

## EMWA Newsblast - January 2019



**Save the date | 48th EMWA Conference Vienna | 7th - 11th May 2019 | Registration Opening Soon!**

### BREAKING NEWS

#### Medical Writer Joint Position Statement Recognized Worldwide

Over the past several months, the Joint Position Statement on the Role of Professional Medical Writers (JPS) has received various organisational endorsements, has had related journal articles published about it, and has been translated into new languages. All this activity is a testament to the longevity and continued interest for the principles laid out in the JPS.

Recognition of the JPS has been underscored by endorsements and communications from organisations around the globe:

- The Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network included the JPS in its list of reporting guidelines, posted on its website.
- European Association of Science Editors (EASE) recently published a Viewpoint article highlighting its endorsement of the JPS.
- Australasian Medical Writers Association (AusMWA) posted the JPS on its website. In addition, AusMWA endorsed the Good Publication Practice (GPP3) guidelines and also posted them on its website.
- Association of Regulatory and Clinical Scientists (ARCS Australia) endorsed and presented the JPS to its membership.
- The Council of Science Editors (CSE) and Board of Editors in the Life Sciences (BELS) shared the JPS with their respective members.

### WEBINARS

Our first webinar of 2019 will be on **Thursday 24th of January**, from 14:00-15:00 CET by **Pablo Mugúerza** on **Writing about state-of-the-art medicine?**

**Here's a brief introduction:** the best way to face the challenges that avant-garde medicine presents to medical writers and translators is to have the language explained by a qualified translator and trainer with a strong, specific medical background. During this 45-minute journey (+15 minutes for questions) Pablo Mugúerza, a physician with almost 35 years of experience as a medical translator and proof-reader and more than 10 years of experience as a medical translators trainer, will provide attendees with crystal clear ideas and concepts about of state-of-the-art medicine, along with tips and tricks to manage the use of the ever-changing related language.

Please click [here](#) to register for this webinar.

#### Plus:

- The Webinar Program's agenda for 2019 is ready - To view click [here](#)
- The Webinar Archive has been updated - watch previous webinars [here](#)

### NEWS OF INTEREST

#### Regulatory Public Disclosure (RPD) Regulatory News

##### Journal Publication of Interest

Boehringer Ingelheim (BI) and the University of Basel describe An Industry Experience with Data Sharing, with BI - as a member sponsor - in listing studies on ClinicalStudyDataRequest.com (CSDR) for data sharing.

##### EMA Temporarily Suspends Clinical Data Publication, and updates Policy 0070 Implementation Guidance

##### Will EMA Retrospectively Publish Clinical Data When the Suspension is Lifted?

**Question from Sam Hamilton to EMA (29 Nov 18):** "As of 01 Aug 2018, EMA has suspended all new activities related to the publication of clinical data. Can EMA confirm if submissions made between 02 Aug 2018 and the (future) date of the lifting of the suspension - will or will not be subject to retrospective publication?"

**Response from EMA (10 Dec 18):** "...EMA is ONLY processing applications adopted by CHMP up to the first quarter of 2017 and which were submitted to the Agency by 31 July 2018 (upon receipt of an Invitation letter).

We cannot currently comment on how the process will be resumed and whether clinical data will be published retrospectively. EMA will contact concerned applicants/MAHs before the restart of clinical data publication, once its relocation to Amsterdam is completed.

We appreciate any preparatory work done by companies regarding their upcoming CDP package submissions, however, and EMA is asking companies simply to pause any ongoing work until further notice.

#### Resources

1. EMA published a meeting report titled "Data anonymisation - a key enabler for clinical data sharing" on their 30 Nov to 01 Dec 18 joint workshop with the US-based Multi-Regional Clinical Trials (MRCT) Centre.
2. TransCelerate Biopharma has released a clinical study report template.

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

#### Medical Devices - Special Interest Group

New [Medizinprodukte-Sicherheitsplanverordnung \(MPSV\)](#) for Germany has been released end of November.

#### Freelance Business Survey

One of the many initiatives from EMWA geared to address the needs of freelance medical writers is the Freelancer Business Survey (FBS). Since 2003, EMWA's triennial FBS has been collecting and analysing freelancer responses on various aspects of the business, and this eventually helps establish standard practices among freelance medical writers.

EMWA's 6th FBS 2018 is now open for participants [here](#).

The survey should take a maximum of 10 minutes to complete. Responses will be collected until **31 January 2019**. Survey results will be published following data analysis in EMWA's official journal, Medical Writing.

Participation is open to all freelance medical writers irrespective of their location or EMWA membership and your help in sharing the link to the survey within your network is much appreciated. Also, thank you for your time and participation.

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