

EMWA Newsblast-January 2021



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We wish you all a very happy and healthy 2021!

This is your last chance to contribute to our virtual learning questionnaire! Please complete the online survey below. The survey will be closed at midday on Thursday January 14th.

<u>Virtual</u> <u>Learning</u> <u>Questionnaire</u>

Thank you for your time.

Information about the EMWA conference in Riga in May 2021

We are sorry to inform you that we will not hold a face-to-face conference in Riga in May 2021. Read more here.

Call for Nominations to EMWA Executive Committee

We remind you that nominations are open until the 15th of January. The positions are: Vice-President, Treasurer, Public Relations Officer and Honorary Secretary. Read more here.

Medical Device SIG Roundtable

The EMWA Medical Device SIG is meeting on Friday, 5 February 2021 (11:00–12:00 CET) for our next virtual roundtable discussion. The topic for February is Safety Reporting and Risk Quantification for the SSCP. In preparation for the call, we recommend reading the MDCG 2019–9 guidance paper (especially Section 4.1). For those of you who missed our last roundtable discussion on IMDRF safety coding, you may also want to review the IMDRF coding for adverse events (IMDRF/AE WG/N43 FINAL:2020).

All EMWA members are welcome to participate. If you are interested in joining the discussion, please meet us on Zoom using this <u>link</u>.

Interested in helping with our webinar programme?

We are looking for new members to join the webinar team to help run our live webinars. We will provide training on using the webinar software and the procedures we use on the day. You will need to be available to run a webinar live on the day.

For more information, contact webinar@emwa.org

Turkish Translation of the Joint Position Statement on Predatory Journals

We are proud to announce the posting of the JPS translation into Turkish by Neslihan Altınbaş and Ahmet Alperen.

In order to access the translation please click here.

We are currently looking for translators. If you would like to volunteer please contact <u>Abe Shevack</u> or the <u>EMWA Head Office</u>.

Webinar Programme News - Preview for 2021

Thursday 21st January 2021, 14:00 CET

Publication Planning

Andrea Rossi - Medical writing, medical communications and scientific affairs consultant,

Julia Donnelly - Medical communications consultant

Thursday 11th February 2021, 14:00 CET

Veterinary articles for scientific journals: Case reports

Dr. med. vet. Cemile Jakupoglu – Cyton AH Biosciences GmbH – a knoell company

Thursday 18th March 2021, 14:00 CET

The impact of COVID-19 on the content of clinical trial documentations: new requirements!

Raquel Billiones

Regulatory News

Click here to read this month's Pharmacovigilance SIG news:

COVID-19 related news:

- EMA starts rolling review of Janssen's COVID-19 vaccine Ad26.COV2.S
- EMA's second public meeting about the new COVID-19 vaccines (08 Jan 2021)
- EMA communication: Information on the first COVID-19 vaccine
- EMA recommends COVID-19 Vaccine Moderna for authorisation in the EU

Would you like to improve your statistical understanding?

PSI (Statisticians in the Pharmaceutical Industry) are delighted to announce a new collaboration with Richard Kay for his training course "Statistical Thinking for Non-Statisticians in Drug Regulation".

Basic statistical skills are more vital than ever, and this course will enable non-statisticians to understand the fundamentals of statistics for clinical trials in the pharmaceutical industry.

Learners who sign up to this course through PSI will receive a special discount. Find out more and sign up here:

https://www.psiweb.org/need-statistical-advice/training-for-non-statisticians



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