EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast- November 2021

|MC:TOC|

An opportunity for Medical Communicators to benchmark salary expectations – extension to survey deadline

We're giving members another chance to complete the EMWA Salary Survey, as we're aware some may have been unable to complete within the original timeframe. You now have until close of business on 1st December to submit your response. Please take 15 minutes to provide your feedback using this link to the survey.

Katrina Burton Named President of the American Medical Writers Association (AMWA)

The members of the American Medical Writers Association (AMWA) have elected Katrina R. Burton, BS, as the 2021-2022 President. In an interview in the AMWA Journal recognizing her as the first Black person to be elected to the role of AMWA President, Burton expressed a deep appreciation for the honor of serving the association and its members in their "essential, critical, and amazing work to promote excellence in the medical communication field." Burton will lead AMWA throughout the 2022 governance year, culminating with the AMWA 2022 Medical Writing & Communication Conference, November 2-5, 2022.

vetSIG's 1st Zoom brunch (early lunch), December 12th @12 noon CET: Discussing the New VMR and One Health with Sarah Moody

We are holding our first ever vetSIG Zoom brunch as a special meeting on Sunday, December 22nd (12 noon CET, 11 am UK time). This will involve an interview with Sarah Moody, author of 'The impact of the new VMR on medicines availability, antimicrobials use and antimicrobial resistance'. We will discuss her article on the EU's new veterinary medical regulations, her perspective on writing as she returns to a mixed practice in the UK after a stint at the Federation of Veterinarians of Europe, and her experiences on a One Health project in Bangladesh. Please e-mail vets@emwa.org for a Zoom invitation or further details.

PV SIG update

Do not miss the first PV SIG Meet&Share on **13 Dec 2021, 2 pm!** We will address the following topics in:

"DSUR requirements other than ICH E2F – Be aware! (Impact of EU-CTR and other local requirements on DSURs)"

- MHRA requirements for DSURs
- EU-CTR requirements and DSURs
- Discussion: ICH E2F vs. EU-CTR; best practices and experience sharing
- Other requirements (e.g., Japan, China)
- Experience sharing on Health Authority's questions about SUSARs for biosimilars - dialogue of clinical safety & PV department

For meeting details, please email info@emwa.org

NEW! In the December issue of the MEW, a new section called "Pharmacovigilance" will be launched. Contact the PV SIG to share ideas on topics or if you would like to contribute with articles.

Save the Date! Next Meet & Share session of the MedComm SIG

Referencing in medical publications

Do you think you know all about referencing? Sure?
At some instances, there is still confusion where to place the references. Or- when you cite a review article – at which instances would you cite the article itself and when would you cite the studies/ references from the review article?

The session will be held on 16 Mar 2022, from 6 to 7 pm CET. Email us to receive the Zoom-link.
We are also open to suggestions on any other topic you would like to discuss during our Meet & Share sessions!

Ambassadors Programme News

The EMWA Ambassador Programme is continuing its efforts to reach out to new audiences to promote medical writing and EMWA.

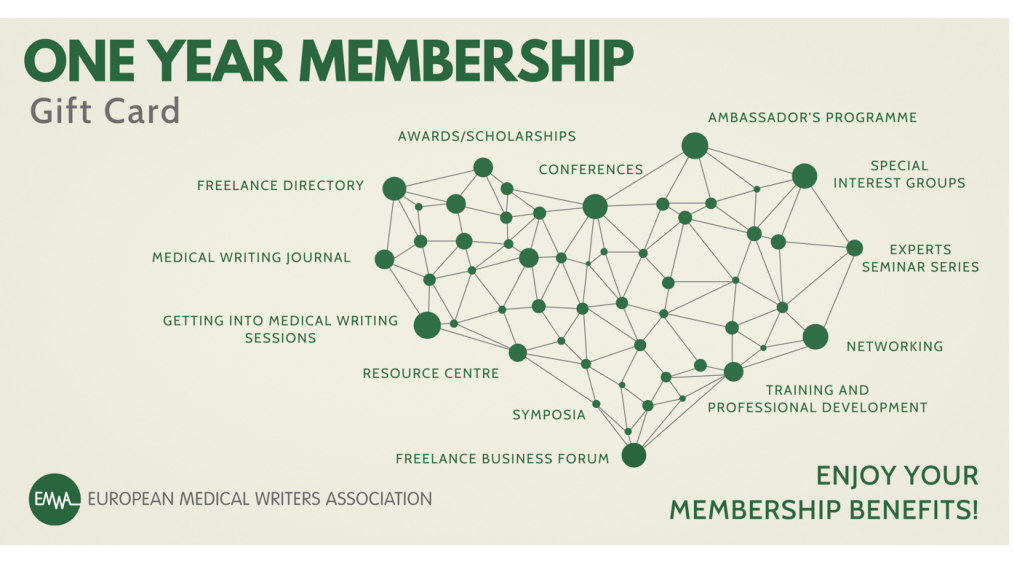
Maria Kołtowska-Häggström gave a talk (in Polish) on medical writing as a profession at the Translation and Localization Conference in Warsaw, Poland on 30 September to 40 participants who provided answers to questions on a check list provided by Maria before the talk. The attendees mostly wanted to know about the education background needed to be a medical writer, what courses are offered at conferences, the general profile of a medical writer, the source of potential clients, and the possibility of combining translation services with medical writing. The presentation was well received with very positive feedback.

Anne McDonough gave a presentation on medical communication (current trends and challenges) at a webinar for Life Science Students at the University of Essex on 14 October to over 60 students. There was a lot on interest and some very good questions from the participants.

Abe Shevack gave a presentation on careers in medical writing and the benefits of joining EMWA on 5t November at the Annual Virtual Careers Fair at Birkbeck University. The event was attended by over 20 active participants who asked a number of interesting questions during and after the presentation. 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).

Have you started Christmas Shopping?

You can now offer a one-year membership gift card to a friend! For more information, email info@emwa.org



Professional Indemnity Insurance - 20% Discount for EMWA Members!

Did you know that EMWA members get a 20% discount on their Professional Indemnity Insurance?

Established in 1992, PIA Commercial works closely with their clients to provide a tailored range of specialist insurance products for both individuals and businesses. Please contact PIA Commercial at info@PIAcommercial.com for any queries or to receive a personalised quote. Or go to their brand new updated website at www.piacommercial.com to view their extensive range of personalised insurance plans for businesses and individuals in the life science, biotechnology and healthcare industries.

Keep up to date with their business news and industry insights by following them on Linkedin, by searching 'PIA Commercial' or calling +44 121 694 6897.

RPD News

Medicines and Vaccines

EMA Publish Statements and Guidances

EMA published their final guideline on registry-based studies on 26 October 2021.

CTIS News: Supporting materials from DIA

Drug Information Associates (DIA) have prepared some materials to support the Clinical Trials Information System (CTIS): Virtual information day held on 11 November 2021:

1. CTIS The future user perspective: Welcome - It includes a brief introduction to CTIS, information on its workspace and public portal, its go-live timeline, purpose, and steps required for its preparation.
2. CTR & CTIS: Key aspects for users to consider when preparing for CTIS - It includes milestones for Clinical Trial Regulation 563/2014 (CTR), the process of CTR assessment, CTIS roles and actions, and CTIS high-level structure. It also includes information on a harmonised dossier, transparency in the CTR, and requirements for CTR submission.
3. How to prepare for CTIS: a user perspective - It explains the process of registration, user management, an overview of CTIS user personas, notices, alerts, and requests for information (RFIs).
4. How to access CTIS training materials and support - It provides links to all the CTIS training modules, sponsor handbook for clinical trial sponsors, reference material, and recording of previous events. It also presents the three phases of CTIS Sandbox.
5. CTIS The future user perspective: Closing - It includes a diagrammatic representation for preparation of CTIS and the countdown for CTIS go-live.

FDA Guidances and News

1. FDA, NIH, and 15 private organizations join forces to increase effective gene therapies for rare diseases. Read the Press Release which states "A clinical component of BGTC-funded research will support between four and six clinical trials, each focused on a different rare disease."

AMA Manual of Style Commentary to Support Guideline Changes

This American Medical Association's 'Style Insider' article 'Updated Guidance on Reporting Race and Ethnicity: Let's Start With the Why' emphasizes that the updated AMA Manual of Style 11th Edition guidance on race and ethnicity is important to help safeguard against unconscious bias.

Real World Evidence

The following two articles are relevant to our understanding of how agencies can use real world data post approval, to support clinical trial findings:

- Comparison of Duration of Postapproval vs Pivotal Trials for Therapeutic Agents Granted US Food and Drug Administration Accelerated Approval, 2009-2018
- Feasibility of Using Real-world Data to Emulate Postapproval Confirmatory Clinical Trials of Therapeutic Agents Granted US Food and Drug Administration Accelerated Approval.

EMA have released a new framework for gathering patient perspectives in Europe. The Innovative Medicines Initiative (IMI) is developing a clear practical framework for their measurement, called the PREFER framework, which is now open for public consultation in the form of an EMA Draft Qualification Opinion that explains how patient preference studies could be used to help inform decisions about medicines approval and their subsequent availability to patients.

Updated TransCelerate Template Assets 2021

In the October 2021 updates of TransCelerate's assets, the Common Protocol Template (CPT), Statistical Analysis Plan (SAP) template, and Clinical Study Report (CSR) template have been updated to reflect estimand considerations, amongst other points. The 'summary of changes' slide deck calls out the changes since the last version assets, and all new assets, as well as a host of other supporting materials are downloadable from the 'Clinical Content and Reuse Solutions' page.

Transparency and Disclosure Resources and News

1. The UK NHS's Health Research Authority has published its Make it Public Annual Report following its conference held on 03 and 04 November 2021. This is "The first Make it Public annual report has been published, telling a story of progress towards trusted information about all health and social care studies being publicly available for the benefit of all." Note the 'Reporting Results' section.
2. This TranspariMED article sets out the key milestones and delivery dates associated – including those for reporting results - for the UK's clinical trial transparency system, which will go live in 2022.
3. The UK's MHRA has published its Patient Involvement Strategy 2021 to 2025. This first strategy document explains how MHRA will "…involve the public and patients at every step of the regulatory journey."
4. This ISMPP article, published in August 2021, describes Pfizer's approach to Plain Language Summary development.
5. As part of the collaboration between EMWA's Regulatory Public Disclosure Special Interest Group (RPD SIG) with the Statisticians in the Pharmaceutical Industry (PSI) Data Transparency SIG, they kindly permitted the sharing of an article on secondary use of data which was published in a PSI 'members only newsletter' earlier in 2021. The article titled 'Secondary use of data - Unleashing Data Assets to Create Value' is published on the EMWA website.
6. The UK's National Institute for Health Research (NIHR) has published its Open Access policy - for publications submitted on or after 1 June 2022. This policy makes all NIHR-funded research findings published in academic peer-reviewed journals freely available.
7. This article from the Publication Plan asks 'What's stopping patients from publishing?' and suggests biomedical research industry should support greater patient participation through encouraging ethical patient authorship.

Devices

Eudamed is officially in place in the EU

On 26 Nov 2021, the European Commission published the final document laying down rules for the European Database on Medical Devices (Eudamed). The Eudamed is the electronic system that contains data on medical devices with respect to clinical trials, market access, and post-market surveillance. Some key information highly relevant to data transparency and public disclosure are provided below:

- Eudamed is accessible via a restricted website for authorized users and a public website for non-identified users. In addition, Eudamed will also be accessible through machine-to-machine data exchange services **(Article 2 Modes of Access)**.
- To facilitate traceability, authorized users have free access to the European Medical Device Nomenclature (EMDN; **Article 4 Nomenclature**).
- Personal data will be processed to comply with the MDR and the IVDR. The European Data Protection Supervisor has been consulted (**Article 6 Ownership and Processing of Personal Data**).
- The Commission commits to providing some sort of sandbox environment to train Eudamed users (**Article 9 Websites for Testing and Training Purposes**).