EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast - October 2018

47th EMWA Conference | 8th - 10th November 2018 | Warsaw - Poland

Register Now!

In addition to the 31 workshops taking place at Warsaw Conference, there will be a number of events outside of the formal education programme, such as the traditional Opening Session, the Networking Reception and an *"Introduction to Medical Writing"* free seminar.

Each conference day will start with an *"Easy Morning Yoga"* session and there will be a number of social events to enjoy Warsaw together with old and new EMWA friends.

To view the conference programme and all other information, please refer to the dedicated conference minisite.

The medical device special interest group (MD-SIG) meeting will take place at our Autumn conference on **Friday 09 November 2018 from 2 to 3 pm in room Brussels**. If you are interested in what we are doing, come and meet us there!

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

NEWS OF INTEREST

Regulatory News

- EMA launched a new version of its corporate website (www.ema.europa.eu)
- CMDh published "Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP"
- EMA updated post-authorization procedural advice for users of the centralized procedure
- EMA news: Company Zhejiang Tianyu no longer authorized to manufacture valsartan active substance for EU medicines due to the presence of NDMA
- EMA news: Guide to be given to prescribers to help avoid medication errors with Amglidia (glibenclamide oral suspension, used for neonatal diabetes)
- EMA news: Educational material (including training video) for patients and healthcare professionals to avoid medication errors with Myalepta (metreleptin, used to treat lipodystrophy)
- EMA concludes the review of medicine for uterine fibroids Esmya: new measures to minimize the risk of rare but serious liver injury
- EMA's guidelines and other documents open for consultation:
  - Q&A's on Data Monitoring Committees issues
  - Draft guideline on the use of minimal residual disease as a clinical endpoint in multiple myeloma studies
  - Draft guideline on biosimilar medicinal products containing a recombinant granulocyte-colony stimulating factor
  - Draft guideline on similar biological medicinal products containing a recombinant granulocyte-colony stimulating factor
  - Draft guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

To read more about this months regulatory news please click here

UK withdrawal from the EU and clinical trials

The European Commission Directorate – General for Health and Food Safety on the UK withdrawal from the EU and its impact on clinical trials has released a statement that can be read here.

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