

EMWA Newsblast - December 2019



The 49th EMWA Conference Report

The 49th EMWA Conference, held at the Scandic Triangeln Hotel, Malmö, Sweden in early November, hosted a total of 238 delegates. Of these, 91 were first-time attendees of an EMWA conference. The core of this EMWA meeting were 21 foundation and 10 advanced EPDP training workshops. Out of the total of 31 workshops, 10 were at capacity. Thank you to all of our delegates, volunteers, head office and sponsors for this [truly memorable event!](#)

Don't forget to save the date for the 50th EMWA Conference at the Clarion Congress Centre, Prague, on 5-9 May 2020.

Webinar Programme News

Our next webinar will take place on 19th December 2019, 14:00 CET.

Please click [HERE](#) to register

Title: Personal experience from transitioning from Pharma to Medical Devices

Speaker: Sarah Choudhury

Summary: The world of medical devices is still considered a relatively new area for medical communicators. In this environment, the role of medical communicators in the medical device industry has gained importance and our skillset is very much in demand. This webinar provides medical communicators with my own personal insight into challenges faced, the many opportunities to be had, and how we can provide much added value to the world of medical devices.

German Translation of the Joint Position Statement Predatory Journals

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) recognize the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices undermining the quality, integrity and reliability of published scientific research. The joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.

By joining with AMWA and ISMPP in both developing and publicizing the Joint Position Statement on predatory journals, EMWA is providing a valuable service to publication professionals around the world by enabling them to more easily read, understand, and apply the principles of this JPS.

In order to raise awareness among non-English speakers about the responsibilities of medical writers and publication professionals concerning this significant issue, EMWA has initiated the translation of this statement into European languages. We are proud to announce the posting of the first JPS translation into German by Anne Bartz and reviewed by Annika Bruger

To access the translation please click [here](#).

We are currently looking for translators. If you would like to volunteer please contact Abe Shevack (aspscientist@gmail.com) or the EMWA Head Office (info@emwa.org).

Ambassadors Programme

On 20 Nov, Abe Shevack gave a talk on careers in medical writing and EMWA at the regular meeting of the Berlin medical writers at the Gran Café on Oranienburger str. Altogether 15 people attended including organizer and EMWA member Paul Wafula and former EMWA President Tiziana von Bruchhausen. There were some lively discussion on the importance of EMWA training and certificates, mentorship of newbies, getting started in regulatory writing, and setting realistic timelines with clients. A good time was had by all.

As part of the continuing collaboration between the German Scholars Organization (GSO) and EMWA, Abe Shevack was interviewed by Dr Anne Schreiber, Managing Director of the GSO. The interview focused on careers in medical writing, transitioning from academia, and the role of EMWA in supporting scientists interested in the field of medical writing.

Please use the following link to access the webinar on YouTube. https://www.youtube.com/watch?v=p_kSPCU0E3U&feature=youtu.be

Regulatory News

- EMA released post-authorisation procedural advice for users of the centralised procedure (28 Oct 2019; EMEA-H-19984/03 Rev. 83)
- First vaccine to protect against Ebola
- EMA confirms Xeljanz (tofacitinib) to be used with caution in patients at high risk of blood clots
- Review of estradiol containing medicinal products: four-week limit for use of high-strength estradiol creams
- Evotaz (atazanavir / cobicistat) - new contraindication (treatment of HIV)
- Measures to minimise risk of serious side effects of multiple sclerosis medicine Lemtrada
- Swissmedic creates signal notification form in change to 2020 requirements
- MHRA November 2019 Drug Safety Update Newsletter now available
The September issue of the Health Product InfoWatch published by Health Canada is now available. This monthly publication provides clinically relevant safety information on pharmaceuticals, biologics, medical devices and natural health products. Please consult the index for a complete listing of previous issues.

[10-Year Update on Study Results Submitted to ClinicalTrials.gov](#)

Zarin DA et al. Read the [full paper here](#)

Abstract: A decade after [ClinicalTrials.gov](#) launched a database for reporting results of clinical trials, the database includes results of approximately 36,000 trials. The authors discuss laws, regulations, and policies relevant to results reporting, trends over time in the frequency of reporting, and adherence to requirements for the completeness and quality of the results reported.

[Data Quality in Registries Remains an Issue](#)

This Nov 2019 [StatNews article](#) shows that although more data are being posted, the quality of the data does not necessarily hold up.

[FDA Guidance 'Certificates of Confidentiality'](#)

FDA have issued DRAFT guidance '[Certificates of Confidentiality](#)' (November 2019) intended to help protect the privacy of human subject research participants from whom identifiable, sensitive information is being collected or used in furtherance of the research. Comments are open for 45 days.

[JAMA Editorial on Data Sharing Challenges](#)

This November 2019 JAMA Editorial by Howard Bauchner and Phil Fontanarosa titled '[The Challenges of Sharing Data in an Era of Politicized Science](#)' provides thoughtful commentary on data sharing and the associated processes, and cautions that scientific process must prevail no matter what challenges are faced.

Medical Devices SIG - News

The new nomenclature for incidents with medical devices is online, [click here](#) to view

Member Benefits

ISMPP is offering a 10% registration discount to EMWA members for its 2020 European Meeting, Precision Communication: Achieving Clarity, Reach and Value, 21-22 January, in London, UK. Learn about the meeting at www.ismpp.org/european-meeting, and enter EU20EMWA10 in the "Discount Code" field when you register. This special discount is available until 8 January 2020.

EMWA News Archive

You can access older EMWA news [here](#).

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