EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast - April 2020

EMWA 2020 Elections

All candidate statements are in and we need you to vote for your next Vice President, Education Officer and Conference Director.

Carola Krause Candidate for Vice President
Marian Hodges Candidate for Education Officer
Slávka Baróniková Candidate for Conference Director

Click Here to vote and to read the candidate statements.

Voting opened on **Monday 16 March and closes at midnight on Saturday 11 April 2020.**

COVID-19

We hope that everybody is safe and well – as far as this is possible in the current situation.

COVID-19 is affecting every part of our life, but we will try our best to help you through these times with the following:

Even though the Spring Conference in Prague had to be cancelled, we will hold our **Annual Meeting** on Wednesday 06 May, at 16.00 UK time; you will also have the option to vote as usual. Details of this virtual event will be provided closer to the time.

As **Expert Seminar Series (ESS)** sessions contain up-to-date and time-sensitive topics, we are planning to have virtual ESS sessions. Further details will follow.

In the meantime, we suggest that you use the wealth of our training material in the Webinars Archive, which we plan to make more user-friendly by preparing search categories.

Stay safe and healthy!

Your Executive Committee.

BELs Exam on 4 May in Prague cancelled

The Board of Editors in Life Sciences (BELs) has been informed about the cancellation of the EMWA conference in Prague. They have now cancelled registration for the exam that was planned for 4 May. We hope to continue EMWA's collaboration with BELs to offer the exam during a future EMWA conference and will keep our members posted. For more information on the BELs exam please check their website.

Polish Translation of the Joint Position Statement on 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 Polish by Dorota Szymańska, Maria Kołtowska-Häggström, Jacek Bil, and Olga Mozenska. In order to access the translation please click here.

Pharmacovigilance Special Interest Group - News

- MedDRA update with new terms and codes related to COVID-19
- Request from EMA and the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePPP) for the registration of Covid-19-related pharmaco-epidemiological studies and public availability of study protocols
- EMA communication: COVID-19 - Update on treatment and vaccines under development and information on chloroquine and hydroxychloroquine DA Takes Action with Indian Government to Protect Consumers From Illicit Medical Products
- FDA guidance on the conduct of clinical trials of medical products during the COVID-19 pandemic
- EMA guidance to sponsors on how to manage clinical trials during the COVID-19 pandemic
- EMA communication: Addressing the potential impact of novel coronavirus disease (COVID-19) on medicines supply in the EU
- EMA notice to stakeholders on the withdrawal of the United Kingdom and EU rules for medicinal products for human use and veterinary medicinal products
- Direct healthcare professional communications
- EMA's restrictions in use of cyproterone due to meningioma risk
- EMA's Review of Yondelis started
- EMA published the 2019 public engagement highlights

To read more, please click here

Webinar Programme News

Given the special circumstances due to covid-19, this month we'll offer an additional webinar: **"Lifestyle choices for medical writers"** by **Carolina Rojido on April 23rd at 2 pm CET.**

Here's what it will be about: our lifestyle frequently underlies the conditions due to which most of us get sick and die. But a healthier lifestyle can prevent and help treat many communicable and non-communicable diseases. This is important for everyone but especially for medical writers since our jobs are sedentary and often stressful. There are many things we can do to improve our health and productivity, from modifying seemingly insignificant habits to greater initiatives. Every day is a new opportunity to take steps that can improve our health and help us reach our maximum performance in all aspects of our lives.

Please click here to register.

Emergency Guidance Documents on Clinical Trials during the COVID-19 pandemic

In March 2020, regulatory authorities issued emergency guidance documents that relate to disruptions in clinical trials conduct during the COVID-19 pandemic. These documents provide recommendations on how to deal with protocol deviations and how to document these deviations and other pandemic-related issues in the clinical study reports. See links to the guidance documents below:

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic.
EMA Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic.

Important Updates on Medical Devices

In March 2020, the European Commission proposed to postpone the MDR date of application for one year. The decision was made with patient health and safety as guiding principle during the COVID-19 pandemic. The proposal was to be submitted for approval to the European Parliament and Council in early April.

Other important links for medical devices are provided below:

- Want to keep track of designated Notified Bodies? Check out the European Commission NANDO site
- The Medical Device Coordination Group (MCDCG) is continuing to develop guidance documents on the implementation of the MDR/IVDR
- Finally, the ISO14155:2020 (GCP for medical devices) is expected to be published in May 2020. In the meantime, check out the summary of the key revisions here.

RPD News

FDA Continues to Support Transparency and Collaboration in Drug Approval Process as the Clinical Data Summary Pilot Concludes.

After soliciting opinion on how FDA might best support disclosure of clinical documents and announcing the conclusion of its Clinical Data Summary Pilot on 26 March 2020, FDA is not currently disclosing clinical documents but has identified a possible approach for disclosing study reports, the framework of which includes the following principles:

- A centralised international library managed by an independent body would be set up where information is made available to the public, rather than each regulatory authority having its own system
- An on-demand system would be set up where some documents, e.g. clinical summaries, index of study reports, would be automatically published. The public could request documents and the sponsors would add them to the library
- Anonymisation and disclosure standards would apply; PhUSE standards are particularly mentioned
- Sponsor commitment to use the international library system would be voluntary.

This RAPS article is an interesting perspective on the development of FDA's thinking.

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 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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