

POSTSCRIPTS

IN THIS ISSUE:

- ORCID^s for Researchers
- IMRAD has a Design Flaw
- Pollution of Scientific Literature
- Role of Patients in Drug Development
- Toastmasters



POSTSCRIPTS

AIMS AND SCOPE

Postscripts is the official publication of American Medical Writers Association (AMWA) Pacific Southwest chapter. It publishes news, notices, job postings, and articles of interest in all areas of medical and scientific writing and communications. The scope covers clinical and regulatory writing, scientific writing, publication planning, continuing medical education (CME) and physician/patient education, social media, current regulations, ethical issues, medical writing training and certification, and good writing techniques.

MISSION STATEMENT

The mission of *Postscripts* is to facilitate the professional development of medical writers and serve as a tool to advance networking and mentoring opportunities among all members. Towards this mission, *Postscripts* publishes significant advances in issues, regulations and practice of medical writing and communications; skills and language; summaries and reports of meetings and symposia; and book and journal summaries. Additionally, to promote career and networking needs of the members, *Postscripts* includes news and event notices covering AMWA Pacific Southwest Chapter activities.

SUBSCRIPTION: *Postscripts* is published monthly except in January and July. The magazine is available as an open access publication and is currently distributed online only.

INSTRUCTION FOR CONTRIBUTORS: We consider articles on any topic of interest to our membership. It is helpful to look at the past December issues for year-end table of contents, and to browse past issues for style and type of articles published. We welcome contributions from AMWA members. Non-member contributions are generally by invitation by the Editor or any member of the Chapter's Board. Detailed instructions are provided in the December 2015 issue, *Postscripts* 2015;5(39):204.

ADVERTISING: *Postscripts* is an advertising-free magazine. However, articles describing products and services relevant to medical writers, editors and communicators may be considered or solicited. As a service to our members, they may submit advertisements for their services or products for free. Please contact the Editor.

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Chapter website: <http://www.amwa-pacsw.org>
AMWA website: <http://www.amwa.org>
Postscripts: <http://issuu.com/postscripts>

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POSTSCRIPTS

June 2016 | Volume 6, No.44

In this issue. . .

- From the President's Desk — ***Susan Vintilla-Friedman, MWC*** **87**
- Editor's Desk: Role of Patients in Drug Development — ***Ajay K Malik, PhD*** **88**

MEDICAL COMMUNICATIONS, PUBLICATION PLANNING

- Now We're All Just Numbers — ***Rebecca J. Anderson, PhD*** **90**
- Praxis: IMRAD Has a Design Flaw — ***Hope J Lafferty, AM, ELS*** **91**
- AMA-zing Style — The AMA Manual of Style Column
— ***Dikran Toroser, PhD, CMPP*** **93**
- Latest Research About Medical Writing Support in Publications
— ***Marissa Romero-Acuña*** **95**

PUBLIC SPEAKING

- My Road to Toastmasters — ***Bernard Delacruz, PhD*** **96**

REGULATORY INTELLIGENCE, CLINICAL TRIALS

- News and Updates from the FDA — ***Lamia Merabet, MS, MBA*** **98**
- Creating the Future of Clinical Trials Today: How Mobile Technologies and
Telemedicine Will Radically Transform Clinical Trials
— ***Roberta Alexander, PharmD, PhD*** **102**

CAREER

- Medical Writing Open Positions — ***Sharyn Batey, PharmD, MSPH*** **107**

DEPARTMENTS

- New Members — ***Gail Flores, PhD*** **104**
- Chapter Upcoming Events **105**
- What's Happening at AMWA National **106**
- Backpage **109**

ACKNOWLEDGEMENT

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COVER:

Oceanside Beach, Southern California. By Sangeeta Dhamija. 2016.

From the President's Desk

This is our last issue of the spring; we'll be back in August, but before some of you head out for vacation adventures I want to make sure you know that we've planned some fun and educational chapter events for when you're back in town:

- June 11 — Regulatory Operations Update lunch presentation in Carlsbad by Antoinette Azevedo, a noted authority on topics such as esubmissions and document management.
- June 22 — Happy hour at the Bella Vista Social Club in La Jolla hosted by our chapter secretary, Brea Midthune, and our chapter treasurer, Elise Sudbeck.
- July 1 — Monthly chapter teleconference, hosted by our past president, Donna Simcoe.
- July 16 — Chapter lunch, presentation, and tour of Lab Launch, a nonprofit biotech facility in Monrovia that provides office and lab space to entrepreneurs and anyone else looking to rent space, including medical writers.

You can check the back pages of the newsletter for more specifics.

We have also begun planning the AMWA Pacific Southwest 2016 Symposium, hosted again by Amgen, on September 10 in Thousand Oaks. Last year's event was very well attended and we are excited about the content being planned. Please do check your emails for more details, coming soon.

By now you should also have received emails from AMWA about the national meeting from October 5-8 in Denver, now called the Medical Writing and Communication Conference. More details can be found at http://www.amwa.org/registration_information, including information about the "Super Saver" rates in effect through June 30. We hope to see you in Denver at the events that will include our annual chapter dinner, which is scheduled for Friday October 7. This should be a beautiful time of the year to see the Mile-High City and maybe even a bit of the Rockies if you have time.

Our June issue begins with an article by Rebecca Anderson about naming conventions for authorship, including a description of ORCID, an organization that assigns a 16-digit number to authors (but presumably doesn't supply a nickname). Hope Lafferty analyzes problems with the classic formatting of scientific articles, and Dikran Toroser discusses the grave problem of scientific misconduct and how it affects publications. If you're ever been interested in improving your speaking skills by participating in Toastmasters, Bernard Delacruz provides a first-hand account of his experiences "making the transition from scientist to science communicator." Two of our writers report on recent meetings of interest – Marissa Romero-Acuña summarizes discussions from the May 6 chapter teleconference that discussed medical writing support in publications, and Roberta Alexander reviews a joint meeting of SDCRN and SDRAN on May 9 that discussed mobile technologies in telemedicine. Our monthly news and updates from the FDA are provided by Lamia Merabet.

Also please do enjoy the very summery painting at the end of this issue by Frida Kahlo (of watermelons, not of herself)!

Susan

Susan Vintilla-Friedman, MWC
President, AMWA Pacific Southwest Chapter



Role of Patients in Drug Development

Last month, about 100 patients with Duchenne muscular dystrophy (DMD) and 1,000 advocates crammed into a Washington, DC hotel ballroom, where 50 patients took the mike to make passionate pleas for the approval of Sarepta's new drug for DMD, Eteplirsen. At these meetings, called advisory committee meetings—composed of independent experts—the sponsor company makes a case for drug approval by presenting the efficacy and safety data from the pivotal trials; the FDA scientists who independently analyze the raw data also present their interpretation of the data. After listening to both sides, the committee recommends approval or denial of the drug by an open vote. The FDA, though not bound by the vote, takes the outcome of this meeting into account when it publishes the final decision a few weeks later.

Patient Power

There were several things that were unusual about the DMD-Eteplirsen meeting. First, the interest from the DMD community was so strong that the meeting, which is normally held in a conference room on the NIH campus, had to be moved to a local hotel ballroom; second, unlike the impassioned testimony from the patients, the company's own data were from a trial with just 12 patients. The trial was poorly run, with a fudged placebo arm, questions surrounding its experimental methodologies, and less-than-convincing efficacy data. One might ask, when and how did the patients start taking center stage in drug deployment and regulation? The answer lies in the thalidomide disaster and the AIDS epidemic.

The thalidomide disaster of the 1960s, swung the pendulum in favor of tighter regulatory control on new drugs, and what resulted over the years was a top-down regulatory paradigm and paternalistic model of drug development. But the 1980s AIDS crisis and slow drug development response compelled patients and their advocates to make their voices heard. Since then, there has been a sea-change in attitude at the political/policy level, support for expedited and targeted investments in research areas and access to drugs. But there remains a lot more that the patients can teach the drug development enterprise.

Section 1137 of FDASIA

In July 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA) into law. Section 1137 of FDASIA has a



provision for the FDA to develop and implement strategies to enhance patient participation in drug development and regulatory processes. Specifically, the law encourages the FDA to actively capture patients' experiences during the time of drug development and solicit their perspective at the time of regulatory discussions.

Currently the FDA is holding public meetings: 4 workshops per year over the course of 5 years. Each meeting will cover a specific disease area and solicit public comment on a variety of questions, including the unmet medical need (eg, the gap the current therapies fail to bridge between pharmacological efficacy and improvement in quality of life) or understanding the severity and burden of the disease, so the regulators can objectively weigh risks and benefits of new medicines; creating a roadmap (codifying the process) of involving patients beginning with the earliest stages of drug development by encouraging the adoption and validation of patient reported outcome (PRO) measures in clinical trials. The spotlight on PRO measures is already being felt in healthcare delivery. Payers are increasingly evaluating PRO data as they determine the value proposition of new medicines before approving insurance coverage for their members.

FDASIA also passed the 5th reauthorization of the Prescription Drug User Fee Act (PDUFA V). The fees collected under PDUFA V are providing resources necessary for the FDA to undertake a patient-focused drug initiative.

Across the Pond

In Europe, patients are already influencing healthcare delivery; for example, in Denmark, patients are the major source of adverse drug reporting (ADR). Since 2003, 11% of all ADRs in the Danish Adverse Reaction Database were directly reported by the consumers (ie, patients).

Last summer, the Copenhagen Center for Regulatory Science (CORS) and Biopeople at the University of Copenhagen, Denmark, organized a workshop, “Patient Involvement in Medicines Development and Approvals: A Paradigm Shift Towards True Patient Impact in Medicines Development and Regulatory Science.” The Copenhagen meeting noted that scientific advice, protocol assistance, qualification of biomarkers, novel methodologies and health technology assessments as some of the areas where patient involvement would benefit drug development. However, it was also noted that effective patient involvement requires an “informed” patient. Towards this goal, the European Patients’ Academy on Therapeutics (EUPATI), established in 2012, was mandated to fill the gap in patient education. EUPATI is a consortium of academia, industry, non-profit and advocacy groups that aims to provide e-Learning, classroom learning and internet library resources.

Similar to the evolution of thinking at the FDA, the Copenhagen group also identified PRO as a critical component that can inform the selection of endpoints in clinical trials. The European counterparts are also moving towards establishing a legal and regulatory framework to secure compliance among all stakeholders and creating a more homogenized inter-operable environment for logistical purposes.

Leaning Over the Horizon

While the involvement of patients in the regulatory process—for example, advisory committees—is welcome, their testimony alone cannot trump hard clinical trial data. The heartfelt pleas of the DMD patient community for the approval of Sarepta’s Eteplirsen in the end could not sway the committee to vote in favor of granting approval: the committee voted 7-3 (with 3 absentees) against approval of the drug. And the FDA has, so far, only allowed compassionate use, while continuing to review the application. The FDA still has the option of ignoring the vote of the advisory committee (that it generally does not do) or granting conditional approval with a requirement to do additional confirmatory trials.

Grand Experiment

The involvement of patients in drug development is part of a grand experiment to bring down the walls between science and public. The logic goes that if the public has its hand on the pulse of scientific and clinical innovation, it is not only more likely to financially support the scientific effort through tax

dollars, philanthropic giving and policy support, but also to inform the scientists and industry on the issues that actually matter to them. This evolution is also expediting the need for transparency, public data access and accountability. As we discussed in several previous issues of *Postscripts*, medical writers and their organizations (ISMPP, AMWA, etc) are at the forefront of this effort. Recently, Danish authorities mandated open access to all research published using tax dollars by the year 2020. We are currently experiencing an inflection point in drug development that history will judge as the Renaissance Period of Drug Development driven by 1960s-style activism! As Pete Townshend of Who said:

“I’ll tip my hat to the new constitution / Take a bow for the new revolution / Smile and grin at the change all around / Pick up my guitar and play, just like yesterday.”

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Ajay K Malik, PhD
Editor, *Postscripts*
AMWA Pacific Southwest Chapter

Now We're All Just Numbers

By Rebecca J Anderson, PhD, AMWA Pacific Southwest Chapter Member

For people whose careers depend on authorship in peer-reviewed journals, name ambiguity is a killer. If you're a Williams, Johnson, or Smith, you know what I'm talking about. It's tricky for people to distinguish **you** in PubMed or Scopus (or internet) searches amongst all the other people sharing the names Williams, Johnson, or Smith. And it's worse if, in addition, your first name is John, Jane, Michael, or Mary.

I have lived this scenario first hand! Every time I've relocated for a new job, there has been at least one other Rebecca Anderson in the same town. Sometimes, there were two of us in the same company. True, it can be fun if your doppelganger is a high-profile lawyer (yes, that's happened). But it can be disconcerting when bill collectors mistake you for a delinquent student loan debtor (yes, that's happened, too). On the lighter side, I've lost count of the times that a fictional character with my name has appeared in television shows and the movies. But usually, she's the villain.

After the establishment of the DOI system for peer-reviewed publications, researchers, funders, and other stakeholders have turned their attention to creating a unique ID for each researcher, but the transition has not been easy. Debates over whether to institute an ID system, and if so, which service to use, have been going on for a decade. *Why?* Most researchers don't have a name ambiguity problem and saw little need to bother with registering their true identity. But as electronic communications have progressively shrunk the world, the problem has massively grown.

For example, there are more than 100 million people named Wang, and more than 10 million people are named Nguyen. The problem is even worse when you consider transliteration of those names into the Roman alphabet, generating multiple spellings of a single person's name.

And then there's the issue of accent marks, umlauts, and the like, which appear or disappear in names from one publication to the next. Journal editors (perhaps inadvertently, but who knows?) create a doppelganger of the true researcher. When reviewing that researcher's next grant application, should the funding agency take into account the publications of the real scientist or his/her doppelganger?

Last year, academic publishers and scientific societies finally drove a spike in the ambiguity problem. In an open letter, they said that they **will now require**—not just encourage—researchers to sign up with ORCID, a nonprofit organization that

uniquely identifies people. ORCID assigns a 16-digit serial number to distinguish you from all the other Jim Johnsons.

Laurel Haak, Executive Director of ORCID, says, not surprisingly, Asians are among the most receptive to ORCID's ID codes—including a lot of Wangs, I suppose. Chinese authors comprise her company's second largest demographic.

Your newly assigned ID number will only automatically tag your papers going forward, but you can (manually) link your past publications through SCOPUS ID. (ORCID will walk you through the process.)

One thing that ORCID hasn't figured out is how to deal with the "dead scientist problem." Haak says, "ORCID requires a living scientist to sign up for the system." Ok. That's a pretty safe bet, unless you're a zombie or something. But after that, there's no way to determine whether the person using the assigned ID is still alive. (Maybe in the future, ORCID will be able to read all the obits via Facebook and say, "case closed.")

Starting in January, a number of large publishers and some grant funding organizations (e.g., *PLOS*, *Science*, IEEE, and the Wellcome Trust) began requiring authors and grant applicants to include their ORCID ID, along with their name.

If your name is Dostoyevsky, none of this probably matters very much. But for the rest of us, welcome to the information age. We've now been literally reduced to a number.

RESOURCES:

- Sign up for ORCID ID here: <https://orcid.org/signin>
- SCOPUS Author ID: <http://www.info.sciverse.com/scopus/scopus-in-detail/tools/authoridentifier> (Scopus Author ID integrates with ORCID)
- ResearcherID: <https://www.researchgate.net/>

REBECCA J ANDERSON, PhD, is a freelance medical writer and the author of two books, *Nevirapine and the Quest to End Pediatric AIDS* and *Career Opportunities in Clinical Drug Research*. Prior to medical writing, Dr. Anderson managed research and development projects for twenty-five years in the pharmaceutical/biotech industry. She holds a PhD in pharmacology from Georgetown University. She lives in Southern California, and when she is not writing, she absorbs the sights and sounds of the West Coast's rich culture and heritage. She can be reached at rebeccanderson@msn.com.



Praxis

By Hope J Lafferty, AM, ELS, AMWA Southeast Chapter Member

IMRAD Has a Design Flaw

At a recent Science of Writing seminar, I started the session the way I always do. I ask my participants how they read research articles. Hands down, the answer is “I read the abstract, then if it’s interesting, I flip to the figures.” My more stalwart participants read the abstract, then dig into the methods section. However they read, though, it’s never a start-to-finish approach.

In writing circles, we’re encouraged to study the genres that we plan to write. Novelists read novels. Poets read poetry. Screenwriters read screenplays. It’s a proven method. No novelist would skip around. No poet would read only the first and third lines. The form follows the function.

In medical and scientific publications, IMRAD is the form. Yet IMRAD (Introduction, Methods, Research, and Discussion—or AIMRAD, if you add the Abstract) does not deliver information the way readers consume it. IMRAD has a design flaw. My seminars stress the importance of reader-centered writing. I spend the day teaching bright, motivated people how to embrace the IRMAD form and to view research articles as written works. And I have been trying to get them to read the articles, to study the form. Perhaps I’m approaching this from the wrong angle.

At the risk of sounding obvious, we’ve changed the way we communicate about everything. We don’t write letters any more. TV is watched on demand.

Radio is delivered via satellite. Emails shifted to IMs, which shifted further to texts and tweets. Everything is customized and fast. And yet the way that information is presented in the medical and scientific literature hasn’t evolved in more than a century. That said, medical researchers have been in front of the curve in how they consume information. Hunting and pecking within the IMRAD form is not a new way to read the academic literature. Reading is transactional. Reading is modular.

How is it that IMRAD persists when even its writers won’t be its readers? For those of us who promote quality scientific writing, we might be focusing on the wrong skillset—or the wrong medium. I wonder when and how we will completely transform the way we present research narratives. If we want what lies ahead to be well-written and scientifically rigorous, we better act fast. The consumers already know what they want.



HOPE J LAFFERTY, AM, ELS, has run her writing and training consultancy, Hope Lafferty Communications, since 2009. Over her career, she has worked as a writer in radio, high tech, engineering, instructional design, and medical research. Hope completed certificates in medical writing and editing from AMWA and the University of Chicago and in training from the Association for Talent Development. She serves as AMWA Annual Conference Chair-Elect and President-Elect of the Board of Editors in the Life Sciences (BELS). When she’s not webcasting, podcasting, or otherwise modeling good writing practice, she takes road trips with her musician husband and comedian dog. Connect with Hope at hope@hopelafferty.com.



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AMA-zing Style — The AMA Manual of Style Column

By Dikran Toroser, PhD, CMPP, Amgen Inc., Thousand Oaks, Calif.

Pollution of Science and Medicine by Scientific Misconduct

A recent article in the *Mayo Clinic Proceedings* highlights the problem of questionable practices that may be “polluting” the scientific literature.¹ The problems discussed in the article include “predatory journals” and other factors that pollute the literature. The AMA Manual of Style is a useful resource that both defines and highlights some of the potential questionable practices, as well as provides some published controversial quotes from famous authors/editors.

We should ignore whining about the supposedly awful pressures of "publish or perish" when we have little credible evidence on what motivates misconduct, nor on what motivates the conduct of honest, equally stressed colleagues. Laziness, desire for fame, greed, and an inability to distinguish right from wrong are just as likely to be at the root of the problem.

Drummond Rennie

In scientific publication, the phrase *scientific misconduct* has major connotations. Recent studies have found that an average of 2% of scientists admitted to having fabricated, falsified or modified data or results at least once – a serious form of misconduct by any standard – and up to 34% admitted other questionable research practices. In surveys asking about the behavior of colleagues, admission rates were 14% for falsification, and up to 72% for other questionable research practices.² Although inadequate record keeping, for example, is not a form of misconduct in itself, it could permit misconduct to occur and make investigations of misconduct difficult to conduct. None of the definitions of scientific misconduct include honest error or differences in interpretation.

Fabrication, Falsification, and Omission are forms of misrepresentation in scientific publication. Fabrication includes stating or presenting a falsehood and making up data, results, or “facts” that do not exist. Falsification includes manipulation of materials or processes, changing data or results, or altering the graphic display of data or digital images in a manner that results in misrepresentation. Omission is the act of deliberately not reporting certain information for a desired outcome.

Misappropriation: Plagiarism and Breaches of Confidentiality. Misappropriation includes plagiarism and breaches of confidentiality during the privileged review of a manuscript. In plagiarism, an author documents or reports ideas of another as his or her own without giving appropriate credit. Plagiarism of published work violates standards of honesty and collegial trust and may also violate copyright law (if the violation is shown to be legally actionable). The best defense against allegations of plagiarism is careful note taking, record keeping, and documentation of all data observed and sources used.

Editorial Policy and Procedures for Detecting and Handling Allegations of Scientific Misconduct. Detection of scientific misconduct in publishing is often the result of the alertness of coworkers and/or other authors of the same manuscript, and much less commonly observed by editors, peer reviewers, or readers. If an allegation of scientific misconduct is made in relation to a manuscript under consideration or published, the editor has a duty to ensure confidential and timely pursuit of that allegation. According to the International Committee of Medical Journal Editors (ICMJE),³ “*If substantial doubts arise about the honesty and integrity of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued,*” but the editor is not responsible for conducting the investigation. An editor's first step after receiving an allegation of falsified, fabricated, or plagiarized work published in her or his journal is to consider contacting the corresponding author, depending on the circumstances, to request an explanation while maintaining confidentiality.

Retractions, Expressions of Concern. After receiving confirmation from the author or authors and/or a report from the author's institution or other agency indicating that fabrication, falsification, or plagiarism has occurred, the journal should promptly publish a retraction. Preferably this retraction will be a signed letter from the corresponding author and all coauthors. If none of the authors will agree to publish a signed retraction, the editor may request such a retraction from the investigating institution, or the editor may issue a retraction on behalf of the journal.

When an article is retracted, the original article should not be physically removed from a journal's website or other online archival publication. The National Library of Medicine does not remove the citation of a retracted article; the citation is updated

to indicate that the article has been retracted, and links between the original citation and the citation to the retraction notice are added. Retractions may also be used for articles that are seriously and pervasively flawed because of honest error that is not a result of fabrication, falsification, or plagiarism.


Allegations Involving Manuscripts Under Editorial Consideration. In the case of a manuscript under consideration that is not yet published in which fabrication, falsification, or plagiarism is suspected, the editor should ask the corresponding author for a written explanation. If an explanation is not provided or is unsatisfactory, the editor should contact the author's institutional authority (ie, dean, director, ethical conduct/research integrity officer) or governmental agency with jurisdiction to investigate allegations of scientific misconduct to request an investigation. In all such communications with authors and institutional authorities, the editor should take care to maintain confidentiality.


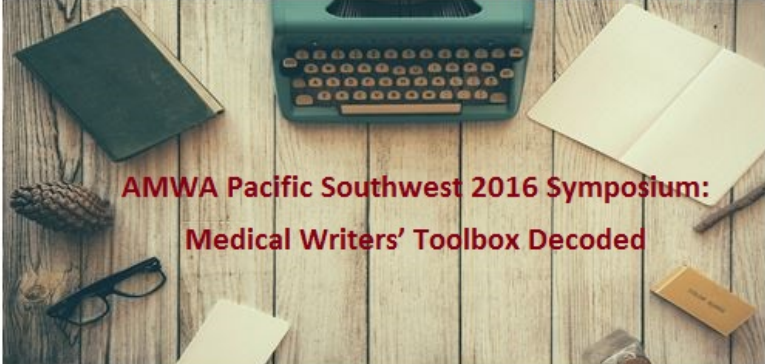
See pages 155-168 in the AMA Manual of Style 10th edition for additional information.

Acknowledgement: Thanks are due to Ajay Malik, PhD, for editorial input.

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3. Available at: <http://www.icmje.org/>

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	<p>Sept 10, 2016 (Sat) SAVE THE DATE Amgen, Inc. One Amgen Center Dr Thousand Oaks, CA 91320</p>
 <p>AMWA Pacific Southwest 2016 Symposium: Medical Writers' Toolbox Decoded</p>	

Latest Research About Medical Writing Support in Publications

Marissa Romero-Acuña, BS, AMWA Pacific Southwest Chapter Member

Last month, Donna Simcoe, the Past-President of the AMWA Pacific Southwest Chapter, organized the Chapter's monthly teleconference on May 6th. The topic for discussion was the role of the medical writer in publication development in biotech and pharma setting. With the ISMPP annual meeting held in April, this was a good time to review the role of and challenges faced by medical writers.

The teleconference included discussion on the following items:

• Challenges faced by medical writers

- Many! An online survey evaluating the medical writer's day-to-day challenges¹ showed that only **50%** of the medical writer's daily work is dedicated to writing. Some of the challenges reported by medical writers included unclear requirements from their clients (20%), frequent changes made to the scope of work by clients (19%), ad hoc requests (17%), working with "difficult people" (24%), multiple iterations (22%), collating comments from multiple reviewers (20%), and task prioritization/management of timelines (13%). During the teleconference, callers agreed that training medical writers in project management skills will help in improving overall project efficiency.

• Online survey regarding the role of medical writers²

- Most authors gave medical writers high scores on "editorial assistance" (84%), "knowledge about manuscript submission procedures" (77%), and author/review project management (69%).

Also, authors gave medical writers a score of 5 on a 6-point scale for the development of publications, suggesting that most authors appreciate the medical writer's role.

• Acknowledgment of medical writing support in publications

- According to Good Publications Practices (GPP3) guidelines, medical writers should be acknowledged as authors when they meet the ICMJE criteria. However, if that is not the case, their participation should be acknowledged avoiding the appearance of "ghostwriting" in peer-reviewed publications. GPP3 states that medical writers may assist authors in the preparation of peer-reviewed publications with accurate and clear findings, avoiding misleading messages, and assist with evolving transparency guidelines.

• Acknowledgment of the role of medical writer – a survey

- A medical consulting company based in the UK³ surveyed PubMed open access literature for Phase 3 clinical studies conducted between 2004 and 2015, and assessed acknowledgment statements for reporting per GPP3 recommendations (medical writer's name, qualification, company, and any third-party medical writing support). They stratified their findings by the years the GPP guidelines were published: first GPP guidelines (2003), GPP2 (2009), and GPP3 (2015). The survey found that of 419 publications (59% of which were industry-sponsored), 38% of the publications from the pre-GPP3 period acknowledged the role of medical writer compared to 67% of publications in the post-GPP3 period. Although, room for improvement was identified, the Chapter teleconference attendees agreed that with further awareness of the GPP3 publications guidelines, the acknowledgment of medical writers' role is expected to rise further.

Acknowledgment: Many thanks to Ajay Malik for comments and editing the early draft.

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MARISSA ROMERO-ACUNA has 15 years of experience working in Regulatory Affairs and Quality Assurance in biotech. Since 2014, she has been working with medical writers supporting everything from creation of documentation templates consistent with ICH guidelines, creating style guides and SOPs, EndNote and referencing support for publication writers, and providing writing and editorial support. Marissa attended the last 2 annual AMWA conferences and is very much involved with the local Chapter. She can be reached via LinkedIn: <https://www.linkedin.com/in/marissa-romero-7b54b3b>

My Road to Toastmasters*

Bernard Delacruz, PhD, AMWA Pacific Southwest Chapter Member

What is Toastmasters?

First, Toastmasters International (TI) is an 80-year-old organization made up of hundreds of clubs around the United States and the world. Its shared mission is "...to provide a mutually supportive and positive learning environment in which every individual member has the opportunity to develop oral communication and leadership skills, which in turn foster self-confidence and personal growth." Second, Toastmasters is the organization that helped me make the transition from scientist to science communicator.

My road to Toastmasters started in college in the late 1980s. While learning to speak in public sounded like a good idea at the time, I was going to be a scientist, I would work in the lab, and speaking skills would be something I could learn later. In 2006, after nearly two decades as an undergraduate, then as a grad student, then as a post-doc in biology, I left the lab bench. Now what?

I lucked out. My first non-bench job was a medical writer at a hospital. I thought if I understood science, then I could communicate science. Foolish me. One of my tasks was to prepare talks from journal articles for different audiences. This was because what scientists need to know from a paper is different from what patient groups need, which is different from what medical students need—and I am not yet including translating jargon!

While working as a medical writer, I started visiting a Toastmasters club run by the grad students. My intention was to write better talks for laypeople. I realized I needed to communicate more effectively to everyone. I still didn't join at that time although they let me visit as often as I wanted. Only when the job ended did I decide it was time to join a club formally and focus on speaking skills.

How does Toastmasters work?

Over the decades, TI has designed a program based around speech manuals. The first manual is *Competent Communication*. In it are ten projects designed to teach you different aspects of giving prepared talks; for example, how to structure a speech, how to use body language, and how to have a memorable message.

Even more important than giving speeches, however, are the speech evaluations. After each speech, a more advanced member gives you constructive feedback. Evaluations let you know what you did well and what you can improve on and—as stated in the TI mission statement—this is all done in "a mutually supportive and positive learning environment." Also, you learn not just from the evaluations you receive, but also from the evaluations others receive. Every speaker—even an experienced speaker—has something they can improve on. Eventually, it becomes your turn to evaluate other members. Evaluating others means learning to give an impromptu speech. You must listen carefully, organize your thoughts quickly, and give useful advice in a supportive manner.

Furthermore, Toastmasters is not just for speaking. The TI motto is "*Toastmasters. Where Leaders Are Made.*" Volunteers drive Toastmasters clubs. Through the *Competent Leadership* manual, you complete projects to gain leadership experience; for example, taking on roles during meetings, organizing club events, and becoming a club officer. Also, as you grow in the club, there are opportunities to participate at higher levels of Toastmasters. It was being an officer in my Toastmasters club that helped me get my next job—at least in part. I volunteered to be the Vice President of Public Relations and to set up and run the club website. This experience prepared me, somewhat, for my next job, writing scientific product descriptions for an online catalog. That was a springboard to my current job that includes rewriting pages to make the company website more accessible for non-technical customers.

How can you get involved with Toastmasters?

I encourage you to take the first step today: find a nearby club and visit it as soon as possible. Visit the Toastmasters International website (www.toastmasters.org) and click on the Find a Club link. You can search by zip code, distance, and day/time of the meeting. Most clubs have an email or phone number to contact; many clubs also have a website. Guests are welcome at most clubs. You can just stop by or you may want to contact the club ahead of time to confirm the meeting. I also advise folks to visit more than one club. There are many kinds of clubs. There are clubs associated with companies or with churches. There are clubs at


*Reprinted from: Postscripts. 2012 Nov; 2(9):7-9

schools and colleges, at community centers, even at restaurants. I know of a club for atheists, a club for wine tasters, and a club for improv comedy! Most clubs meet weekly but some specialty clubs may meet less frequently. While each club has a different personality and each club runs a little differently, as stated in the Toastmasters mission statement, all clubs *"provide a mutually supportive and positive learning environment."*

Joining is easy and affordable. Every club will have application forms or you can download one from the Toastmasters International website. Presently, dues for Toastmasters International are \$36 for six months, and there is a new member fee of \$20 to get your first manuals. Additionally, each club may have their own dues to cover club costs. Even better, if it is a company club, your company might cover your fees. You can also join more than one club and transfer to a new club if needed.

If I had a time machine, I would go back and tell my college self, "Join Toastmasters NOW. It will be the most bang-for-your-buck you will ever get!" If you find yourself tongue tied, remember this: everyone in the club will have a story of walking into a Toastmasters club for the first time. You can talk about that.

BERNARD DELACRUZ, PhD, is a medical and technical writer with experience working in the biopharma and medical device companies, including Medtronic, Bachem, and Life Technologies. He has passion for words and public speaking. He was awarded Toastmasters Advanced Leader Bronze award and is past President of Narrators Toastmasters. He has been interviewed about scientist-as-communicators. Bernard holds a PhD in Cell & Molecular Biology from University of California San Diego. He currently resides in the San Fernando Valley area of Los Angeles, California, and can be reached at Bernard.Delacruz@gmail.com or via LinkedIn: <https://www.linkedin.com/in/bjdelacruz>



Happy Hour in San Diego!

Please join the AMWA Pacific Southwest chapter for good food, drinks, and conversation! With an expansive outdoor area and beautiful views, Bella Vista Social Club & Caffé is the perfect place to chat with colleagues and enjoy the fresh summer air.

When: Wednesday, June 22, 2016 at 5:30 pm - 7:30 pm

Where: Bella Vista Social Club & Caffé
2880 Torrey Pines Scenic Drive, La Jolla
(858) 534-9624

Hosted by: The AMWA Pacific Southwest Chapter

RSVP: Brea Midthune, secretary@amwa-pacsw.org or
Elise Sudbeck, treasurer@amwa-pacsw.org

Notes: AMWA-PacSW will provide some appetizers.
Pay for your own drinks.
Happy hour specials, 4-7.
Non-AMWA members welcome!

News and Updates from the FDA

Lamia Merabet, MS, MBA, AMWA Pacific Southwest Chapter Member

During the last two months, the FDA granted approval for novel treatments for rare disease indications including severe hepatic veno-occlusive disease (VOD), a chronic lymphocytic leukemia (CLL); and breakthrough therapy designation for first-in-class targeted treatment for bladder cancer.

Defitelio

At the end of March, the FDA approved the first therapy for treatment of severe hepatic VOD, a rare and life-threatening liver condition in which veins become blocked, causing swelling and an internal blood flow decrease, which may lead to liver damage. In its most severe form, patients might also develop failure of the kidneys and lungs. Hepatic VOD can occur in patients who receive chemotherapy and a hematopoietic stem cell transplantation (HSCT). The efficacy of Defitelio (Jazz Pharmaceuticals) was evaluated in the transplantation community through prospective clinical trials where higher survival rates were reported.

Defitelio received an orphan drug designation, and the FDA granted its application priority review status.

Venclexta and Vysis FISH probe kit

In early April, the agency granted approval to the first treatment for chronic lymphocytic leukemia (CLL) in patients with a specific chromosomal abnormality. Venclexta (AbbVie Inc. and co-marketed with Genentech USA Inc.) is the only agency-approved therapy for CLL patients who express the so-called 17p deletion. This targeted therapy inhibits the B-cell lymphoma 2 protein, which supports cancer cell growth and is overexpressed in many patients with CLL. Venclexta is indicated for daily use after detection of 17p deletion is confirmed through the use of the FDA-approved companion diagnostic Vysis FISH probe kit (Abbott Molecular). The FDA granted the Venclexta application breakthrough therapy designation, priority review status, and accelerated approval for this indication. An orphan drug designation was received.

Tecentriq and Ventana PD-L1 (SP142)

Tecentriq (Genentech) is approved by the FDA as a new, targeted treatment for the most common type of bladder cancer, urothelial carcinoma. In the last two years, FDA has been approving many in the broader class of PD-1/PD-L1 targeted biologics. Tecentriq, a PD-1/PD-L1 inhibitor, targets the PD-1/PD-L1 pathway (proteins found on the body's immune cells and some cancer cells), and might help the body's immune system fight cancer cells by blocking these interactions. While the safety and efficacy of Tecentriq were studied in a clinical trial, the greater effect was observed with treated patients who were classified as "positive" for PD-L1 expression and thought to be more likely to respond to treatment with Tecentriq.

The FDA also approved the Ventana PD-L1 (SP142) (Ventana Medical Systems) assay complementary diagnostic for Tecentriq. It would detect PD-L1 protein expression levels on patients' tumor-infiltrating immune cells, and might help physicians determine which patients may benefit from treatment with Tecentriq. The FDA granted the Tecentriq application breakthrough therapy designation, priority review status, and accelerated approval for this indication.

Voluntary recalls were issued by Well Care Compounding Pharmacy and Medtronic.

A few **advisory committee meetings**, as well as several other events have been scheduled for May, June, and July, as detailed below.

Selected FDA Announcements

Date	Announcement
05-17-16	Well Care Compounding Pharmacy performed a voluntary statewide recall in Nevada on all unexpired sterile compound products due to the FDA's concern over lack of sterility assurance. The recall impacts all sterile compounded products distributed between 01/01/2016-04/29/2016. Administration of a sterile drug product intended to be sterile that is compromised may result in serious and potentially life-threatening infections or death. ¹

- 05-05-16 The FDA finalized a rule extending its authority to all tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco. Since the first Surgeon General’s report on Smoking and Health in 1964, which warned Americans about the risks associated with smoking, significant progress has been made to reduce smoking rates. In 2009, Congress took a historic step by passing the bipartisan Family Smoking Prevention and Tobacco Control Act (TCA) giving the FDA authority to regulate the manufacturing, distribution and marketing of tobacco products to protect the public health. The TCA is implemented with the finalized rule, whereas new provisions aimed at restricting youth access, will go into effect in 90 days. All manufacturers, importers and/or retailers of newly regulated tobacco products -not on the market as of Feb. 15, 2007- are subjected to these requirements: registering to the FDA of manufacturing establishments and listing products; reporting ingredients, and potentially harmful constituents; requiring FDA premarket review and authorization of new tobacco products; placing health warnings on product packages and advertisements; and not selling modified risk tobacco products (including those described as “light”, “low” or “mild”) unless authorized by the FDA.²
-
- 04-29-16 A federal judge entered an order of permanent injunction between the United States and Paul W. Franck, a Florida drug manufacturer and distributor doing business as Franck’s Compounding Lab and Trinity Care Solutions. The action was brought by the U.S. Department of Justice, on behalf of the FDA. According to the complaint filed with the consent decree, Franck unlawfully manufactured and distributed adulterated and misbranded drug products. In 2014, Trinity Care Solutions recalled all sterile drugs and ceased compounding operations after an FDA’s inspection revealed violations that could compromise drug sterility. In 2012, contaminated ophthalmic drugs compounded by Franck’s Compounding Lab were linked to eye infections, including temporary or permanent vision loss; subsequently, the company recalled all sterile products, ceased operations, and received a warning letter from the agency. The order of permanent injunction prohibits Franck from manufacturing, holding and distributing sterile drug products until he complies with the Federal Food, Drug and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements.³
-
- 04-22-16 The FDA announced a proposal to ban electrical stimulation devices (ESDs) used for self-injurious or aggressive behavior because they present an unreasonable and substantial risk of illness or injury to public health that cannot be corrected or eliminated through changes to the labeling. The agency stands ready to work with health care providers to help facilitate safe transition to alternate care for all of those in need since the proposed rule, if finalized, would ultimately remove these devices from the marketplace completely. In making this determination, the FDA considered all available evidence, including clinical and scientific data, input from experts in the field and state agencies, comments from the Judge Rotenberg Educational Center (JRC) – the only one facility that is using these devices in the US, individuals and parents of individuals on whom ESDs have been used, and disability rights group, as well as insights from an April 2014 FDA advisory panel. The proposed rule is available online for public comment for 30 days.⁴
-
- 04-20-16 Medtronic is notifying customers worldwide of a voluntary recall for the battery pack used in its Covidien Oridion labeled CapnostreamTM20 and CapnostreamTM20p Patient Monitors. Capnostream monitors are external (non-implantable) medical devices used to assess patients’ respiratory status and identify changes in breathing, which prescription is operated by trained healthcare professionals in a clinical setting and in the home. This voluntary recall is being conducted due to a battery manufacturing defect that may increase the risk of thermal damage in the battery pack. The scope of this recall includes battery pack model numbers 016400 and 010520 that were manufactured by a contract manufacturer between April 2014 and February 2016.⁵

Selected FDA Approvals

Drug	Indication	Company
Inflectra®	Inflectra (infliximab-dyyb) is approved as a biosimilar not an interchangeable to Janssen Biotech, Inc.’ Remicade (infliximab), originally licensed in 1998. Prescribed for multiple indications: active Crohn’s disease (adult and pediatrics), active ulcerative colitis, active rheumatoid arthritis, active ankylosing spondylitis, active psoriatic arthritis, chronic severe plaque psoriasis ⁶	Celltrion, Inc. for Hospira

Nuplazid®	First FDA-approved drug to treat hallucinations and delusions associated with Parkinson's disease. ⁷	Acadia Pharmaceuticals Inc.
Crestor®	First FDA-approved generic version of Crestor (rosuvastatin calcium) tablets with diet observance for treatment of hypertriglyceridemia and primary dysbetalipoproteinemia, and either alone or in combination with other cholesterol treatment for adult patients with homozygous familial hypercholesterolemia. ⁸	Watson Pharmaceuticals

DEVICES

Cobas® Zika Test	The FDA's Center for Biologics Evaluation and Research announced the availability of an investigational test to screen blood donations for Zika virus. Used under an Investigational New Drug application (IND), it might help protecting the nation's supply of blood and blood components during the outbreaks. ⁹	Teva Pharmaceuticals
Micra® Transcatheter Pacing System	First FDA-approved leadless pacemaker to treat heart rhythm disorders. Micra is intended for patients with atrial fibrillation or other dangerous arrhythmias, such as bradycardia-tachycardia syndrome. ¹⁰	Medtronic

May & June 2016 Advisory Committee Meetings

Date	Committee
06/09/16	Meeting of the Antimicrobial Drugs Advisory Committee Meeting Announcement – Discussion of the Biologics License Application (BLA), submitted by Merck Sharpe & Dohme Corp. ¹¹
05/24/16	Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting Announcement – Discussion, recommendations and vote on information related to the premarket approval application submitted by St. Jude Medical. ¹²
05/11/16	Vaccines and Related Biological Products Advisory Committee Meeting Announcement – Discussion of updates of the research program in the Laboratory of Bacterial Polysaccharides, Division of Bacterial, Parasitic, and Allergenic Products, Center for Biologics Evaluation and Research, FDA. ¹³
05/03-04/16	Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement– Discussion of results from assessments of the extended-release and long-acting (ER/LA) Opioid Analgesics REMS (Risk Evaluation and Mitigation Strategies). ¹⁴

June & July 2016 Conferences, Workshops and Public Meetings

Date	Title
07/11-12/16	Third Annual Drug Discovery and Development Symposium for Pulmonary Hypertension. ¹⁵
06/19/16	The FDA and co-sponsor American Association for Cancer Research (AACR) are announcing a public workshop entitled "Liquid Biopsies in Oncology Drug and Device Development". ¹⁶
06/13/16	The FDA, in co-sponsorship with the American Association for Cancer Research (AACR), is announcing a public workshop entitled "Oncology Dose Finding Workshop". ¹⁷
06/10/16	Public Meeting: Over-the-Counter Monograph User Fees. ¹⁸
06/05-08/16	Fifth annual FDA-ISPE Quality Conference. ¹⁹

WEBLINKS

- For additional information on approvals, including labeling revisions, tentative approvals, efficacy supplements with supporting clinical data, manufacturing changes or additions, or chemistry; new strength, see <http://www.fda.gov/NewsEvents/Newsroom/default.htm>
- For additional information on recalls, market withdrawals, and safety alerts, see <http://www.fda.gov/Safety/Recalls/default.htm>

- For information on current drug shortages, see <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>
- For information on drugs to be discontinued, see <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>
- For Orange Book drug product list additions or deletions, see <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm>

- ¹<http://www.fda.gov/Safety/Recalls/ucm501543.htm>
- ²<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm499234.htm>
- ³<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm498447.htm>
- ⁴<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm497194.htm>
- ⁵<http://www.fda.gov/Safety/Recalls/ucm497035.htm>
- ⁶<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494227.htm>
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- ⁹<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm493081.htm>
- ¹⁰<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm494417.htm>
- ¹¹<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm496386.htm>
- ¹²<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm495808.htm>
- ¹³<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm491263.htm>
- ¹⁴<http://www.fda.gov/AdvisoryCommittees/Calendar/ucm490628.htm>
- ¹⁵<http://www.fda.gov/Drugs/NewsEvents/ucm489693.htm>
- ¹⁶<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm494610.htm>
- ¹⁷<http://www.fda.gov/Drugs/NewsEvents/ucm492762.htm>
- ¹⁸<http://www.fda.gov/Drugs/NewsEvents/ucm499390.htm>
- ¹⁹<http://www.fda.gov/Drugs/NewsEvents/ucm482626.htm>

LAMIA MERABET, BS, MS, MBA, is a member of the AMWA Pacific Southwest chapter and a Postscripts columnist on regulatory trends. She narrated several networking events and discussions including "To Borrow a Page from the Freelancers Book." Lamia is a Quality and Regulatory professional at Arianne Corp. handling international projects on diagnostics and pharmaceutical compounds. Her career spans the fields of clinical research, medical writing, safety reporting, post-market surveillance, and regulatory compliance in pharma and medical devices. She earned her MS in Clinical Pharmacology from Henri Poincaré University (Nancy, France), and her MBA in Healthcare Administration from National University (San Diego, California). At the San Diego Regulatory Affairs Network (SDRAN) Program Committee, she broadcasts keynote speakers. She can be reached at LamiaMerabetProBono@gmail.com and via LinkedIn <https://www.linkedin.com/in/lamiamerabetclinicaltrialfda>



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Creating the Future of Clinical Trials Today: How Mobile Technologies and Telemedicine will Radically Transform Clinical Trials

Roberta Alexander, PharmD, PhD, Exagen Diagnostics, Inc, Vista, Calif.

SAN DIEGO, May 9th, 2016

The San Diego Clinical Research Network (SDCRN) (<http://theclinicalresearchconnection.com/>) and the San Diego Regulatory Affairs Network (SDRAN) (<http://www.sdran.org/>) came together to discuss ways to utilize telemedicine and mobile technologies in clinical research. Speakers were Dr. Kevin Bruhn from Science 37 (<https://www.science37.com/>) and Kim Tyrrell-Knott, a partner at the law firm of Epstein, Becker & Green (<http://www.ebglaw.com/>). The event was moderated by Dr. Brad Pruitt from Parallel 6 (<http://www.parallel6.com/>) and took place at BD (formerly Carefusion) in San Diego. Many members of SDCRN and SDRAN attended, in addition to others interested in clinical research and digital medicine.



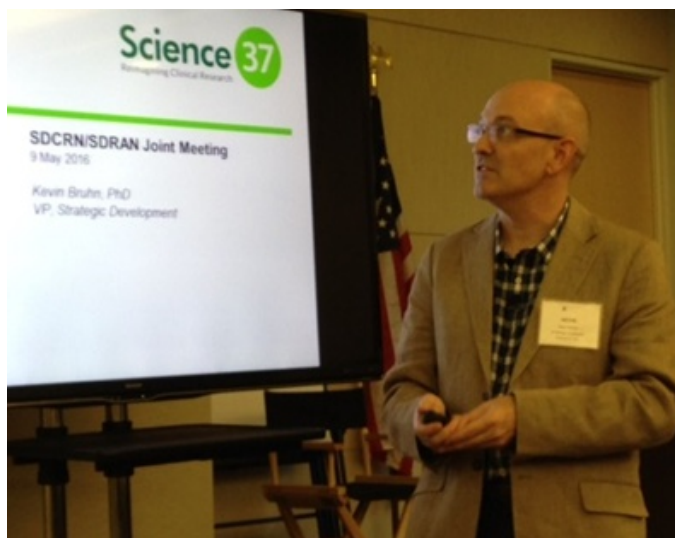
Dr. Teresa Gallagher of SDCRN

PATIENT RECRUITMENT AND ENGAGEMENT IN CLINICAL RESEARCH

Dr. Kevin Bruhn of Science 37

It is definitely an exciting time to use mobile technology in clinical research to reach more patients and keep them engaged. In fact, although 90% of patients say that they would like to participate in a clinical trial, only 3% actually do. Many patients live too far away from a site, don't know that a study is even going on, or maybe they lack trust and education about clinical research. Patient recruitment suffers, and time and costs go up. It takes 6 to 9 years to do the necessary trials to get a new drug approved, and clinical trials account for approximately 40% of the total budget of drug

development. In addition, lengthy clinical studies leave less and less time for patent protection. Science 37 aims to streamline clinical trials by decentralizing them and facilitating virtual interactions between the patient and the investigator. Science 37 uses a unique platform called NORA (Network-Oriented Research Assistant) that functions as electronic medical record storage and database for data collection and management. Patients can interact with NORA via an app and stay engaged throughout the trial, without the inconvenience of traditional site visits. They can interact with the investigator and study coordinator via the app, have blood draws and other lab tests done at any local lab, and non-specialized assessments can be done by a local physician. Science 37 acts as a metasite to coordinate protocol approval through a central IRB, patient recruitment, and study implementation via a network of local physicians and nurses and via the use of mobile devices that keep the patient at the center of the study. This setup allows them to reach a greater number of patients in all geographical areas and of all racial backgrounds, increasing the enrollment of minorities in the study. Science 37 was founded by Noah Craft in 2014, and has already collaborated with sponsors and CROs on several trials in various therapeutic areas. So far, their focus has been on oncology, dermatology, and rare diseases, where traditional patient recruitment is particularly slow. Science 37 has helped to accelerate studies and cut costs, and has established collaborations with various organizations, including Genentech, Harvard Clinical Research Institute, and Los Angeles Biomedical Research Institute, among others.



Dr. Kevin Bruhn



Kim Tyrrell-Knott

THE REGULATORY FRAMEWORK IN THE ERA OF TELEMEDICINE


Kim Tyrrell-Knott of Epstein, Becker & Green

Clinical research, either done in a traditional way, or done using modern technologies like those implemented by Science 37, is highly regulated. Good clinical practices, patient rights, privacy laws, rules by the department of Health & Human Services (HHS) and other federal or state laws, all regulate clinical research. From a digital health perspective, many changes are happening, and the FDA is taking a more liberal and risk-based approach. Overall, certain aspects of digital health are still highly regulated, while others are not regulated at all. A good example of an unregulated technology is the FitBit: lots of people have one, and each collects lots of data, but how to use these data for a highly regulated process like a clinical study, if the device

itself is not regulated at all? Cybersecurity is also an issue with telemedicine for the FDA and other entities. The Food and Drug Administration Safety and Innovation Act (FDASIA) has drafted a guidance for industry for the use of mobile medical applications. For example, clinical decision-support (CDS) software are more or less regulated based on the significance of the healthcare decision (eg, diagnose vs. treat disease) and on the severity of the condition. Overall, data acquired via telemedicine and mobile devices need to be regulated in ways similar to data acquired in more traditional ways, avoiding the risk of subjecting new technologies to higher standards!

SDCRN and SDRAN are each planning other exciting events throughout the summer, and we look forward to the networking opportunities and the learning experience!

ROBERTA VEZZA ALEXANDER, PharmD, PhD, is the Associate Director of Clinical Research and Medical Affairs at Exagen Diagnostics, Inc. where she designs and oversees the Company's clinical studies. Dr. Alexander transitioned recently in the diagnostics space, as she spent most of her career in drug discovery working in the pharmaceutical industry. She holds a PharmD and a PhD from the University of Perugia, Italy, and came to the USA for a postdoctoral fellowship at the University of Pennsylvania. She has been living in San Diego with her husband since leaving Philadelphia, and loves to walk on the beautiful beaches of Southern California. She can be reached via LinkedIn: www.linkedin.com/in/robertavalexander/





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DIAglobal.org/DIA2016

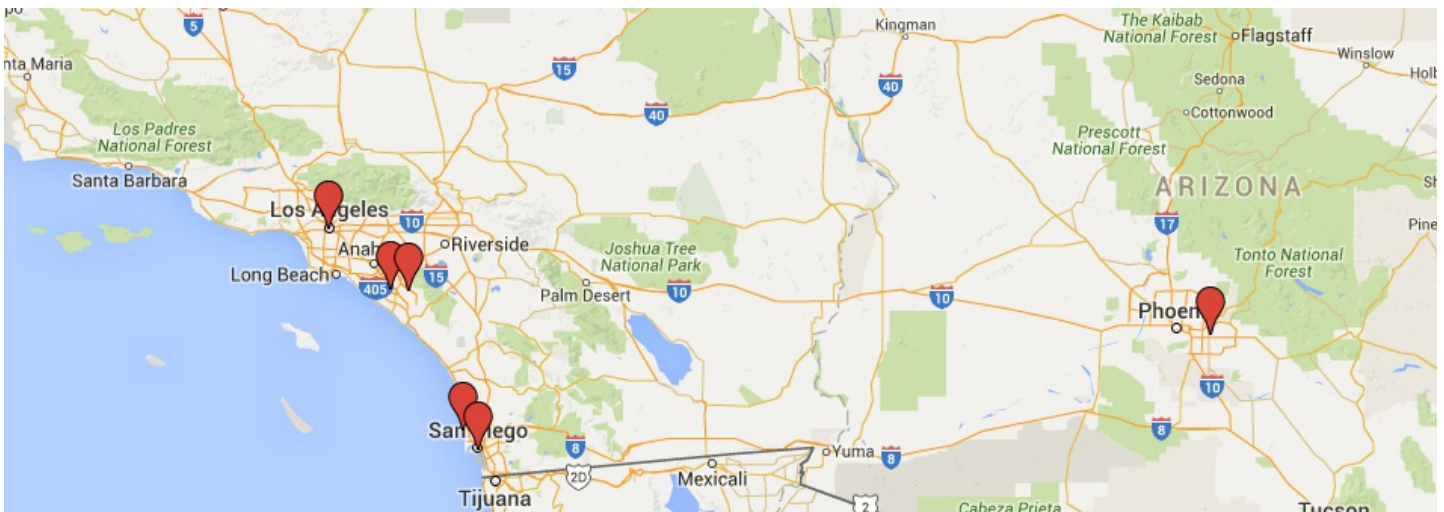
A GATHERING OF GLOBAL PROPORTIONS



<http://www.diaglobal.org/DIA2016>

AMWA Pacific Southwest Chapter Warmly Welcomes Our New Members

Malini Vashishtha - Irvine
Leslie Bruce - La Jolla
Garima Chaudhry - Foothill Ranch
Kathleen Wood - San Diego
Vanita Gupta - Los Angeles
Miranda Rindlisbacher - Mesa, AZ



List courtesy of Gail Flores, PhD, AMWA Pacific Southwest Chapter membership coordinator.
Email: member-coordinator@amwa-pacsw.org



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Upcoming Chapter Events

AMWA Pacific Southwest Chapter Lunch (Monthly) Teleconference Occurs First Friday of the month, 12-1 PM Pacific time

Hosted by Donna Simcoe, Past President of the Chapter

Dial in number: 706-913-1155

Participant code: 0204157# (or from your iPhone: 706-913-1155,0204157#)

Saturday, June 11 - Lunch Presentation: Regulatory Operations Update for Medical Writers

Are you interested in learning more about current regulatory operations and best practices for medical writers? Regulatory operations work is an important part of the process for submission of documents and drug data to regulatory agencies worldwide, and includes work with electronic document management systems (EDMSs) and document templates. On Saturday, June 11 please join us for an educational lunch presentation given by Antoinette Azevedo, an independent consultant who has extensive experience advising life sciences companies on solutions for regulatory publishing and document management.

In this presentation, Antoinette will describe the latest eCTD mandates from the FDA, the standardizing of content through template use, and best practices for MS Word and conversions to PDF.

Location: Carlsbad by the Sea, 2855 Carlsbad Blvd, Carlsbad, CA 92008

Agenda:

11:30am-12:00pm: Registration

12:00pm-12:30pm: Lunch (a catered lunch will be provided)

12:30pm-12:45pm: AMWA chapter announcements

12:45pm-2:30pm: Presentation

Cost: \$25 AMWA members, \$30 non-AMWA guests

Deadline for registration or cancellation is June 6, 2016.

Wednesday, June 22, 2016 at 5:30 pm - 7:30 pm, Happy Hour in San Diego!

Please join the AMWA Pacific Southwest chapter for good food, drinks, and conversation! With an expansive outdoor area and beautiful views, Bella Vista Social Club & Caffé is the perfect place to chat with colleagues and enjoy the fresh summer air.

Where: Bella Vista Social Club & Caffé, 2880 Torrey Pines Scenic Drive, La Jolla
(858) 534-9624

Hosted by: The AMWA Pacific Southwest Chapter

RSVP: Brea Midthune, secretary@amwa-pacsw.org or Elise Sudbeck, treasurer@amwa-pacsw.org

Notes: AMWA-PacSW will provide some appetizers.

Pay for your own drinks.

Happy hour specials, 4-7 PM.

Non-AMWA members welcome!

Save the Date! September 2016

AMWA Pacific Southwest's 2016 Annual Medical Writers' Toolbox Symposium

What's Happening at AMWA National

AMWA 2016 Medical Writing & Communication Conference REGISTRATION NOW OPEN!

Be a Super Saver. Save \$100 on if you register by June 30. (And an extra \$25 off Saturday workshops)
www.amwa.org/conference

New this year – Workshops will be held before and after the general conference activities. Note: BOD meeting will be on Saturday, so there may be a conflict there, but otherwise workshops do not conflict with general sessions or networking events.

CORE Reference

AMWA partnered with EMWA to create the CORE Reference, a user manual to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content.

<http://www.amwa.org/core>

AMWA Online Learning

Our catalog of online learning activities continues to grow with more coming this month! Interactive, self-guided online learning includes:

- The Role of the Regulatory Writer
- Drug Development Essentials: Regulatory Documents for Developing Clinical Studies and Reporting Clinical Data
- Drug Development Essentials: Regulatory Documents for Getting a Drug to Market and Monitoring Safety
- Ten Characteristics of Effective Tables and Graphs
- Harness the Power of EndNote: Manage Your Library's Data

Find these activities, archived recordings of AMWA Live Webinars, Pocket Trainings, and more in AMWA Online Learning at www.amwa.org/online_learning.

Live Webinars – upcoming webinars in June:

June 15, 2016

Unlock the Secrets to Freelance Success: Bad Behaviors That Can Sabotage Your Business

http://www.amwa.org/calendar_day.asp?date=6/15/2016&event=1602

September 8, 2016

Unlock the Secrets to Freelance Success: Getting the Clients You Deserve

http://www.amwa.org/calendar_day.asp?date=9/8/2016&event=1599

Visit the AMWA Event Calendar (http://www.amwa.org/calendar_list.asp) for a full list of upcoming events.

MWC –

Next exam administration, October 6, 2016 in Denver, CO, in conjunction with the Medical Writing & Communication Conference. Application information at: http://www.amwa.org/mwc_apply

Essential Skills package

Purchase all 7 Self-Study Workbooks and earn the AMWA Essential Skills certificate at your own pace. Certificate enrollment is included. http://www.amwa.org/es_express

Package sale price: \$950 member/\$1,250 nonmember
ES Express Package offers over 25% in savings!

Medical Writing Open Positions

Compiled By: **Sharyn Batey, PharmD, MSPH**

Employment Coordinator, AMWA Pacific Southwest Chapter

Medical Writer

Greenkey Resources recruiting for undisclosed company in Arizona

http://www.greenkeyllc.com/jobs/134677/pharmaceutical/medical-writer/arizona-az/?utm_source=Indeed&utm_medium=organic&utm_campaign=Indeed

Medical Writer

Ambry Genetics, Aliso Viejo, CA

<http://job-openings.monster.com/monster/83c13884-1eac-4a76-b667-722f79fe578f?mescoId=2700440001001&jobPosition=8>

Medical Writer, Senior Manager

Avanir Pharmaceuticals, Inc, Aliso Viejo, CA

<http://chm.tbe.taleo.net/chm04/ats/careers/requisition.jsp?org=AVANIR3&cws=1&rid=814&source=indeed.com>

Medical Writer - Promotional Activities

Arbor Scientia, Carlsbad, CA

<http://jobview.monster.com/Medical-Writer-Promotional-Activities-Job-Carlsbad-CA-US-162248413.aspx?mescoId=2700440001001&jobPosition=9>

Grant Writer

Targazyme, Inc, Carlsbad, CA

<http://jobview.monster.com/Grant-Writer-Job-Carlsbad-CA-US-168132527.aspx?mescoId=2700440001001&jobPosition=8>

Scientific Writer

City of Hope, Duarte, CA

<http://job-openings.monster.com/monster/594c0047-5695-45a5-98d8-f233d6f9c533?mescoId=2700440001001&jobPosition=17>

Director, Medical Writing

Atara Biotherapeutics, Los Angeles, CA

<http://app.jobvite.com/CompanyJobs/Careers.aspx?k=Job&c=qk0aVfw9&j=o7CS1fwm&s=Indeed>

Medical Content & Scientific Writer

Insyght Interactive, Inc, Los Angeles, CA

<http://job-openings.monster.com/monster/798b9be6-665b-478c-adb5-7e1566fd7700?mescoId=2700440001001&jobPosition=12#>

Scientific Writer I

Public Health Institute, Monrovia, CA

<https://www.phi.jobs/postings/3619>

Medical Writer/Senior Medical Writer

Advanced Clinical, San Diego, CA

Recruiting for undisclosed company in San Diego, CA

<http://jobview.monster.com/med-writer-sr-med-writer-job-san-diego-ca-us-167517834.aspx?mescoId=2700440001001&jobPosition=7>

Principal Medical Writer

Halozyme, San Diego, CA

<http://job-openings.monster.com/monster/a6881191-7a82-43a2-8969-d02063759154?mescoId=2700440001001&jobPosition=12>

Lead Medical Writer

NuVasive, San Diego, CA

<https://nuvasive.avature.net/careers/JobDetail/Lead-Medical-Writer/321?source=Indeed>

Manager, Marketing Communications

Tandem Diabetes Care, San Diego, CA

https://tandemdiabetescare-openhire.silkroad.com/epostings/index.cfm?fuseaction=app.dspjob&jobid=1321&company_id=16293&version=1&jobBoardId=1112

Medical Writer

Tocagen Inc, San Diego, CA

<http://www.biospace.com/jobs/job-listing/medical-writer-352509>

Medical Writer (part-time)

Recruiting for undisclosed company in San Diego, CA

Morgan McCormick of Aerotek: mmccormi@aerotek.com

Senior Medical Writer

Precision for Medicine, Inc, Santa Ana, CA

<http://chp.tbe.taleo.net/chp01/ats/careers/requisition.jsp?org=PRECISIONFORMEDICINE&cws=39&rid=567&source=Indeed.com>

Medical Writing Manager

Amgen, Thousand Oak, CA

http://careers.amgen.com/job-en/6537661/medical-writing-mgr-thousand-oaks-ca/?aasi=2&codes=JB_Indeed

Regulatory Writing Senior Manager

Amgen, Thousand Oak, CA

<http://www.biospace.com/jobs/job-listing/regulatory-writing-sr-mgr-357405>

Scientific Communications, Senior Manager

Amgen, Thousand Oak, CA

<http://careers.amgen.com/job-en/6428810/scientific-communications-sr-mgr-thousand-oaks-ca/>

Medical Communication Manager (2-year contract)

Hart Employment Services recruiting for Amgen, Thousand Oak, CA

<http://hartjobs.com/careers/?cjobid=HS938238527&rpId=16202>

Senior Medical Writer - Remote

MMS Holdings Inc, Thousand Oaks, CA

http://mmsholdingsinc.applytojob.com/apply/job_20160324195943_2AWKLUK7SF9W17VR/Senior-Medical-Writer-Remote?source=INDE

If you want to share job leads with the members of the Pacific Southwest Chapter, please contact Sharyn at employment-coordinator@amwa-pacsw.org.

Viva la Vida by Frida Kahlo



Frida Kahlo - Viva la Vida, Watermelons. 1954. Oil and masonite on canvas

Frida Kahlo de Rivera was a Mexican painter famous for self portraits, depiction of Mexican culture and heritage, and feminism. Her personal life was full of struggles, starting from polio at the age of 6, that left her left leg thinner than the other; a near-death experience in a bus accident at age 18 that left her bed-ridden for months, robbing her of her ability to bear children; and an anxiety disorder. She was married to Diego Rivera, also a famous Mexican artist. Besides her strong identity as a Mexican, she also embraced her father's German Lutheran heritage by becoming fluent in German. In 2001, she became the first hispanic woman to be honored on the US postage stamp. Her life has been a subject of books, musicals, and music albums.