

# DELAWRITER

The quarterly newsletter of AMWA-DVC

January 2024



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## Effectively Communicating Clinical Trial Data

by *Sadia Chaudhry-Zutshi*

Kim Jochman, PhD, Senior Director of Medical Writing at Merck & Co, Inc, led an interactive workshop at the 2023 AMWA Medical Communication Conference in Baltimore that was a helpful introduction to the interpretation of clinical trial data. Many regulatory writers need help knowing where to start when presented with dozens of tables, listings, and figures. The workshop discussion centered on the purpose of clinical trial data for a document, predominantly for Module 5 of the electronic common technical document (eCTD). The main takeaway was that clinical trial data requires interpretation.

A medical writer may not think intuitively about inferential (regression analysis, confidence ranges, and hypothesis testing) versus descriptive (mean, median, and mode) statistics, but an understanding of these concepts is critical to be able to write about clinical data. Dr Jochman noted that the writer should not regurgitate information, but instead must tie study results back to the objective(s) and endpoint(s). Linking the objectives and endpoints with the clinical trial data is critical to achieving positive outcomes from regulatory authorities.

The workshop also reinforced the importance and need for consistency in the description of clinical trial data. Specifically, when submitting regulatory documentation to health authorities, it is essential to use consistent language across all documents; eg, “subject” versus “patient,” “blinded” versus “masked,” or “mean” versus “median.” Typically, medical writers prefer to follow a style guide and have access to previously submitted documents. However, these materials are not always available. Access to the complete picture of the study design or drug-development program depends on many factors, including whether you are a consultant, independent contractor, freelance writer, or full-time employee. Each of these situations is unique in terms of access to the source documents or the subject-matter experts to write up a document per the health authority’s requirements and the marketing applicant (sponsor).

Finally, this workshop emphasized that when asked to write about clinical trial data, you should closely focus on the tables, listings, and figures to gather critical information about that data relating to the objectives and endpoints of the clinical study. This attention to detail is key to interpreting the data for a regulatory authority in a nuanced manner that goes beyond basic listing of data.

*Dr Sadia Chaudhry-Zutshi has 11 years of industry experience and is currently leading a medical writing team in rare diseases. She is passionate about positive social change through all facets of her life.*



## CALL FOR VOLUNTEERS

President-Elect Jennie Jacobson is seeking volunteers for the 2024-2025 nominating committee and to fill other important positions. This is a great chance to support your AMWA chapter and have fun with local colleagues. Join us! Contact Jennie at [president-elect@AMWA-DVC.org](mailto:president-elect@AMWA-DVC.org)



**Register now!**

### **AMWA-DVC Mid-Winter Warm-Up**

**Harvest Moon Brewery & Cafe, New Brunswick, NJ**

**Wednesday, January 31, 2024, 6:00 to 8:30 pm EST**

We will be meeting in person at the Harvest Moon Brewery & Cafe, 392 George Street, New Brunswick, NJ 08901.

**Agenda:** Socialize with colleagues and make new connections. The discounted registration fee includes dinner, 2 drink tickets, unlimited coffee/tea/soda, and participation in door prizes (gift cards) and a raffle (free registration for the 2024 Freelance Workshop or the 2024 Princeton Forum). There will be a cash bar. The program includes:

- Networking
- Welcome and introductions

- Dinner
- Update on chapter activities and opportunities to get involved
- Drawings for door prizes and raffle

**Dinner details:** See registration link.

**Cost:** AMWA members \$15, non-member \$20, retirees/students/postdoc AMWA members \$10

**Registration:** [Register now!](#) Registration will close at midnight EST on Tuesday, January 23, 2024.

## **Communication Culture Club: Navigating Corporate Perceptions Embedded in Language**

*by Mia Nagarajan*

Robin Whitsell, BPh, the founder and president of Whitsell Innovations, Inc (Chapel Hill, North Carolina) led an informative and engaging educational session at the 2023 AMWA Medical Communication Conference in Baltimore. Her talk focused on leadership and management and considered different corporate communication cultures prevalent at our workplaces. Company culture comprises the shared norms, priorities, values, attitudes, and practices that form a collective identity and “language” that heavily influence all roles and tasks. This then guides employees in interacting with their coworkers, direct reports, and supervisors. Company culture produces the communication culture.

Whitsell presented five main types of communication culture and described what each “sounds like” plus their pros and cons. She also played video clips from television series as examples.

### **Workplace Cultures**

#### **1. Art of War**

In an “art of war” workplace culture, being seen as smart, strategic, and in charge is highly valued. It is critical to communicate the most intelligent idea.

Sounds like: “Clearly, my idea is the best because...” “This is about the win.” “Tell me why you disagree.”

Pros: Being strategic or decisive, promoting big goals, being direct without artifice, and offering a clear understanding of who is in charge.

Cons: May be perceived as intense, aggressive, political, competitive, curt, or rude. There is no time or effort expended to learn from mistakes, and questioning of leadership is not welcomed.

Cultural reference: Billions Season 1: Episode 1

#### **2. Performance Image Exposure (PIE)**

In a “PIE” culture, performance, image, and exposure determine how an employee is seen and valued. Demonstrating a hard-working and capable character positions an employee for success. In this culture, people are self-driven and not shy about their accomplishments, often talking about what they have done.

Sounds like: “I have done/presented/researched...” “I’d like to revisit my idea about...” “As you can see from my assessment ...”

Pros: Prioritizing excellence and recognizing achievement and individual responsibility, with clear rules.

Cons: May be perceived as showy or braggy, competitive (perhaps offering no incentive to collaborate); creates a me/you versus us/them mentality. No tolerance for

mistakes. The loudest or most confident voice dominates.

Cultural reference: Blackish Season 8: Episode 9

### **3. Nice**

In a “nice” culture, everyone agrees publicly and goes with the flow, even if they disagree privately.

Sounds like: “Oh! That’s great” (when maybe it isn’t). “Do we all agree?” “No, it’s ok. I don’t mind.”

Pros: This is a warm, accepting culture with a collaboration focus that highlights team over individual accomplishments.

Cons: Not addressing issues with feedback or correcting mistakes. Workload may not be evenly distributed, and individual achievement and growth may be neglected.

Cultural Reference: Abbott Elementary Season 2

### **4. Hot Potato**

In a “hot potato” workplace, topics are passed along like a hot potato and discussed exhaustively without taking action. In this culture, people are hesitant to make decisions.

Sounds like: “Well, I’m not sure.” “We probably need more discussion. Have you talked to....”

Pros: Deliberate decision making, consideration of all aspects, and thoughtful and cautious approaches.

Cons: There may be no owner or decision maker; responses are slow or confusing, sometimes leading to overthinking.

Cultural reference: Ted Lasso Season 2: Episode 2

### **5. Invisible**

In an “invisible” culture, each person focuses on their own work. They know their own accomplishments, and do not seek praise or attention.

Sounds like: “I’m quietly doing my own thing.”

Pros: There is no pressure to perform, contributions are solo, and there are no forced interactions.

Cons: There can be limited feedback. This can be isolating, and contributions may not be rewarded appropriately.

Cultural reference: Parks and Recreation Season 5: Episode 20

Whitsell noted that as medical writers working with different teams, we will probably recognize aspects of these cultures from our own experience. All have pros and cons; therefore, one is not better than another. Learning to notice and copy the culture of the company helps employees or freelancers be more effective. In some organizations, success may depend on fluency in the preferred culture. In such cases, you may consider matching or adapting to the preferred style, which may require masking your individual style to a degree. However, it is important to be aware of balance, because adopting a style that feels unnatural to you can become exhausting over time.

Leaders can support their teams in observing and learning the prevalent cultural lingo. Teams may create their own language, which may have positive or negative results. Whitsell shared an example of an ineffective communication style used by a manager that was adopted by and became ingrained in their team. Leadership ultimately had to deliberately curb the distracting style that was not working for the team and the company.

Communication culture in our workplaces has a significant impact on employees' professional experiences, their motivation and engagement, and their productivity and retention. Teams need to factor this in for long-term success of their business and the overall reputation of the company.

*Mia Nagarajan, PhD, is a Director of Medical Writing at Merck Sharp & Dohme LLC in New Jersey and has been a writer of medical and scientific communications for 15 years.*

## UPCOMING EVENTS



### **AMWA-DVC 22nd Annual Freelance Workshop (Virtual)**

**Tentatively scheduled for Saturday,  
March 9, 2024 (12:30-3:30 pm EST).**

### **AMWA-DVC 27th Annual Princeton Forum (Virtual)**

**Date will be announced soon.**

**A request from AMWA-DVC member Monica Nicosia:**



### **2024 Freelance Medical Communicator Tools of the Trade Survey**

#### **Why take this short survey?**

- ✓ Contribute valuable data on the digital tools we use in our work.
- ✓ Help yourself and other freelancers upgrade their digital toolbox.
- ✓ Receive a copy of summary findings.

**Take the [survey](#).**

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