient access, add to your phone home screen.
- Click on sponsor logos to visit their pages and see job openings.

Attendee Survey

- Please scan the QR code and complete our survey for a chance to win free registration to our 2025 conference!

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