

Medical Writing

Observations and Observational Studies

Our publication, *Medical Writing*, has always been a work in progress, continually evolving to meet our members' needs and desires. Originally a four-page newsletter called the *EMWA Newsletter*, it was renamed *The Write Stuff* in 1998 and, under the guidance of Elise Langdon-Neuner, grew to a larger publication renamed *Medical Writing* in 2011. Since taking over as Editor in 2012, I have focused on shifting *Medical Writing* to an in-house publication and to a more dynamic format.

Due to the recent addition of a Managing Editor, Victoria White, I have finally had a moment to take a step back and reflect on how far we have come. Thanks to Chris Monk, our layout specialist, as well as Vicki, the Editorial Board, and contributors, we are producing a visually impressive publication full of high-quality, practical articles. And based on the comments I have received, it is considered a key and valuable benefit of EMWA membership. I also know that it's a great calling card for our association and members. I am happy with what we have accomplished, and I want to sincerely thank everyone who has contributed.

This issue of *Medical Writing*, which focuses on observational studies, is a great example of the high quality of our journal – it's packed full of great articles on observational studies, as well as all kinds of other useful information. The issue begins with an article by **Maria Kołtowska-Hägström** on the basics of observational studies. She explains what

observational studies then are, how they differ from randomised clinical trials, why their importance in evidence-based medicine is increasing, and how patient registries



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and research databases can be used as a source of medical information. **Tom Lang** follows with an article on the basic terminology and statistics used in observational studies to describe risk and association. **Willi Sauerbrei and colleagues** then talk about the STRATOS initiative, which aims to provide guidance for the design and reporting of observational studies, and **Andrea Rossi and colleagues** describe the guidelines available for reporting observational studies in peer-reviewed publications. Meanwhile, **Namrata Singh** and **Vasudha** update us on the current status and expected changes in requirements for registering and obtaining ethics committee approval for observational studies. Articles by **James Visanji** and **Greg Morley** cover the regulatory aspects of NI-PASS (non-interventional post-authorisation studies), which are used to collect data on approved products and **Karin Eichele's**, in her section "The Webscout," summarises information available on the web about observational studies.

Looking at the last few issues, I am honestly blown away.

Also in this issue

This issue of *Medical Writing* also includes excellent articles on subjects unrelated to observational studies. **Silvia Paz Ruiz** discusses the usefulness of patient-reported outcomes, and **Tiziana von Buchhausen and Sven Schirp** present the EMA's Good Pharmacovigilance Practice Module V, which provides updated guidance on risk management plans. Finally, **Kathryn Lee** talks about the importance of mentoring tomorrow's medical writers and how you can help.