Medical Writing

Obserations 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 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-Häggström 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 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.

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.

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