EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA News Blast - June 2018

CONFERENCE UPDATES

Barcelona Conference

The 4th EMWA ESS programme, aimed at the experienced EMWA contingent was well-received with the highest numbers of participants attending to date.

Industry leaders, patient engagement and competent authority speakers joined us to share their expertise in such diverse areas as pharmacovigilance; orphan drugs and rare disorders; regulatory matters including the highly topical GDPR, clinical data disclosure and Cochrane's evolving use of regulatory information sources in their work; and medical journalism.

Session Chairs and expert panels interacted with the ESS audiences to expand on particular points of interest, increasing the practical relevance of each of the sessions. Thanks to all concerned for a well-delivered 2018 ESS programme.

Freelance Business Forum report

The sub-committee report of the highly successful Freelance Business Forum, held at the recent 46th EMWA Barcelona, is now available. An overview and photographs of the event are presented, summarising the outcomes of Freelance Business Forum table discussions and the guest speaker presentation.

The table discussions continue to provide valuable expert advice in numerous areas of medical writing, editing, and translation work, for both experienced and new freelancers.

The report can be accessed at https://www.emwa.org/freelance/freelance-resource-centre/

Winners of the Barcelona conference photo competition

At the Barcelona EMWA conference, members were asked to submit photos involving their EMWA 25th anniversary badge for a competition. Photos were sent by email or Twitter. The joint winners, selected by the Executive Committee, are Jane Marshall, Laura Kehoe, and Allison Kirsop. Thanks to everyone who participated!

Photo by Jane Marshall

Photo by Laura Kehoe and Allison Kirsop

NEWS OF INTEREST

Regulatory News

- The EMA has released for public consultation a draft guideline on clinical evaluation of vaccines intended for the prevention of infectious diseases (Revision 1)
- The FDA announced the availability of a guidance for industry entitled "Clinical Trial Imaging Endpoint Process Standards. (IDRAC 274221)". This guidance assists sponsors in optimising the quality of imaging data obtained in clinical trials. It is intended to support approval of drugs and biological products, where imaging is used to assess a trial's primary endpoint or a component of that endpoint
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Assembly has adopted under Step 4 of the development process the Questions and Answers for the ICH S9 Guideline: Nonclinical Evaluation for Anticancer Pharmaceuticals
- The PRAC confirmed that the risks of the multiple sclerosis medicine Zinbryta (daclizumab beta) outweigh the benefits for patients. Zinbryta poses a risk of serious and potentially fatal immune reactions affecting the brain, liver and other organs. On 27 March 2018, the marketing authorisation was withdrawn at the request of Biogen Idec Ltd, the company that marketed the medicine. The press release can be found here.

PV SIG update

The pharmacovigilance (PV) ESS in Barcelona was a great opportunity to learn how to implement in practice the revised guidance on risk management plans from true experts: Val Simmons (EU QPPV at Eli Lilly and member of the EFPIA PV Committee) and Sven Schirp (Head of global PV writing at Boehringer Ingelheim).

The speakers were also available at the PV lunch roundtable for further informal discussions. Many thanks to the participants of the ESS and the lunch roundtable for contributing to the interactive discussions!

Webinars

Our next LIVE webinar will take place on Thursday 28th of June at 2 pm CET!

Carolina Rojido will talk about How to organise and deliver a webinar yourself: Now that internet-based learning and working are commonplace it can be useful to know how a webinar is done. Most of you probably know how to deliver training or a presentation. The EMWA webinar team can support EMWA webinar speakers by providing all the technical support necessary.

However, you might find yourself in a situation where you need to be speaker AND organiser, or may be asked if you have this skill. You will find out how to prepare and run an engaging webinar smoothly.

This month you will receive an email on June 7th with the information above and the link to register. Otherwise, registration will open on June 7th on https://www.emwa.org/training/emwa-webinars-programme/

GEOFF HALL SCHOLARSHIP 2018

Up to Two scholarships are available in memory of one of the founding fathers of EMWA, Geoff Hall, who sadly passed away in 2010.

The essay title for 2018 is "The medical writer: partner or servant?"

The submission deadline for entries is **30 September 2018**.

Eligible applicants must be new medical writers: that is, they intend to enter the profession or have been employed for no longer than one year as a professional medical writer, including freelance work. They need not be current members of EMWA.

Applicants must include a short statement declaring what work they do or have been doing and that they meet the eligibility criteria.

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