

EMWA vetSIG 2022 2nd Quarterly Meeting (June 3rd) Observer Report

Our rescheduled Q2 meeting for 2022 had protocol writing as its main topic, but we also touched on the topics of shared decision making and having an animal medicine special issue in the EMWA journal.

For the discussion on protocol writing, we had the pleasure of welcoming Céline Nicolas and Sallie Cosgrove, as two expert speakers from the animal health pharmaceutical company Virbac, as our panelists.

Both Céline and Sallie are veterinarians, researchers, and writers with impressive portfolios of their own published work, but we concentrated on their protocol-writing experiences. Céline (based in France) had been doing her own neuroscience research before joining Virbac at around the same time as Sallie (six years ago), and Sallie (based in the United States) came to Virbac with wide experience of animal pharmaceutical companies such as Zoetis/Pfizer. Céline mainly works on non-medicine protocols and cross-marketing studies while Sallie mainly works on research for market authorizations. So, our two speakers represented a great blend of experience and perspectives.

For Céline, protocol writing is only one part of her work (along with journal articles, poster presentations, launch documentation, etc.). On the other hand, study protocols and reports account for a lot of Sallie's time, but she commented that "There's no such thing as a typical day"; her writing workload changes on a daily basis!

Both Céline and Sallie write protocols as medical writers for other investigators to implement, i.e., they are not the principal investigators themselves. For Céline, this represented a change from her time in academic research where she essentially drew up protocols for her own experiments, and these were dovetailed with her grant writing. Her protocol writing now involves a lot of communication with "Key Opinion Leaders" (KOLs), the people involved with achieving research objectives at the sharp end. Sallie commented on the need to keep the investigators in the loop, and above all, to make sure that the protocol was realistic for these investigators working in their own clinics.

The need for communication with the relevant people was a constant theme in the discussion. Most obviously, this involved the scientists implementing the study. Many times, both speakers emphasized the need to work together with the scientists and investigators. Medical writers bring their writing skills to the process, but shouldn't be hesitant about approaching the scientists with the specific knowledge to discuss the study design and other issues. A study protocol is not something a medical writer could just create in isolation on their own on their kitchen table (although Sallie pointed out she has multiple monitors on her kitchen table! So, kitchen-table protocol writing is possible, but

extensive consultation with the KOLs is still needed).

Investigators are not the only people medical writers have to communicate with though. A long talk with a biostatistician is essential when setting the number of animals, sampling points, etc. for a study. Some liaison with the marketing side is also helpful, as they are the people who ultimately have to sell the product. Many members of marketing departments will have veterinary backgrounds, but others may not. As a personal observation, I was struck by the point that a marketing perspective may be needed at the protocol stage. As medical writers, we are often focused on the approval for marketing, but marketers need to sell the drug; part of the protocol design should be generating evidence to highlight the advantages (potentially the competitive advantages) of a medical product.

We also focused on some aspects of regulatory protocols in particular. The requirements governing protocols for non-medicines may not be so strict, but regulatory knowledge is vital when it comes to dealing with drugs that will require marketing authorization. Even for proof-of-concept studies, pilot studies, or other studies that will not form part of the submission, it is desirable to approach the protocol as if it will be conducted under the relevant GxP. This helps ensure consistent implementation by investigators, and also furnishes the writer with text that can easily be recycled when developing the next regulatory protocol. A medical writer dealing with protocols should study the materials available from the regulatory authorities, and there is often a case for complying with the strictest potentially applicable requirements (e.g., Europe vs. USA), as an application may well be made in more than one jurisdiction. Meetings with regulators to review protocols are also required to get “regulatory concurrence”, the approval to proceed. Sallie introduced us to a new (for me) acronym: PTRS. This stands for “prospect of regulatory and technical success”: the possibility that the protocol will result in a successful trial. The protocol writer needs to determine the variables that will most enhance the PTRS when they are evaluated in a study.

In discussing recent developments and the future, Sallie highlighted some changes she had noticed. Nowadays, companies have the option of outsourcing protocol writing to a medical writer, consultant, or CRO, so now they can make a judgment as to whether protocol writing was the best use of in-house expertise. As for future changes, we discussed the possibility that AI or some form of automated writing might come in the future, but both panelists felt this was unlikely. Automation could help with things like Table of Contents, but never really replace the human medical writer.

Finally, we tackled the question of who could do protocol writing, and what they needed to do it. This was certainly a job veterinarians could do; writing skill is key so it

could be open to many scientifically literate non-veterinarians as well. That writing skill is used (together with background knowledge and regulatory understanding) to shape the inputs from the relevant scientist into a protocol. It does involve a lot of reading and research (especially when jumping into a new area) and can be initially challenging, but time brings experience (plus text that can be recycled for similar studies). The progress to reach this point can be accelerated by mentors, and even things as simple as company templates. Sallie's take-home message was "Don't be afraid to take it on. You are not alone". She enjoys protocol writing, and sees good protocol writing as being the basis of good report writing. Céline said that protocol could be difficult at the start, but could be mastered with a little reading and patience, especially when all the relevant cooperation was available.

After the protocol writing discussion, Jennifer Freymann introduced us the topic of shared decision making, which we plan to discuss in detail in our October meeting. Shared decision making has become a hot topic in human medicine, and has the potential to become an issue of particular interest for medical writers in the veterinary field, as it would involve the need for communication with multiple stakeholders. Although shared decision making might sound like a companion animal-related topic, in fact researchers have also been looking at the issue in large animal medicine. Jen has identified one speaker from small animal medicine, and one from large animal medicine, to act as panelists for an interview-style discussion. Jen is preparing for the discussion with a shared Google document, so please mail her (or Henry) if you want to contribute to the questions for this discussion in October.

We then moved on to discussing the idea of a special issue on Anima Health for the EMWA journal. Jen Bell has been involved with special issues (for other SIGs), and pointed out the benefits of having a special issue led by veterinarians. A number of journal issues are already planned, so the earliest possible date for a veterinary special issue would be sometime in 2024. The SIG would need to provide two volunteers as guest editors, responsible for finding (and then presumably editing) six guest articles. One potential volunteer emerged during the meeting, and we will use the LinkedIn discussion group, and maybe the next meeting to discuss how to proceed.

We had planned to review EMWA's spring conference, in particular our SIG's first Expert Seminar Series, but due to technical problems, we postponed that discussion to the July meeting. We also had a quick review of other potential discussion topics, but we will continue that in the LinkedIn group meeting.

We closed our meeting with a reminder that our Q3 meeting (on schedule) is planned for Friday, July 29th

