

nate what we would call the copy-paste of the world,” Allred related.

As a first step, Merck made the core content uniform by standardizing for all heavy numbers in the outline. Next, Merck worked to make the tech-enabled CPT increasingly complex by adding specific content libraries and operational activities. Allred then reviewed MStAT, pointing out various features and options, including outline format and table of contents, instructional text and content libraries, inclusion and exclusion criteria, and extraction capabilities. If the development timeline held, MStAT was to go live with Version 5 on December 2, 2017.*

Allred then described the process through which TransCelerate CPT and Merck content outlines were merged. Updates to the common language occur monthly.

Automation Engine Behind MStAT

Horowitz addressed the more technical aspects of the presentation. Utilizing MStAT starts by inputting the type of trial into a request form. Based on this selection, specific content is prepopulated into a docx template, including a specified content library. This results in a customized protocol. Elements of protocol documents include content controls, binding pre-specified content (which may be pulled out later), destination controls for user-inserted library content, and presence of both mutable (editable) or immutable (untouchable) content. Variations in shading, which may later be removed, delineate mutable versus immutable text for document review. Of note, Merck stores content libraries in a central location rather than on individual laptops to make for easier updates.

Further Benefits

Allred noted that additional benefits include shortened writing time, more efficient use of reused text, and more focus on libraries and content. Reuse of text within a document offers improved consistency and reduction in errors. Understanding of content reuse is essential, as phrasing is often vetted and changes are unacceptable. Multiple opportunities for reuse must be explored. Examples given included reusing text in other documents (such as informed consent or lay-oriented documents) and the potential for language translation. The “XML bubble” was denoted as a section of text that may be extracted and inserted into other types of documents in the future.

Developing Content Models

Per Horowitz, a content model includes the structured information (or content) and how the content is created, described, managed, and used in outputs (such as a protocol). Note that MStAT has limitations and may be inefficient in such areas as visibility and traceability. The general process of developing a

content model involves identifying a piece of content that is variable, identifying how to reuse it, identifying information policies on how the content should be reused, and determining who should know about it. To standardize and harmonize content, first find inconsistencies. For example, in different locations within or even between documents, is “randomization” the same as “treatment assignment?” Next, look to see if it makes sense to develop a structure to carry through that content together. In addition, remember to look at the actual output document to see if the content is truly following across as anticipated. Remember to think of related instructional text.

Question and Answer

The session concluded with a brief exercise, available online, to familiarize the audience with the use of some features of MStAT. A short question-and-answer session followed, during which it was noted that while MStAT can help medical authors, they must still use their own judgment. Also, MStAT development drew participants from multiple disciplines, including scientists, study teams, and physicians. Finally, smaller companies may incorporate CPT with less customization than larger companies.

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Mary Rykert-Wolf is a physician in western New York.

Author contact: rykertwolf@gmail.com

PROFESSIONAL DEVELOPMENT FOR MEDICAL WRITERS: CREATE, PROMOTE, AND MONITOR PROGRAMS AND TOOLS FOR GROWTH

Speaker

Linda Yih, BSc

Director, Medical Writing Services, PAREXEL International, Lyme, CT

By Kelly Schrank

Linda Yih works for a large international contract research organization (CRO) that employs approximately 160 medical writers and 30 managers. She believes that having a structured professional development program for medical writers can differentiate a company and is “central to employee retention in today’s work environment.”

The development program for medical writers that Yih described had 6 parts, and her presentation was broken into 6 matching sections: onboarding, development, support, development directory, promotion, and metrics.

Onboarding

For the onboarding process, the company has an “Onboarding Checklist for Line Managers,” which Yih says is good for new

managers or those who don't onboard new employees often. It includes details like requesting access to shared drives and assigning new hire mentors. There is also onboarding training for managers to assist them in getting new medical writers onboarded.

The "Onboarding Presentation for New Hires" covers 5 topics: department overview and training (including an organizational chart), writing tools and administrative information, meetings and communications, development tools and programs, and performance management. There is a template, and it can be customized to different regions within the medical writing department.

Some best practices for new employees include providing first projects that are easy wins and/or in which they collaborate with other more experienced medical writers; having them start on days when the manager is in the office; and, if possible, having a cohort of new medical writers start and go through onboarding at the same time. Similarly, if remote teams can be brought on site for onboarding, that is often better.

Development

An important component of their development program is the Medical Writer Skill Standards, which include necessary skills for each level of medical writer. These standards include proficiencies required at each writing level, for consistency across a global writing team. For instance, one of the functional competencies is "Time and Project Management," which is defined as the "ability to manage the time spent on tasks and proactively identify deficiency" and the "ability to understand all necessary steps in a project, plan steps ahead, and identify critical paths." Functional competencies encompass document experience, some of which may be region-specific. These "hard skills" are divided into "core documents" and "non-core documents," which are defined in the skill standards. The writer is evaluated for these types of documents by job level and given a check mark in the corresponding box.

Yih mentioned that this is an "objective, consistent way to evaluate writers," as the documents and competencies align with job descriptions. They are evaluated based on a quality assessment, such as QC checks by managers or peer feedback, as well as how many documents of a certain type they have authored as the lead writer. This is a great tool for promotion-readiness and justification.

The Manager Skill Standards are more focused on soft skills such as decision-making, problem-solving, holding others accountable, and collaboration. They are rated as "Basic," "Proficient," or "Advanced" in these areas. Because the Manager Skill Standards are also used as a promotional tool, managers are expected to exhibit skills at previous levels before being considered for the next level. Yih mentioned that

most managers already have documentation experience, so it's usually the soft skills where development is needed, and the Manager Skills Standards identify areas on which to focus.

The Individual Development Plan is completed by each writer and documents what that writer wants to accomplish. It lists short-term (0 to 1 year), mid-term (1 to 3 years), and long-term (>3 years) goals for the medical writer as well as "planned actions" for how to accomplish them. It begins with a "current profile" that provides general information, document experience, other work experience and skills, and professional strengths. It's considered a living document that is owned by the writer and can be updated if interests or business needs change. The short-term goals should match annual development goals and are reviewed on a quarterly basis.

The Writer and Manager Mentoring Programs are an essential element of the development plan. There is New Hire Mentoring for new writers as well as Project-Based Mentoring, which can be used for new writers or experienced writers. The project-based mentoring may assist a writer in learning how to write a new type of document or get the writer up to speed on a soft skill, such as project management or communications. There is mentoring for managers as well, such as New Manager Mentoring (which may focus on managing former peers) or Developmental Mentoring for Managers (where the focus may be on leading high-performing teams).

Essential in writer and manager growth is access to soft skills trainings. There are instructor-led and online training and presentations available for both writers and managers. Soft skills training for writers includes conflict management, negotiations, time management, leadership, and communications. Soft skills training for managers includes performance management, providing feedback, and fostering collaboration.

Support

Yih discussed the company's "Medical Writing Handbook," presented at last year's AMWA conference. It is a living document and updated periodically. She described it as a "single source for information about roles, processes, and guidelines," which contains hyperlinks on shared drives to everything needed within the medical writing department.

Similarly, the Manager's Toolkit is a "single source" for managers with information about recruitment, on- and off-boarding, training, mentoring, and performance management.

Development Directory

An important component of the development program is the Development Directory, which houses links to the Development Newsletter, Medical Writing Handbook, Medical Writer Skill Standards, New Hire Onboarding Checklist, and New Hire Onboarding Presentation. This document lists the

available tools, anticipated users, description/when to use, and location on share drives. Its purpose is to provide easy access to all of the departmental development resources.

Promotion of Tools and Programs

The Development Newsletter is distributed quarterly and shows how the development program and its tools can “facilitate growth and careers.” It provides links to resources; introduces new development opportunities, tools, and programs as they become available; offers recommended trainings and advice for how to fit professional development into “busy work schedules”; and announces new hires, promotions, and group and individual achievements. The Development Newsletter is helpful in keeping everyone apprised of new information while also building team morale.

Metrics

The medical writing management team gathers metrics to measure the success of the programs and find areas for improvement. For example, management measures participation in the writer mentoring program by gathering the number of mentor/mentee pairs, the types of projects, and the time spent on activities. They have also been gathering feedback from surveys completed by mentors and mentees, which are submitted at the end of the mentoring relationship.

The company started this initiative 3 years ago, and Yih stated that some aspects of the program are very popular and that others are gaining traction.

Lessons Learned

1. Ensure senior management buy-in on employee development plans. Time and effort need to be invested and supported to implement long-term development plans.
2. Work closely with your HR representative to ensure your department plans align with company policies and plans.
3. Think big picture and long term; consider long-term goals planned for your team and how your development plan will support these goals.
4. When drafting guides, programs, or tools, circulate for global review so they are applicable across a global team.
5. Pilot projects within a region or small groups to see what works and what needs adjustment; feedback via focus groups is useful.

Kelly Schrank is a Contract Technical Writer and Medical Editor near Syracuse, NY.

Author contact: headbookworm@gmail.com

ZIKA—THE BITE HEARD ROUND THE WORLD

Speakers

Larry Lynam

Principal, The Lynam Group, LLC, Coral Springs, FL

R Michelle Sauer, PhD, ELS, CRA

Director of Office of Sponsored Programs, Prairie View A&M University, Prairie View, TX

By Rebecca Mueller, PA-C, MSc

This open session sought to update professionals in the medical writing industry on the history, science, and current state of the public health situation surrounding the Zika virus and the mosquito vector, *Aedes aegypti*.

The Virus

Mosquitos, the deadliest animals in the world, are linked to 475,000 human deaths annually. Both Florida and Texas have had hot spot zones that were monitored by the Centers for Disease Control and Prevention (CDC), though most recently, Texas has been removed as a hot spot. Texas and Florida have over 80 species of mosquitos; however, only 1 has been confirmed as a transmitter of the Zika virus—*A. aegypti*.

The Zika virus is part of a unique group of viruses known as the Flaviviridae. Viruses of the flavivirus family are most often transmitted through vectors, most commonly mosquitos and ticks. Some members of the flavivirus family, including Zika, have been associated with sexual transmission and blood-borne transmission. Cross-reactivity has been a problem in diagnosing the specific flavivirus, but the cross-reactivity of the antibodies has not proven to be protective between species of virus. Zika appears to be unique in the flavivirus family in that it has proven both competent at crossing the placental barrier during pregnancy and capable of causing congenital abnormalities.

The Zika virus was first identified in 1947 in primates of Uganda. The vector for these primates was a mosquito in the Ugandan forest that was active at night and fed off primates, not humans. The virus has now jumped vectors to a human-biting mosquito, *A. aegypti*, that feeds during dawn and dusk. The first serious Zika outbreak was in Yap, a Micronesian island, in 2007. The virus has continued to spread east throughout the years, complicating the 2014 Olympics in Brazil. Climate change has allowed *A. aegypti* to live farther north, aiding the spread of the virus farther into the United States, giving rise to the title of this talk: “Zika—The Bite Heard Round the World.”

Researchers from the Chinese Academy of Science in Beijing have linked a single gene mutation, S139N, to the virus’ ability to cause microcephaly in utero and Guillain-Barré syndrome. The switch of serine to glutamine at the 139th posi-