



## EMWA Newsblast - December 2018

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



A record number for an EMWA November conference was reached in Warsaw, at the 47th EMWA Conference, with a total of 214 attendees.

We ran a very successful education programme in Warsaw, thanks to all of our workshop leaders.

Thanks also to all the participants for completing your evaluation forms. The education committee looks at all of them, and finds them very helpful.

We are currently planning the workshop programme for Vienna. We expect to have more than 50 workshops, including some new topics: look out for more information in January. If you have a proposal for a workshop that you would like to run at the November 2019 (or later) conference, do get in touch with me at [education@emwa.org](mailto:education@emwa.org)

We will also very soon be publishing the 2019 webinar programme, which will include lots of new and interesting topics.

[Click here to view the Warsaw minisite](#)

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

## NEWS OF INTEREST

### PV SIG Regulatory news

- Update of EMA pre-authorisation procedural advice for users of the centralised procedure
- GVP specific considerations on paediatric population published on 25 Oct 2018
- EMA Consultation: Discussion paper: Use of patient disease registries for regulatory purposes – methodological and operational considerations
- European Commission published reports and other material on vaccination
- Fluoroquinolone and quinolone antibiotics: PRAC recommends new restrictions on use following review of disabling and potentially long-lasting side effects
- US FDA Draft Guidance for Industry: Presenting Quantitative Efficacy and Risk Information on Direct-to-Consumer Promotional Labelling and Advertisements

To read more about this month's regulatory news, please click [here](#).

### Regulatory Public Disclosure (RPD) Regulatory News

#### Journal Publication of Interest

Hopkins and colleagues' BMC paper (September 2018), entitled "Data sharing from pharmaceutical industry sponsored clinical studies: audit of data availability" assesses if data sharing policies are facilitating independent researcher to access participant-level data from industry-sponsored trials 2 years after publication of the primary results.

#### Broken Link for EMA's Policy 0070 Implementation Guidance page reported to EMA

EMA have been notified that their static webpage that houses the Policy 0070 implementation guidance documents is showing as 'page not found', and a request has been made for the page to be reinstated.

#### Data Sharing Conference, Brussels February 2019

On 12 and 13 February 2019, the ECCRT Data Transparency Conference will take place in Brussels. The programme on "Demystifying Clinical Data Transparency: Lessons learnt so far" includes speakers from the CORE Reference development team. Registration is now open.

To read more about this month's regulatory news, please click [here](#).

## Medical Writing Journal

### Upcoming issues of Medical Writing

The following are the next planned issues of Medical Writing. If interested in contributing an article to a specific theme issue, please write the contact person. For other contributions or enquiries, please email [mew@emwa.org](mailto:mew@emwa.org).

- **December 2018** – Patient-reported outcomes (Guest Editor: Diarmuid De Faioite). The issue is closed to new feature articles.
- **March 2019** – Careers in Medical Writing (Guest Editors: Raquel Billiones and Brian Bass). Deadline for feature articles: December 10, 2018. Contact: [medical.writing@billiones.biz](mailto:medical.writing@billiones.biz)
- **June 2019** – Generics and Biosimilars (Guest Editor: Diana Radovan). Deadline for feature articles: March 10, 2019. Contact: [Diana.Radovan@trilogymwriting.com](mailto:Diana.Radovan@trilogymwriting.com)
- **September 2019** – Trends in Medical Writing (Guest Editor: Somsuvro Basu). Deadline for feature articles: June 10, 2019. Contact: [somsuvro.basu@ceitec.cz](mailto:somsuvro.basu@ceitec.cz)
- **December 2019** – Artificial Intelligence & Digital Health (Guest Editor: Evguenia Alechine). Deadline for feature articles: September 9, 2019. Contact: [ealechine@epsilonsci.com](mailto:ealechine@epsilonsci.com)

### Member Offers



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