EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast - November 2018

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

Welcome to Warsaw! Don't forget to check the dedicated conference minisite to view the conference programme and last-minute updates.

Conference Minisite

News from the MD-SIG

ROOM CHANGE: The medical device special interest group (MD-SIG) meeting will take place at our Autumn conference on Friday 9 November 2018 from 2 - 3 pm in Salon C.

If you are interested in what we are doing, come and join us there (
ROOM CHANGE: The medical device special interest group (MD-SIG) meeting will take place is limited)!

The meeting agenda is as follows:

1. Medical Device Expert Seminar Series 2019 and 2020
2. Medical Device Workshops
3. Preparing for MDR and IVDR – exchange of experiences
4. Any other business

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

NEWS OF INTEREST

Regulatory News

- PRAC elects new vice-chair
- EMA publishes additional information material to improve understanding of biosimilars in the EU
- The US FDA released a final guidance for industry entitled "Physiologically Based Pharmacokinetic Analyses—Format and Content"

PV SIG Regulatory news

- EMA's Pharmacovigilance Risk Assessment Committee (PRAC) elected Dr. Martin Huber, PRAC member Germany since 2012, as the new vice-chair to take over from Dr Álmath Spooner.
- The EMA and the European Commission have published additional information material on biosimilar medicines, as part of their ongoing collaboration to improve understanding of biosimilars across the European Union (EU).
- The new material includes an animated video for patients that explains key facts on biosimilar medicines and how EMA works to ensure that they are as safe and effective as their reference biological medicines. The video is available in eight European languages
- The Food and Drug Administration announced the availability of a final guidance for industry entitled "Physiologically Based Pharmacokinetic Analyses—Format and Content'

To read more about this month's regulatory news, please click here**.**

Regulatory Public Disclosure (RPD) Regulatory News

FDA Guidance Documents

- FDA issued draft guidance titled "Civil Money Penalties Relating to the CT.gov Data Bank"
- FDA guidance releases on protocol development relevant to publicly disclosed documents, such as clinical study protocols

Developments in Europe

- The European Commission (EC) issued a Notice to Stakeholders "Withdrawal of the UK and EU rules in the field of clinical trials"
- EMA is compiling a report listing those Sponsors on EudraCT who are not compliant with results posting requirements. This information was

communicated directly by an EMA representative at a web meeting of the DIA's "CTD Community".
- EudraCT Clinical Trials Tracker is fully established.
- In September 2018, the launch of cOAlition S was announced.
- By 1 January 2020, the aim is to fulfil this main principle: “By 2020 scientific publications that result from research funded by public grants provided by participating national and European research councils and funding bodies, must be published in compliant Open Access Journals or on compliant Open Access Platforms.”

Journal Publication of Interest

- The 2018 BMJ Article: "Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource" describes compliance of 50% for results posting on EudraCT over a 1-year period to 21 December 2016. This paper also describes the EudraCT Clinical Trials Tracker.

Resources

- A recording of the TransCelerate Webinar Session on their Common Protocol Template, along with a PDF slide deck is available.

To read more about this month's regulatory news, please click here.

Ambassador’s Programme Update

The EMWA Ambassador’s programme is going along at a steady pace as we are spreading the word about medical writing and EMWA at universities and career events across Europe. Raquel Billiones presented at the MedTech conference in Stuttgart in Apr and gave a full day workshop on regulatory documents and trial disclosure with Abe Shevack at a BioM biotechnology network event in Munich in July.

Anne McDonough gave a talk at Anglia Ruskin University – Faculty of Medical Sciences and Public Health Careers Day at their campus in Essex on April 18, 2018. John Carpenter attended two MedComms career events at the University of Westminster in June and at the University of Manchester in Sept. On 24 Sept, RaquelBilliones was in Asia and represented EMWA at a career talk at her alma mater, the University of the Philippines Cebu Campus. In October, Franziska Abreu presented about careers in medical writing and the benefits of joining EMWA at an event organized by doctoral candidates and post-doctoral fellows at the Max Planck Institute in Marburg, Germany. She writes about some of these events in the MEW Regular Section named Getting Your Foot in the

Door (GYFD).

The Ambassador's group will hold a lunch table meeting at the Warsaw conference on 8 Nov in the Sheraton hotel restaurant from 11:45 to discuss the current status of the programme and ideas on how to proceed. Everyone interested in this programme is invited to attend.

The Ambassador's program has its own page on the EMWA site listing news and past and upcoming events.

In order to keep the momentum going, we are always looking for experienced presenters who have previously volunteered as either workshop leaders or on one of EMWA's committees. If you are interested in serving as an Ambassador or if you have heard about any upcoming career events which EMWA might attend, please contact Abe Shevack (aspscientist@gmail.com) or EMWA Head Office (info@emwa.org)

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