EMWA Newsblast - March 2020



EMWA's 50th Conference – Prague, 05–09 May 2020

The conference is proceeding as planned and registration is going well.

We are, of course, closely monitoring the situation with coronavirus disease (COVID-19), acting on advice from the World Health Organization (WHO) regarding precautions, and considering different options.

Appropriate health and safety precautions will be implemented to ensure our commitment to the safety of our attendees. In the meantime, the conference venue has put in place measures that are detailed in the following link:

Hotel Statement

We look forward to seeing you in Prague!

In the meantime, EMWA member, **Thanga Bhuvanesh**, has written a piece about the upcoming conference for new members. Read more <u>here!</u>

BELs Exam Update

Do you want to become a Board-Certified Editor?

The Board of Editors in the Life Sciences (BELS) Exam will be offered in Prague on 4th May 2020 from 1 to 4 PM at the EMWA conference venue in (Clarion Conference Center Prague, Freyova 33 in the Benada Lounge).

All candidates need to apply for candidacy to BELs (more about application requirements <u>here</u>) and once approved may register for the exam.

The registration deadline is 6th April 2020.

Joint Position Statement on Predatory Publishing translation

We are now pleased to announce that six months after publication, the JPS is available in nine languages: Chinese, Japanese, German, Italian, Dutch, Portuguese, Swedish, Romanian and English.

The Chinese and Japanese translations of the Joint Position Statement are available on the ISMPP website. Translations into German, Italian, Dutch, Portuguese, and Romanian are accessible on the EMWA website. EMWA has planned future translations into the following languages: Swedish, Polish, Greek, Spanish, French, Catalan, Arabic, Armenian, and Hebrew. You can read more on this here.

We are proud to announce the posting of the first JPS translation into Swedish by Wendy Hartig-Merkel and Anna Nordle Gilliver. You can read this translation <u>here</u>.

Pharmacovigilance Special Interest Group - News

- EMA published an update of the Guideline on good pharmacovigilance practices (GVP): Module VII - Periodic safety update report - Explanatory note (02 Mar 2020)•
- ICH E9(R1) and S5(R3) to take effect in the EU by the end of July 2020
- PRAC confirms four-week limit for use of high-strength estradiol creams • EMA consultation: Public statement on the use of herbal medicinal
- products containing estragole Update from the HMA/EMA Task Force on Big Data – final report (phase
- two) published
- 25th EMA anniversary Conference "From data to evidence in medicines regulation" on 22 April 2020 Useful websites related to updates on the Coronavirus outbreak
- To read more, please click here.

Regulatory Public Disclosure Special Interest Group -News

- EMA's approach to CCI vindicated
- Replica Analytics: Webinar resources on de-identification Resources to support medical writers in their daily work
- TransCelerate release December 2019 CSR template: PHUSE Survey on Data Sharing
- UK MHRA Updated Guidance on Regulating Medicines: Transition Period Update to UK Medicines Regulatory Framework
- Public Disclosure of Information Via EMA's Pharmacovigilance System White Paper - Preparing CSRs for external sharing

Reidentification risk from a disclosed CSR – El Emam Publication

To read more, please click <u>here</u>

Webinar Programme News

Our next webinar will be on **Thursday 2nd April 2020**, **14:00 CET**.

Please click <u>here</u> to register.

Title: The obstacles to data transparency and how to overcome them

communications and scientific affairs consultant.

Summary: Why most of the results included in abstracts presented at

Speaker: Andrea Rossi, Past president of EMWA - Medical writing, medical

congresses are not published? Why several registered trials are nor reported in due time, even if data transparency is requested by editors and regulatory authorities? In this webinar, the available objective data on the lack of data transparency will be shared together with their causes, to provide the instruments that could be applied to ensure data transparency.

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them on Linkedin, by searching 'PIA Commercial'.

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