

## EMWA Newsblast - September 2019

### Malmö Conference: Registration is now open! Book early to guarantee your place at your favourite workshops!



### EMWA 2019 Nick Thompson Fellowship Award

Established in 2001, The **Nick Thompson Fellowship Award** recognises service to EMWA above and beyond what would normally be expected of members or those who hold or have held elected offices.

Nick Thompson, for whom this award is named, was a member of EMWA who embodied the collegial spirit, bonhomie, and professional dedication which represent the core persona of the organisation. He died tragically young. EMWA wishes to recognise and preserve those values that were so important to Nick. The Award confers lifetime EMWA membership and registration at association conferences on the elected Fellow. Fellows serve informally, in the capacity of advisors to the organisation, given their length of service, knowledge of the history of EMWA, and their involvement in the profession.

Nominations of candidates can be made by any EMWA member except a Nick Thompson Fellow or a sitting member of EMWA's Executive Committee (EC). Members of the EC may be nominated.

If you consider that any EMWA member would deserve this award, please submit your nomination to EMWA Head Office: [info@emwa.org](mailto:info@emwa.org)

Nominations must be received by EMWA Head Office by 1 October 2019. They must be accompanied by a statement of qualification, including details of the candidate's special contributions to EMWA and justification for the nomination (not less than 200 words). The Fellows will consider all nominations and will advise the EC, via the President, of the results of their deliberations. Please do not inform the candidate that you have nominated them.

### Geoff Hall Scholarship 2019

**Up to two** scholarships are available in memory of one of the founding fathers of EMWA, Geoff Hall, who sadly passed away in 2010.

The essay title for 2019 is "*How would you go about identifying a predatory journal?*"

The submission deadline for entries is **30 September 2019**.

Eligible applicants must be new medical writers: that is, they intend to enter the profession or have been employed for no longer than one year as a professional medical writer, including freelance work. They need not be current members of EMWA.

Applicants must include a short statement declaring what work they do or have been doing and that they meet the eligibility criteria.

Please submit your application to EMWA Head Office: [info@emwa.org](mailto:info@emwa.org)

### Ambassadors Programme News

As part of the **EMWA Ambassador Programme's** continuing efforts to reach out to new audiences to promote medical writing and EMWA, John Dixon and Abe Shevack took part in a webinar organised by Medic Footprints ([medicfootprints.org](http://medicfootprints.org)). The target audience was medics interested in exploring careers outside of medical practice. The Webinar on "Key Steps to Success in Medical Writing" recorded on 9 July 2019 can be viewed on YouTube. To see the webinar click [here](#).

In other news, Abe has initiated a collaboration with the German Scholars Organization (GSO) (<https://www.gsonet.org/>) headed by **Dr. Anne Schreiber**. This is a not for profit group with around 5000 members. Their main focus is helping young academics to find positions in Germany through career counseling advice, workshops, webinars, and other activities. The GSO has agreed to promote EMWA at an upcoming career event organised by the German International Academic Network (GAIN) to be held in San Francisco on 24 Aug. Future collaborations for promoting medical writing and EMWA may include articles in the GSO newsletter, an interview, and a webinar.

Upcoming Ambassador events: John Carpenter will attend a Network Pharma, Medcomms event in Manchester on 10 Sept. Tiziana von Bruchhausen will address a group of clinical training professionals at the Dr Notghi Academy in Berlin on 13 Sept. John Carpenter will be a speaker at a career fair at the University of Birkbeck in London on 28 Sept.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador or if you know of any upcoming career events in your locality please contact Abe Shevack ([aspscientist@gmail.com](mailto:aspscientist@gmail.com)).

### Pharmacovigilance News

#### EMA news:

- Survey on the renovation of the ICH Good Clinical Practice Guidelines (ICH E6)
- Review of cyproterone-containing medicinal products - review started (meningioma risk with cyproterone medicines)
- Review of methotrexate-containing medicinal products - PRAC recommendation (new measures to avoid dosing errors)
- Updated restrictions for Gilenya: multiple sclerosis medicine not to be used in pregnancy

#### FDA news:

- FDA notice of availability: Risk Evaluation and Mitigation Strategies: Modifications and Revisions; Guidance for Industry
- FDA notice of availability: Final Guidance for Industry and FDA Staff on Postmarketing Safety Reporting for Combination Products

To read more, please click [here](#)

### Regulatory Public Disclosure News

- Lancet Oncology - Editorial on clinical trial registry reporting
- EMA Call for Sponsors to Publish Clinical Trial Results
- Re-identification Risk from Datasets
- Lebanese Clinical Trial Registry
- Cybersecurity in Healthcare
- EMA Tutorials on Posting Clinical Trial Results on EUDRACT

To read more, please click [here](#)

### New 2019 CORE Reference Open Access Publication

Clarity and Openness in Reporting: E3-based (CORE) Reference, developed by the Budapest Working Group (BWG), a partnership of AMWA and EMWA, is a user manual designed to help medical writers navigate relevant guidelines as they create clinical study report (CSR) content. CORE Reference was one of two principal sources used by TransCelerate BioPharma Inc., an alliance of biopharma companies, in the development of its CSR Template released in November 2018. A new CORE Reference open access publication, Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table was published in August 2019 in the BIOMED CENTRAL journal, Research Integrity and Peer Review:

**Hamilton S, Bernstein AB, Blakey G, Fagan V, Farrow T, Jordan D, Seiler W, Gertel A, (the Budapest Working Group [BWG]). Critical Review of the TransCelerate Template for Clinical Study Reports (CSRs) and Publication of Version 2 of the CORE Reference (Clarity and Openness in Reporting: E3-based) Terminology Table. Research Integrity and Peer Review 2019** (<http://dx.doi.org/10.1186/s41073-019-0075-5>). PDF <https://rdcu.be/bM7ft4>)

Key resources from this publication can be downloaded on the CORE Reference website (from <https://core-reference.org/core-reference/>) and include the BWG's unabridged comments on the TransCelerate CSR Template and the CORE Reference Terminology Table Version 2.

### News from the Webinar Programme

Our next LIVE webinar will take place on 19th September 2019, 14:00 CET!

**Title:** Pharmacovigilance writing: monitoring and enhancing patients' safety throughout the life-cycle medicinal products

**Speaker:** Tiziana von Bruchhausen

**Summary:** This webinar addresses participants with no or little experience in pharmacovigilance (PV) writing. The presentation will provide an overview of the basic concepts involved in PV writing, such as the life cycle of the medicinal product, benefit-risk balance, and safety concerns. There will be a brief introduction to the main PV documents required from clinical development up to marketing authorisation renewal, with focus on how these documents reflect specific PV activities to monitor and enhance patients' safety. Interactions and synergies between PV documents and other clinical or labelling documents will also be briefly shown. Furthermore, an overview of the writing activities beyond submission will be provided. The webinar will indicate which EMWA workshops offer intensive training on the various topics presented.

To register, please click [here](#)

Next on October 10th 2019, 14:00 CET we will have a private company webinar: **How medical writers can create a CV that wins more work and / or secures a higher rate** by Alistair Morris, CV and Interview Advisers.

### Predatory journals could damage the legitimacy of scientific publishing - Joint Position Statement

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. This [joint position statement](#) complements several other sets of guidelines that have helped define the characteristics of a predatory journal.



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