PACEMAKER

Summer 2020

Highlights

Table of Contents

Letter From Our Chapter President

AUGUST 2020

Hello from your 2020 AMWA Northern California Chapter President,

I began planning this letter at the end of February, shortly after our first chapter event of 2020. It was a lovely event, held at the Delancey Street Restaurant in San Francisco. We welcomed many new chapter members and celebrated members who have been in our chapter for more than 30 years! Everyone had fun, the food was good, it was a beautiful day. Across the street from the restaurant, the bay sparkled in the February sunshine. Several chapter members took center front of the banquet room and, one by one, shared their unique experiences attending the National AMWA conference that was held months earlier, in November 2019, in San Diego. These short presentations allowed the presenters a chance to recollect their conference experiences. For the members who did not attend the national conference, these presentations provided a glimpse of what awaits them when they are able to attend a future conference.

In early March, Bridget Mazzini (chapter Vice President) and I were out and about, scouting locations for our Pacific Coast Conference (PCC). We decided on the scenic, historic Presidio of San Francisco. Bridget began filling out the paperwork and put down a deposit to secure the location. We barely had time to celebrate this first step in planning the conference when California Governor Gavin Newsom called for a shelter-in-place order for our state. Not knowing how long this order would be in effect, the PCC committee held an emergency Zoom call and took a vote on postponing the conference. It was unanimous; we would push our conference out to 2021. I encourage you all to visit the presidio.gov website and explore the beauty of this venue that will be waiting for us next year. Our PCC will be a lovely getaway, just a short drive from home, providing a relaxing and inspiring event for educational and networking opportunities with a medical communications theme. Please stay tuned as we figure out what the 2021 PCC will look like.

As to how we can connect as a chapter for the balance of the year, we just upgraded to a Zoom Pro account. Our first official Zoom event was an Aperitif Hour (a gentle twist on a happy hour), held Wednesday, July 29, from 6:30 to 7:30 p.m. We are considering other creative ways to use our Zoom account to connect our chapter members going forward. Possibilities include a game of Trivial Pursuit, Pictionary, or online Charades … Or a themed happy hour discussion. Themes suggested so far include container gardening in the city and collecting Mid-Century Modern pottery. We also plan to have at least one educational webinar in the fourth quarter of the year.

Although I am disappointed that AMWA will not be holding the 2020 conference in Maryland as originally planned (I was looking forward to trying the famous Maryland

crab cakes at our chapter meet-and-greet dinner), I know the virtual conference scheduled for October 20–22 will be an excellent event. I hope you will join me virtually in taking advantage of the amazing lineup of relevant educational workshops being offered at this year's conference.

As we move through the second half of 2020, it is hard for me to know what else to say in this letter. I was told that I should mention COVID-19, but I do not think there is anything I can say that has not been said elsewhere. In May, AMWA sent members a survey to evaluate how the pandemic has impacted our careers. The survey results are available on the AMWA website, presented in the infographic, *AMWA Survey: Impact of the COVID-19 Pandemic on Medical Communicators*.

So many things have changed for us all in such a short time. Those of us in the Medical Communications field are luckier than many. Our jobs have always been such that they can be performed successfully from a remote location. Lately I have noticed a plethora of medical writing job openings. The pandemic has certainly made remote working the norm. Medical Communications jobs from around the world can now be filled by writers working from anywhere.

I searched the national AMWA website for the term COVID-19 and found an inspiring article, "Freelancers: Be Your Own Employee of the Month." The article outlines the soft skills that make freelance writers invaluable to their clients. The article points out that in the time of the COVID-19 pandemic, all of us working remotely should embrace these soft skills and be: Reliable, dependable, positive, efficient, productive, disciplined, dedicated, and responsible.

I want to remind those of you who have not yet purchased the long-awaited *AMA Manual of Style* (11th edition); it is now available, and your AMWA membership allows you to purchase it at a discount.

The last thing I want to mention is that our AMWA chapter is always looking for volunteers to help make our chapter strong. We need innovative, energetic people to join us and to contribute their ideas and skills. In a few weeks we will begin recruiting for 2021 officers. Please consider running for office or joining one of our committees (Communications, Programs, Bylaws, and Chapter Procedures). The experience you will gain and the friendships you will make will enrich your life and your career.

Be well. Stay safe.

Andrea Johnson, 2020 President, AMWA Northern California Chapter

Chapter Board of Directors, Chapter Leaders 2020

Office	**Elected Officers**
President	Andrea Johnson
Immediate Past President	Sandra Ruhl
Vice President	Bridget Mazzini
Secretary	Barbara Arnoldussen
Treasurer	Rose Tomey
Programs Committee Chair	Maggie Norris
Bylaws/Chapter Procedures Committee Chair	Nancy Katz
Communications Chair	Snehal Mohile
Pacemaker Co-Editors	Mimi Wessling Michele Anderson
Membership Chair	Suzanne Canada
Jobs List Administrator	Nisha Nair

Letter From the Editors

Happy summer! This issue of *Pacemaker* provides an update on chapter activities by way of letters from our Chapter President and articles by our members on topics ranging from the demon of anxiety to drug protocols for children.

Enjoy reading.

Kind regards,
Mimi and Michele

And this from Mimi:

Following the excellent advice of Matthew Walker's *Why We Sleep* (see Book Nook in this issue), I closed my iPad at 8 p.m. and dug into my stack of back issues of the *New Yorker* magazine. In the March 30 issue (yes, the stack goes even further back) I read Jill Lepore's fascinating article "Don't Come Any Closer." The picture caption reads: "Stories of epidemics are stories of language made powerless and man made brute." Is that true of our present battle against COVID-19? I hope not. None of us are rejoicing over having to stay away from others; we do see—perhaps too much—of powerful words. We try to keep physical distance and wear our masks, N95 if available.

After I finished reading the article, I thought about us AMWA Northern Cal members and how different our situation is from, say, Boccaccio's 14th century nobles who were able to escape while those less powerful stayed and risked infection. We have our devices that allow us to communicate, sometimes virtually, but a way to simulate face-to-face without risk. We have our computers and the internet.

But more cogent to the present, I got to thinking of how our professional organizations have given us strength to pursue our work at home. We have benefited intellectually from our workshops, such as the webinars about emergency authorization for COVID-19 and documents required in the regulatory process for approval of drugs for pediatric use. We have had ample opportunity to get to know our colleagues at face-to-face meetings. Our Vice President Bridget Mazzini and our President Andrea Johnson have donated their time to set up the next Pacific Coast Conference in spring 2021—which may seem far away, but reading about it gives us hope for another of these wonderful conferences with ample time to interact with our colleagues in person.

While I'm on the topic of contributions, I'd like to apologize for an omission in the Editors' Letter in the Fall 2019 issue. Here it is:

"Mimi Wessling, AMWA NorCal Newsletter Editor, has published this edition of *Pacemaker* with assistance from former Editor Michele Anderson," should have

indicated, “Mimi Wessling, AMWA NorCal Newsletter Editor, has published this edition of *Pacemaker* with assistance from former Co-Editors Michele Anderson and Nisha Nair.” It was Nisha who obtained the “Serendipity” article, which was included in that issue of *Pacemaker*, from the author, Sanil Pillai.

Free AMWA Resources

Did you know that **AMWA Online Learning** has many on-demand videos and articles available to members? The best part is that many of these resources are available for **FREE** to members!

Below are just a few of the complimentary resources available:

- Editing Text and Reviewing Comments in Adobe Acrobat
- Eliminate Tedious, Manual Processes from Medical Authoring
- Exploring A Career in Medical Communication
- From Bench Science to Medical Writer: Career Alternatives for Life Scientists|
- Guidelines for Document Designers
- How to Find the Best Journal for Your Scientific Manuscript
- How to Modernize Document Quality Review and Handle Change Management
- Leveraging LinkedIn

To see all the complimentary offerings, check out the online course catalog **here**.

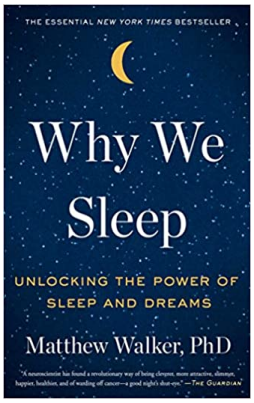
Check Out Our Northern California LinkedIn Group!

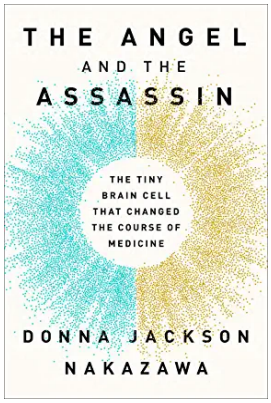
Contact our Membership Chair, Suzanne Canada, for more information.

Book Nook

***Why We Sleep: Unlocking the Power of Sleep and Dreams*, by Matthew Walker**
(Scribner, 2017)

***The Angel and the Assassin*, by Donna Jackson Nakazawa**
(Random House/Ballantine, 2020)





This issue's BookNook won't be a book review as such: I want you to read these books not only for their interesting content but also for the authors' skill in presenting complex science at a level that the intelligent nonscientist can understand and appreciate. Although we might be skilled in some areas of medical science, there are other areas where our knowledge is inadequate. Matthew Walker's *Why We Sleep* (Scribner, 2017) treats a topic that is universal to the human race: sleep.

'Why We Sleep'

And for those of us who work under deadlines, sleep is sometimes put aside to satisfy a commitment to a client. This book spent many, many months on the *New York Times* nonfiction best-sellers list, giving us notice that we are among a large number of readers for whom the title asks a very fundamental question—even without a question mark. Walker spends his Part I, "This Thing Called Sleep," exploring the basic science behind sleep: what governs the body-brain relationship. Words like adenosine, thalamus, and circadian rhythm might be familiar to us as medical writers, but the challenge Walker takes on is showing how these words—and others—relate to an understanding of the bodily processes that control sleep. He uses analogies very effectively, urging the reader to think of the circadian rhythm as a "rousing marching band approaching from a distance." An important and effective componentof this first part is his use of line graphics depicting the sleep-wake process, and equally clearly and effectively, the

relationship between rapid eye movement sleep (REM) and nonrapid eye movement sleep (NREM).

This is a hefty book, more than 300 pages. Walker wisely limits his Part One to five reasonably brief chapters. Beyond his introduction to the science of sleep, he offers tantalizing information about the genetics and evolution of sleep.

'The Angel and the Assassin'

The first chapter of Donna Jackson Nakazawa*'s The Angel and the Assassin* (Random House/Ballantine, 2020) is similar to Walker's procedure in that she devotes a section to describing the immune process at a level that is both scientifically accurate and accessible to a reader with basic scientific literacy. However, in contrast to the sleep disorders Walker describes, the understanding of autoimmune disorders, even among her literate intended readers, is likely to be limited. Thus, she constructs her chapters in an integrated flow of discussions with persons suffering from autoimmune disorders, physicians who treated them, and scientists who were exploring alternative theories of immunity.

What interviewees with autoimmune disorders told her, to a person, is that misfunctions of their mental capacities was as severe a problem for them as the physical aspects of their autoimmune illness. For years, medicine had assumed the mental problems like depression and loss of memory were emotional reactions to disability. It was assumed that the body's immune system did not extend to the brain and that the body and the brain each had its own,independent immune system.

Connecting the dots

Nakazawa, a science journalist, knew this misery only too well from her own struggles with Guillain Barré syndrome. After a second disastrous attack that robbed her of use of her leg muscles, she began "connecting the dots." She encountered studies published in 2012 in which immunologists were exploring the role of the microglia, tiny neuronal cells, in the brain and explored the stories of persons with autoimmune disorders of various types and the changes these persons experienced in their mental state. The microglia were communicating between the body's immune cells and the brain, and scientists were recognizing a connection between bodily inflammation and immune changes in the brain. What she learned was th at "microglial cells had long been functioning as the white blood cells of the brain, governing the brain's health" and that "between 2012 and 2017… the discover of microglia's true role in brain health" (p. 17) would cause neuroscience and immunology to merge into one field.

Dual nature

How then are the microglia described, as the title of Nakazawa's book refers to—angels and assassins? The angelic behavior of the microglia describes their ability to clear amyloid plaques from the brain of Alzheimer patients by enhancing a receptor gene, the TREM2. However, through various stressors, this gene becomes corrupted, so to speak—an "epigenetic shift"occurs, and TREM2 no longer is able to restrain the activity of the

microglia. Like the overreaction of the body's white cells to an infection (a cytokine storm), the microglial cells that contributed to brain health now have gone wild and caused severe tissue damage: The angel morphed into an assassin.

For both sleep science and the body-brain immune system, research is ongoing. Both fields have moved beyond the mind-body dualism that was the accepted thinking for so long. The unification of the body and brain immune systems has been described (reflecting on the words of the philosopher of science Thomas Kuhn) as the second scientific revolution. The deep information presented in Walker's *Why We Sleep* is invaluable in its approach to the problem we have often ignored–insufficient sleep. I hope this brief introduction to these two very important books will inspire you as it did me.

Mimi Wessling is a medical editor and translator based in Oakland, CA. Her main fields are epidemiology and immunology. Her past career includes positions at Stanford and the University of Michigan as a historian of medical ethics.

Point of View

Fear and Anxiety, Friend or Foe?

I sat in in my rocking chair, with my favorite book in my hand. Engrossed and captivated by this book, I could not sense anything of my surroundings. Suddenly, I felt my heart pound and jump in my chest. My breathing became shallow and rapid, my thinking very unclear and foggy. The air seemed too thick to breathe. I could not connect with my book anymore. I closed my eyes and decided to take the time and recognize these familiar sensations. What are they and why are they within me? I thought to myself, I was just having a good time. Soon I realized they were the common but uncomfortable feelings in our life known as anxiety and fear. But how did they manage to creep in my mind …why now?

With a heavy breath and a determined sigh, I sank deeper into my chair. Meekly, I set my book aside and decided to understand these feelings as they ruled my heart, my breath, my mere existence. They took away my moment, my joy of being in that moment and above all my peace. With my eyes still closed, I took a trip down the lane that leads to Fearland where this demon called Anxear resided. I weakly walked down the lane, tired and frail, but somewhere in the corner of my mind I wa set to study this notorious monster Anxear. I reached my destination of research; my home called my Mind, and took a sneak peek around. My breath was still shallow, but my brain was slowly getting immensely aware of the transparent doors and windows around. I saw Anxear had made itself comfortable in my home.

Unwelcome guest

Anxear is an unwelcome guest who takes over my mind. This demon has the power to seep through the doors or windows of my mind, without my knowledge, and thus makes itself at home. I thought I had no option as I was already in the grip of this nightmare. I was also rather keen on understanding this monster. So I gathered the courage and feverishly stepped inside my own home. I wanted to know what Anxear wanted, what it enjoyed and thrived on, but most importantly what weakened this demon? My feet trembled, palms cold and clammy, eyes dilated, mouth so dry and parched that I could barely feel myself living. I sat across Anxear, with the familiar and uncomfortable sensations rising again. However, this time I was focused on studying this demon with great intent.

When I closely looked at it, I saw Anxear bore a black cape that floated in the air, had powerful sharp teeth, and had a deep, scary voice that hummed as it sat down. Its hands and legs were so stretchy that they could just engulf anything in its vicinity. Glaring into the eyes of this two-faced demon, I was being devoured by darkness!

What the demon wants

I took a deep breath and with all my might, I asked what was it that Anxear wanted from me. Why does it ferociously sneak into my home uninvited and turn my life upside down? And what would it take to make this monster go away? Anxear snarled and boasted,

> I feed on self-doubts, negativity, insecurity, and the rushes of the future. I thrive on uncertainty of the unknown, self or social judgment, and lack of self-care. I enjoy and grow on these qualities in anyone. As I smell these from far away, I sprint to such food, hoping to quench my hunger. However, what I cannot stand is a self-caring individual, filled with positivity, who has the ability to stay in the moment. My greatest weakness is confidence and a full breath. I lose my powers when I sniff on confidence. When you have these traits, they make me feeble and I cannot be called Anxear, anymore. The anxiety dilutes and fear cannot work its powers with such mighty strengths in place.

I listened to Anxear very intently and consciously, took a deep breath while reminding myself of what I'd learned. My full, deep breathing started to change Anxear's demeanor. It got visibly uncomfortable, its black cape started to droop, its face lost the color of darkness, the hum weakened, and Anxear floated out of the window.

Suddenly, the air felt light, breath felt fresh and deep, my heart calmed down, and every bit of my body revived with new life. I slowly opened my eyes and found myself still sitting in the rocking chair with the book on my lap. The uncomfortable sensations had

left me and new sensations of rejuvenation had entered my mind. I thought to myself, the demon that I faced with such courage and determination taught me today the most valued lesson of my life. Anxear the monster who was my greatest, darkest foe left me with teachings that befriended me for my lifetime!

Snehal Mohile is a clinical research coordinator in the Oncology field at Stanford University.

Key Issues

Emergency Use Authorization (EUA) for COVID-19

On April 28, 2020, Shannon Clark of UserWise, Inc., presented "How to Secure an Emergency Use Authorization (EUA) for COVID-19" at the meeting of the Bio2Device Group. She explained what an EUA is, the classes of products suitable for EUA, what you need to include in your EUA submission, how to expedite obtaining an EUA, and how to prepare to sell the product after the EUA expires.

Clark began her presentation by describing the purpose of EUAs, using the COVID-19 EUA Declaration as an example. The EUA Declaration allows products not currently approved, cleared, or licensed by the US Food and Drug Administration (FDA) to be used for the duration of the emergency, provided that the disease or condition is life-threatening or serious, and that the approved alternative treatments are either unavailable or inadequate.

FDA authorization for emergency use requires a lower level of evidence for effectiveness than typically required for FDA approval, licensure, or clearance. For an EUA, the FDA looks for evidence that the product *might* be effective and performs an analysis of the risks and benefits.

For the COVID-19 emergency, the FDA is focusing on in vitro diagnostics, ventilators, personal protective equipment, and therapeutics; however, other medical devices are also being considered. Candidate products are typically either already approved for other uses but not for COVID-19 or are in an advanced stage of development but not yet approved.

First step

As a first step in obtaining EUA approval, Clark recommended contacting the relevant FDA medical product center for guidance:

- Center for Biologics Evaluation and Research (CBER)

- Center for Drug Evaluation and Research (CDER)
- Center for Devices and Radiological Health (CDRH)

If your product is a ventilator or a diagnostic, the FDA provides specific guidance and COVD-19-specific email addresses for Pre-EUA submission data:

- Ventilators: CDRH-COVID19-Ventilators@bda.hhs.gov
- Diagnostics: CDRH-EUA-Templates@bda.hhs.gov

Plethora of proposals

If your product can help with the pandemic, the FDA *wants* it in the marketplace, but right now the agency is being bombarded with proposals. Consequently, the more complete, polished, and well thought out your initial proposal is, the more likely it is to be noticed and acted upon. If your product is in an advanced stage of development, be sure to let the FDA center know this so they will favor your product.

Clark recommended that you prepare to engage the FDA by submitting an email to the appropriate FDA center. The email should contain a well-organized summary of the available scientific data on your product's safety and effectiveness, the product's risks and benefits, and any available approved alternatives.

If the FDA informs you that your product is eligible for an EUA, you need to work with the agency to identify the information that needs to be included in the formal EUA submission. For example, the submission must include "fact sheets" for patients receiving the product and for health care providers that administer the product. For details on what to include, refer to FDA-supplied templates and policies for various applicable products (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations) or see the FDA guidance on EUA submissions (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities).

Endgame

What happens when the emergency is over? At that point, the FDA terminates the EUA Declaration and the product can no longer be sold. Patients who began using the product before termination can still use it, but any unused product and associated labeling must be disposed of. Sales can resume only after the product has passed the normal FDA approval, licensure, or clearance process. In fact, the FDA expects the EUA sponsor to apply for product approval, licensure, or clearance within one year of receiving the EUA, and it periodically reviews the sponsor's progress toward this goal. Product sponsors must pursue the normal FDA submission pathway concurrently with emergency use.

When appropriate, clinical trials required for the normal approval process can be run in parallel with an EUA during the public health emergency.

Services available

Clark concluded her presentation with a description of UserWise services specific to EUAs. UserWise, a medical device consultant firm, can help at all stages of the EUA process, not only by providing essential Human Factors information for submission, but also by establishing a post-market surveillance process for adverse-event monitoring and reporting; preparing pre-EUA correspondence and EUA final submissions; and providing documentation and testing of deliverables in parallel with post-EUA continuation of sale. More information on UserWise can be found at its website: https://userwiseconsulting.com/

We wish to thank the Bio2 Device Group for organizing and scheduling this webinar.

Nicki Davis, PhD, wrote her first user guide two years before she earned her PhD in chemistry. Since then she has worked to improve product usability in the pharmaceutical and medical device industries. Nicki is a member of the American Medical Writers Association (AMWA) and is president of the Berkeley chapter of the Society for Technical Communication (STC).

Documents for Drugs for Pediatric Use

Children are not small adults, and the drug regimen appropriate for one child isn't appropriate for another. Recognizing this, the regulatory authorities in both the US and Europe require drug sponsors to submit specific documentation for clinical studies with pediatric patients.

Nancy R. Katz, PhD, MWC, recently conducted a webinar for our AMWA chapter that described the documents that are used to support pediatric drug development as well as the medical writer's role in preparing them.

How kids are different

Katz noted that children are not small adults and that a range of pediatric categories exists (for example, preterm infants, term neonates [1 to <28 days], infants and toddlers [28 days to <24 months], children [2 to <12 years], and adolescents [12 to 16 or 18 years, depending on the region]). Therefore, a drug may not only act differently in children than it does in adults but might also act differently in children of different ages. For example, many cancers in pediatric patients have the same molecular targets as adult cancers but start in different organs. Thus, drug testing in children must not be performed as an afterthought: rather, clinical trials in pediatric populations must be designed by individuals with specific expertise and sensitivity.
Because of these differences, regulatory agencies require drug sponsors to provide plans

for investigating a drug's effects in children of different age groups before the drug can be approved and sold commercially. The European Medicines Agency (EMA) requires a paediatric investigation plan (PIP) at the end of Phase 1 clinical trials, whereas while the US Food and Drug Administration (FDA) requires a pediatric study plan (PSP) at the end of Phase 2. (Check the current guidelines and regulations for any changes to these requirements.)

In addition, protocols for clinical trials in children must follow the efficacy guidelines for clinical studies in children (E11) provided by the International Council for Harmonisation of Technical Requirements for Human Use (ICH). In the US, the Research to Accelerate Cures and Equity for Children Act (RACE for Children Act) addresses the innovation gap in drugs for childhood cancers by mandating pediatric studies that were not required previously.

Developing document content

Katz explained that PIPs, PSPs, and protocols (including protocol amendments) are complex documents that require a large team of subject matter experts (SMEs). Furthermore, these documents need to be developed during a time that is not optimal for the drug sponsor, specifically, when a sponsor is unsure how its intended therapy is working in adult patients. Consequently, medical writers are often called upon to initiate and manage the document development process from beginning to end. When experts disagree, the writer might need to perform literature searches and/or ask the drug sponsor to consult with key opinion leaders on the subject. In all cases, Katz stated, one of the writer's most important roles is "is to ask the right questions."

PIPs and PSPs

Regulatory agencies provide guidelines for creating PIPs and PSPs. The content of these documents is very similar, although the information is organized differently. Topics include the following:

- Characteristics and seriousness of the disease in children: symptoms, current diagnostic methods and treatments, molecular target, epidemiology, and prognosis
- Characteristics of the drug or biological product, including its mechanism of action, extrapolation data to pediatric populations, safety or efficacy information, and anticipated therapeutic benefit to children
- Plans for pediatric clinical studies and nonclinical studies
- Formulation development for children
- Timeline for executing the plan; if time is short, the drug sponsor can provide a protocol synopsis and/or request a deferral with a commitment to future testing in

children

- Agreements for pediatric studies with other regulatory agencies (PSP only)

Under special circumstances, a request can be filed to waive doing pediatric studies, for example, if the disease does not exist in children, or if it is already known that the drug will be ineffective or unsafe in children.

The writer's job does not end when documents are submitted to regulators. The writer may still need to respond to questions from the regulatory agency within a defined time frame and, if necessary, revise and resubmit the documents. Katz stressed that the writer must be careful to respond to all questions from regulators, even those that are phrased as comments.

Protocols and protocol amendments

Protocols and protocol amendments provide the nuts and bolts of carrying out clinical trials in children. The ICH E11 guidelines define the content and help the writer to ask the right questions. Katz advises writers to "think like an Institutional Review Board (IRB) or Ethics Committee (EC) member" when designing the study.

Katz concluded her presentation by reiterating that children are not small adults; that clinical trials in children are not an afterthought, but require specific expertise; that including children in clinical trials specifically designed for them does not harm them but rather protects them; and that the medical writer plays a key role in producing these complex documents by asking the right questions.

Resources

Resources are available to help the writer get started:

- ICH guidelines on the design, conduct, safety and reporting of clinical trials in children (E11) are available at www.ich.org

- For a one-page description of the RACE for Children act, see https://www.kidsvcancer.org/wp-content/uploads/2017/03/RACE-for-Children-Act-ONE-PAGER-.pdf

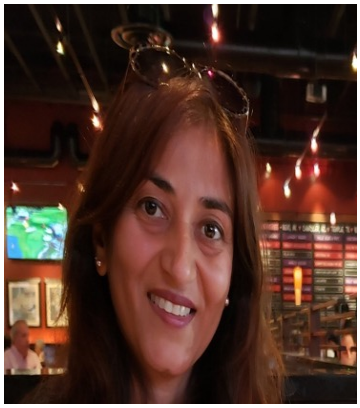
- EMA guidelines for PIP content are available at https://www.ema.europa.eu/en/human-regulatory/research-development/paediatric-medicines/paediatric-investigation-plans/paediatric-

investigation-plans-templates-forms-submission-dates

- FDA guidelines for PSP content are available at https://www.fda.gov/media/86340/download.

Nancy R. Katz, PhD, MWC is a longtime member of AMWA's Northern California chapter. She is founder of the Illyria Consulting Group, Read more about her at http://www.illyriaconsulting.com/Background.html

Member Profile— Snehal Mohile



How did you get into medical writing? I was looking for an opportunity in the clinical research field. I spoke to some colleagues who work in the industry and they recommended I could also look into medical writing and be a member of AMWA. I read about what AMWA does and got very interested. I took a few courses from AMWA, UCSC, and UCSD. These courses helped me understand the art of medical writing and what it entails.

Tell us how you got involved with AMWA. I became an AMWA member in 2018. I was encouraged by Nancy Katz AMWA's Past President, to consider the role of communications chair for the NorCal AMWA chapter. I was enthused by this idea and under the able guidance of Nancy and Sandra Ruhl I assumed this role.

What, in your opinion, are the key features every member should make use of? AMWA has a variety of courses available and I encourage every member to make use of the services available. The Pacemaker and AMWA journals are great resources for learning, building knowledge, and finding networking opportunities.

What type of medical writing or editing do you do? I am active in clinical research/trials at Stanford School of Medicine. I hope to venture into the medical writing/editing field soon.

Could you please share an anecdote/epiphany from your tenure? I was inspired to see the variety of avenues these fields offer and to be a contributor to the field of science in a constructive way.

What do you love to do during your free time? I love to read books, especially the ones on neuroscience. I enjoy reading other genres, listening to music, dance, crochet, painting, meditation, and writing small heartfelt articles.

What do you think others should know regarding AMWA? AMWA is a good platform to learn about the resources, courses, and networking. To join AMWA is the first step toward a medical writing career.

Finally, a message for our members? Enjoy the abundant resources and tips AMWA provides. AMWA socials are a great way to connect with experienced people. Joining AMWA helps in understanding medical writing and its facets.

Welcome New Members!

Wendy McCleod

Susan Mashiyama

Susie Bryan

Kaleigh Whitehall

Saitu Duggal

Phil Dutt

Christelli Carmona

Chris Oldham

David Smith

Robyn Pierce

Salena Marie Preciado

Hannah Ledford

Christine Nguyen

Aisha Jones

Joelle Pauley-Fine