EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast- September 2021

|MC:TOC|

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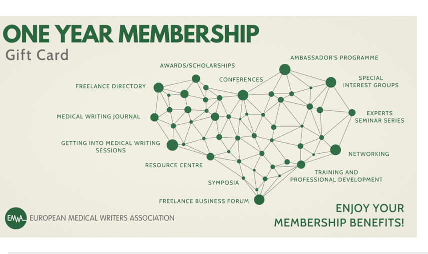

Medical Communication SIG news

EMWA's Special Interest Group on Medical Communication has headed a reply to an article which made unfounded derogatory remarks about medical writers (MWs). Without providing any evidence the authors Del Paggio JC, Berry JS; Hopman WM et al. in an article about the development of oncology RCTs (doi:10.1001/jamaoncol.2021.0379) state:

"There is reason to be concerned that medical writers may unduly influence the interpretation of trials. Additionally, their role is contrary to accepted scientific principles whereby first authors should take responsibility for writing their own manuscripts. This is an issue that requires serious discussion by clinicians and journal editors, as it is unlikely that medical writers have a neutral effect on the clinical trial reporting." In the same section, they insinuate that the involvement of MWs in oncology RCTs is violating ICMJE authorship criteria.

The authors of the Letter to the Editor (Schindler T, Marchington J, Flores G; doi:10.1001/jamaoncol.2021.3341) point out that contrary to the accusations, studies have shown that the involvement of MWs in preparing manuscripts improves several outcomes, including better adherence to reporting guidelines, more complete reporting of trial results, a greater rate of publication over time, and a lower risk of publication retraction owing to misconduct. Furthermore, they highlight that MWs are highly trained professionals, many with advanced degrees in life sciences who help scientists achieve clear, objective, and understandable descriptions of study data. They add that MWs are trained in good publication practice and that their organizations have developed principles of ethical conduct.

The letter to the editor was endorsed by the presidents of the 3 organizations, ie Beatrix Doerr for EMWA, Susan Krug for AMWA, and Rob Matheis for ISMPP. This showcases the importance of ongoing alignment and exchange between the different MW organizations. MWs who come across published negative statements about medical communicators should inform the professional organizations to enable adequate responses. For the current case, everybody is welcome to comment on the JAMA Oncology website responding to the authors' response.

Update from PV SIG

Upcoming webinar "An Overview of EU Pharmacovigilance" (28 October, 2 PM CEST) - Interested in learning about the intricacies of pharmacovigilance in the European Union? EMWA's PV SIG is planning a webinar with Joan D'souza, one of our PV SIG active volunteers, to learn about EU pharmacovigilance. The content will be of interest to those working in regulatory writing and is open to all medical writers. We look forward to seeing you there!

Regulatory news

Awarded Paper: Utilizing Advanced Technologies to Augment Pharmacovigilance Systems: Challenges and Opportunities
EMA (EU):

- EMA's consideration on core requirements for PSURs of COVID-19 vaccines - corePSUR19 guidance
- Explanatory Note to GVP Module VII Rev. 3 dated 19 April 2021 (EMA/670256/2017)
- EMA's post-authorisation procedural advice for users of the centralised procedure - 23 Jul 2021
- EMA consultation: Guideline on core SmPC, Labelling and Package Leaflet for advanced therapy medicinal products (ATMPs) containing genetically modified cells
- EMA's public consultation on draft of EU Common Standard for Electronic Product Information (ePI)
- EMA's annual report 2020
- EMA's monthly Newsletter
- EMA's updates on COVID-19 vaccines

MHRA (UK) / Canada:

- MHRA-Canada guidance on DSURs

FDA (US):

- Global Regulations Paradigm Shift Toward Inclusion of Pregnant and Breastfeeding Women in Clinical Research for Medicines and Vaccines

NMPA (China):

- Good Pharmacovigilance Practice in China

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 https://www.emwa.org/about-us/emwa-awards/nick-thompson-award/
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.

Present holders of the Award are Julia Cooper, Stephen de Looze, Barry Drees, Art Gertel (Chair), Barbara Grossman, Sam Hamilton, Marian Hodges, Wendy Kingdom, Julia Forjanic Klapproth, Elise Langdon-Neuner, Phil Leventhal, Alistair Reeves and James Visanji. The late Geoff Hall was an inaugural Nick Thompson Fellow.

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.
Nominations must be received by EMWA Head Office by 1 October 2021. 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.
If you consider that any EMWA member would deserve this award, please submit your nomination to EMWA Head Office: info@emwa.org

Please do not inform the candidate that you have nominated them!

Geoff Hall Scholarship

This is a quick reminder that entry to the Geoff Hall Scholarship Essay Competition will close on 30th September. The title for this year's essay is 'The Ethics of Medical Writing'. The essay must be in English and not longer than 1000 words, excluding the title and any references, but including any subheadings. Essays may also include tables and figures, but each table or figure will be counted as 250 words. The winner(s) receive free membership for 2 years from January of the following year or from the first renewal of membership after the time of the award, free Conference registration (4 conferences) over a maximum of 3 years starting from the time of the award, and one free Foundation Workshop at the first conference. Please submit your essay to EMWA Head Office: info@emwa.org

A View from the USA Followed by an Alpaca Controversy: vetSIG Meet&Share, October 29th (on-line)

At the vetSIG's next Meet&Share, the main topic will be a talk by Matthew Krecic, DVM, MS, MBA, DACVIM titled Veterinary Medical Communication: A North American Perspective. Matthew is the President of the American Association of Industry Veterinarians (AAIV), Publications and Communications Manager at Xeris Pharmaceuticals, and sole proprietor of K-File Medical Writing and Editing Services, LLC. He will talk about AAIV and comment on his experiences in veterinary medical writing. After the main discussion, we will briefly discuss the case of Geronimo the Alpaca (who controversially tested positive for bovine TB) from the viewpoint of veterinary medical writers.

The meeting will be held at 3 pm CET on Friday, October 29th. Please e-mail vets@emwa.org for a Zoom invitation or further details.

MedComm-SIG Meet & Share sessions

The first Meet & Share session of the Medical Communications Special Interest Group (MedComm-SIG) covered the topic of ethics in publishing. While it is common knowledge that medical writers have to be acknowledged, particularly newcomers sometimes have difficulties to insist to be acknowledged. Through the joint discussion several useful strategies to deal with this issue were unveiled that will be summarized in the next issue of Medical Writing.
The next Meet & Share Session will be held on Oct 13th, 5 to 6 CEST). It will cover additional topics on ethics in publishing. Situations that will be discussed include:

- Authors/ sponsors want to draw conclusions that are not substantiated with data (including press releases)
- You are asked to add an author that has not participated in the study and preparation of the article

If you want to participate, drop a note to info@emwa.org
Note: Chatham House rules apply

Spanish, Chinese and Japanise translation of the Joint Position Statement on Medical Publications, Preprints, and Peer Review

The American Medical Writers Association (AMWA), European Medical Writers Association (EMWA), and International Society for Medical Publication Professionals (ISMPP) announce the availability of translations into Chinese, Japanese, and Spanish of their Joint Position Statement on Medical Publications, Preprints, and Peer Review (https://doi.org/10.1080/03007995.2021.1900365), published in Current Medical Research and Opinion (CMRO) in March 2021.

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.

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EMWA Collaborate with the Asian Council of Science Editors (ACSE) at the 7th ACSE Annual Conference

The Asian Council of Science Editors (ACSE) hosted its 7th Annual Conference, themed around "Pandemic Driven Scholarly Publishing: Ways to Ensure Future Resilience and Sustainability," bringing together industry and academic experts to discuss the current status and future challenges to Asian Publishing Industry.
The conference was held on the 21st of August 2021 and more than 200 people took part in it, including speakers, moderators, panel experts, and participants, from different countries, like China, Korea, Japan, Thailand, London, California, United Kingdom, Greece, Turkey, Egypt, Oman, Saudi Arabia, Nigeria, Pakistan, India, Iran, Australia, Malaysia, Argentina, Indonesia & Turkey.
EMWA was one of the collaborators in this conference, together with AMWA, ISMPP, and other professional organisations. Check out more about the ACSE Annual conference at Link. For more info, contact Maryam Sayab, maryamsayab@theacse.com.

First Face to Face Meet up of the Swiss Medical Writers and Communicators Group

Finally, our first meet up took place on Saturday, 21 Aug 2021 in Bern, Switzerland. It was a gathering of people from different demographics but who share a common passion for health communications. Of the 12 attendees – a majority already EMWA members but some non-EMWA members too - three were freelance, and four were exploring to transition to the field. We had three attendees who got their first break at the EMWA Vienna conference in 2019, which was key in their MW career path. One attendee transitioned from academia to MW after hearing a talk by an EMWA ambassador. The experience and interest include med comms, editing, pharmacovigilance, regulatory writing, and consultancy. The medtech sector was especially well-represented with four attendees working fully in the medical device sector. The meet up was slightly dominated by female attendees but our male members insist they will be at the next one. We hope to continue this success and plan more meet ups in the near future. We hope you will join us next time! You can find the group on LinkedIn Swiss Medical Writers & Communicators | Groups | LinkedIn

Call for Ideas for Journal Covers

Put your creations up front!!! If you are into visual communications, digital design, or photography, consider showcasing your work on the front cover of our journal. Upcoming themes include Medical Journalism, Sustainability, Medical Devices, Working from Home, and Open Science. Contact editor@emwa.org.

RPD news

Medicines and Vaccines

European Commission Decision (EU) 2021/1240: CTIS Go Live Date 31 January 2022

The EU Decision (L275) on the compliance of the EU portal and the EU database for clinical trials has been published in the Official Journal of the European Union.
This critical Decision announces that the EU portal and the EU database have achieved full functionality and meet the functional specifications, as referred to in Article 82(2) of Regulation (EU) No 536/2014. This Decision shall enter into force on the day of its publication in the Official Journal of the European Union (31 July 2021).

This means that Clinical Trial Regulation No 536/2014 will enter into force on 31 January 2022, and the Clinical Trials Information System (CTIS) will become active. CTIS will contain the centralised EU Portal and Database for clinical trials foreseen by the Regulation.

The CTIS Sponsor Handbook Section 9 'Data Transparency' is particularly useful in clarifying Sponsor public disclosure obligations. Sponsors may submit 'version for publication' documents alongside the 'not for publication' versions of the Clinical Study Protocol, Investigator's Brochure, Informed Consent Information Sheet, and Clinical Study Report. The Plain Language Summary (PLS) will also be publicly available through CTIS.

CTIS Highlights is out for August 2021. Read it here for everything you need to know about the go-live plans, training and registering for CTIS.

FDA Non-compliance Letter

At the end of July 2021, FDA issued a second letter of non-compliance to Accuitis for failing to submit results for a study of the efficacy of ACU-D1 in the treatment of acne rosacea (NCT03064438). The record does not appear to have been updated in 2 years, despite Accuitis having received a previous FDA letter in October 2020 requesting they review the record for this trial. The status of the trial on clinicaltrials.gov is 'Unknown'. As with the Acceleron study which was subject to the first FDA non-compliance letter earlier this year, a (very recent) publication link does appear in the results tab.

This again reiterates the importance of Sponsors ensuring their clinicaltrials.gov records are accurate and up to date. This can be a time consuming and challenging task, especially for old studies.

Transparency and Disclosure Publications and Resources

1. This British Medical Journal (BMJ) Opinion article "Working towards harmonised access to clinical trial data across European drug regulatory agencies" illustrates the disparity of access to clinical study reports (CSRs) in some European countries because the old EU Trial Directive 20/2001/EC7 remains applicable until the Clinical Trial Regulation comes into force on 31 January 2022. This loophole means that national European regulators are not obliged to adhere to European transparency policies – yet…An open letter from researchers and NGOs has asked the EMA Heads of Medicines Agencies (HMA) for harmonised access across European drug regulatory agencies sooner rather than later.

2. The UK's Information Commissioner's Office (ICO) – which upholds information rights in the public interest and promotes openness by public bodies and data privacy for individuals - is calling for views on its Draft anonymisation, pseudonymisation and privacy enhancing technologies guidance.

3. This BMJ paper titled 'Clinical trial transparency and data sharing among biopharmaceutical companies and the role of company size, location and product type: a cross-sectional descriptive analysis' uses the Good Pharma Scorecard (GPS) to evaluate and score companies on T&D. In short, larger companies are better at data sharing.

4. This fantastic PHUSE resource – PHUSE-Xogene CTT Regulations Portal – can be used to stay on top of global clinical trial transparency compliance requirements. There is an 'at-a glance' map, as well as the option to select by country or by mandatory/voluntary registration/results. The individual pages per country also include the latest updates as well as links to the relevant registries.

5. Regulatory Focus have developed a global COVID-19 vaccine tracker which is regularly updated. It shows all approved vaccines and lists all those still in development. Click the green '+' to reveal details about a particular vaccine.

6. The UK's NHS Health Research Authority (HRA) has published its 2021/22 Business Plan. Objectives have research transparency high on the priority list, with an aim to '… Publish a summary of all approved studies and their findings on the new IRAS website by the end of March 2022'.

7. The Clinical Trials Transformation Initiative (CTTI) is a public-private partnership between the FDA and Duke University. CTTI is interested in learning the experiences and perspectives of key stakeholders on clinical trial registration and the submission of clinical trial results information into ClinicalTrials.gov. CTTI will write an aggregated summary of the interview findings for the FDA, including non-identifiable participant quotes. CTTI will also use the summary to develop public recommendations to support and strengthen more timely, accurate, and complete registration of clinical trials and reporting of clinical trial results information into ClinicalTrials.gov. To find out more, email sara.calvert@duke.edu

8. ISMPP have published "The ISMPP authorship algorithm: standardising the application of the ICMJE authorship criteria". The new ISMPP Authorship Algorithm aims to bring a standardised approach to the interpretation and application of ICMJE authorship criteria (focusing on criterion 1), in particular for publications of pharmaceutical industry-sponsored research.

9. This August 2021 JAMA editorial 'Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals' provides helpful guidance on language to support demographic information presentation.

10. The original Consolidated Standards of Reporting Trials (CONSORT) 2010 statement helps improve reporting of RCTs through transparency and completeness. Details of an extension to CONSORT for RCTs conducted using cohorts or routinely collected data, CONSORT-ROUTINE, were published in the BMJ in April 2021.

Continuing Professional Development Resources

1. This is a free Webinar on Plain Language Summaries (PLS). I suggest exploring the rest of the Plain Language Summaries Site too.

2. Do not miss Life Science Academy's courses running in September 2021 on Quality of Life and other Patient-reported Outcomes (PROs).

3. Khaled El Amam's Replica Analytics is running a FREE webinar on 22 September 2021 on how to measure the risk of re-identification. This is applicable to synthetic data generation and de-identification methods. Risk measurement is fundamental to responsible sharing of health data. The webinar will explain what happens when you do not get risk measurement right, and some recent advances from our team on risk measurement with the results of some very accurate risk estimators. The webinar is entitled Measuring Re-identification Risk in Synthetic and Anonymized Data, and you can register here.

Medical Devices

The EU Medical Device Coordination Group (MDCG) continues to work on important guidance documents and templates to help the medical device industry comply with the requirement under the EU MDR 2017/745 and IVDR 2017/746. One of the key changes in this regulation (compared to the superseded directive) is transparency and visibility of the activities of the different stakeholders (also called "actors"). Below we provide some updates.

Updates on Quality Management of Medical Devices

Having a better oversight of the Quality Management System (QMS) helps ensure patient safety. MDCG 2021-23 Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 was released in August to provide guidance on audit and certification of QMS, especially in relation to repackaging and relabelling.

The EMA also recently updated their Guideline on quality documentation for medicinal products when used with a medical device. The document focuses on product-specific quality aspects of a medical device, or device part, that may have an impact on the quality, safety and/or efficacy (and hence overall benefit/risk determination) of a medicinal product.

Update on Safety Reporting for Medical Devices

Safety reporting is another important improvement under the MDR. Check out the MDCG 2020-10/1 Safety reporting in clinical investigations of medical devices and the accompanying form.

MDCG is working closely with the International Medical Device Regulators Forum (IMDRF). Check out the IMDRF documents on Adverse Event Reporting released this year.

Update on Drug-Device Combination Products

By analysing publicly available information on US FDA website, researchers came up with new visualisation models of the designation pathway and group categorisation for drug device combination products. These tools will help innovators and developers in determining the predictability and acceptability of these products' designation under the US FDA requirements. Check out the open access paper by Uemura et al. on "New Visualization Models of Designation Pathway and Group Categorization of Device–Drug and Device–Biologic Combination Products Classification in the United States: Analysis of FDA Capsular Decisions."

Regulation (EU) No 536/2014 Questions & Answers Version 4 was updated in July 2021. However, Question 1.10 remains redacted. Prior to redaction the question read "*A study might involve a medical device – what does this mean in terms of EU regulation of clinical trials*?" We hope we will get clarity on this soon.

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