EMWA News Blast - June 2018

CONFERENCE UPDATES

Barcelona Conference

The 46th EMWA Conference, held at the Barcelona Convention Centre, was another resounding success! Attendees from all over the world reunited to share the latest developments in medical writing and publishing. The conference was a forum for networking and exchanging ideas, with sessions on topics such as clinical trial reporting, medical writing, and medical journalism.

Freelance Business Forum report

The Freeland Business Forum, held at the recent EMWA Barcelona Conference last year, is now available. The conference and related photographs from the event are also available. The conference focused on the challenges and opportunities facing freelance medical writers in today's market.

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

Eligible applicants must be new medical writers: that is, they intend to enter the medical writing 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.

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 competition

The submission deadline for entries is 30 September 2018.

The winners of the Barcelona conference photo competition

The winners of the Barcelona conference photo competition were announced. The winning photos captured the essence of the conference, showcasing the vibrant and engaging atmosphere.

NEWS OF INTEREST

Regulatory News

- The EMA has reminded companies to public-commit on a "no-no" list to avoid publications that include incorrect information or information intended to influence patients' decisions (Franchino). The list includes specific types of information, such as the use of the term "cure" or "treatment," which can be misleading.

- The FDA has announced the availability of a guidance for industry entitled "Questions and Answers for the ICH S9: Nonclinical Evaluation for Anticancer Pharmaceuticals." The guidance is intended to help companies understand the requirements for nonclinical evaluations for anticancer drugs.

- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has released a draft guideline on the use of imaging in clinical trials. The guideline is intended to help companies understand the requirements for using imaging in clinical trials, including the selection of imaging modalities and the interpretation of imaging data.

Pharmaceutical News

- The European Medicines Agency (EMA) has 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 SIG (PV SIG) in Barcelona was a great opportunity to learn how to implement in practice the revised guidance on risk management plans from the International Council for Harmonisation (ICH).

- The PV SIG confirmed that the role of the multiple sclerosis medicine Zinbryta (daclizumab beta) requires careful monitoring, especially for patients. The speaker noted that the PV SIG planning committee is in the process of developing a new guidance for risk management plans, which will be shared during the upcoming EMWA Conference in September.

- The PV SIG planning committee is also discussing the role of the PV SIG in the future EMWA Conference and how to involve more companies in the planning process.

- The speakers were also available at the PV SIG lunch for further informal discussions. Many thanks to the members of the PV SIG and the lunch meeting participants for their contributions.

Geoff Hall Scholarship 2018

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

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Eligible applicants must include a short statement declaring what work they do or have done and that they meet the eligibility criteria.

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