

EMWA Newsblast - September 2018

We are pleased to announce that Warsaw Conference Registration is now open!



The EMWA Professional Development Committee has prepared a comprehensive education programme, with 20 foundation and 11 advanced workshops that will cover a broad range of topics related to medical writing and communication.

In addition to the workshops, the conference offers a number of events outside of the formal education programme, such as the traditional Opening Session, the Networking Reception, as well as a free seminar entitled 'Introduction to Medical Writing'.

Each conference day will start with an 'Easy Morning Yoga' session and on Friday evening we have planned a number of social events so that you can enjoy Warsaw together with old and new EMWA friends.

Save the date | 48th EMWA Conference Vienna 7th - 11th May 2019

NEWS OF INTEREST

Regulatory News

- EMA released its first annual report on clinical data publication under Policy 0070 (Oct 2016 to Oct 2017).
- Brexit preparedness: EMA to further scale back and suspend activities.
- EMA released for public consultation draft questions and answers on Data Monitoring Committees issues.
- EMA adopted and published the guideline on the clinical investigation of human normal immunoglobulin for intravenous administration and the guideline on core SmPC for human normal immunoglobulin for intravenous administration.
- EMA released for public consultation a draft guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells.
- FDA released final guidance for industry on labeling for biosimilar products.

To read more about this months regulatory news please click [here](#)

Regulatory Public Disclosure (RPD)

Look out for the new dedicated RPD Section in Medical Writing (MEW) from September 2018. Section Editor, Sam Hamilton, would like to hear from you if you have contributions: sam@samhamiltonmwservices.co.uk

Members can access the dedicated page of the RPD Special Interest Group (SIG) [here](#).

Look out for a summary of the information shared this summer 2018 with those signed up to receive emails from the CORE Reference website (<http://www.core-reference.org/>).

To receive these updates in 'real time', join the mailing list at <http://www.core-reference.org/subscribe>.

Topics covered:

- Interruption to EMA's clinical data publication activities due to EMA Brexit preparedness
- TransCelerate's common protocol template: December 2017 version
- Merging of EMA portal and EU database planned for 2019
- ATMPs guidance – stakeholder consultation; contributions due by 31 October 2018
- CSRs in systematic reviews
- Policy 0070 webinar released by AMWA
- Clinical data publications in the first year of policy 0070
- Data transparency and the noncommercial sector

OTHER NEWS

Did you know that existing EMWA members can receive a **10% discount** off their next year's EMWA subscription for referring a new* member to EMWA.

This discount is only valid for a maximum of one new member per year and a full year's subscription must be paid by the new EMWA member before the discount can be given to the referrer.

In addition, the new member needs to include the name of their referrer on the membership application form.

Please note that discounts are not cumulative, nor can they be rolled over into subsequent years – i.e. the maximum discount possible in any given year is 10%.

**A new member can be completely new to EMWA or they may be a lapsed EMWA member who has not been a member for a minimum period of 3 full years (i.e. 36 months) in order to be considered a 'new' member again.*

EMWA members, once logged in, can find this and other [exclusive member offers online](#).



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