## **EMWA Newsblast - July 2018**



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

### **EMWA's Seventh one-day Symposium**

Would you like to learn more about Rare and Orphan diseases?

The one day EMWA symposium at the spring conference in Vienna (7th-11th May, 2019) will deep-dive to this topic from clinical, regulatory, rare diseases companies and patient perspectives too.

#### Internship Forum – Call for volunteers

We are looking for EMWA members that want to actively volunteer with the Internship Forum team. Interested members.

Please e-mail us at pr@emwa.org for more information.

### Barcelona 2018 – 10+pin badges

We appreciate your commitment: 10+ workshop pins were given to 13 workshop leaders and 20+ badges to 4 workshop leaders:

Laurence Auffret Lisa Chamberlain James Claudia Frumento Tom Lang Phil Leventhal Shanida Nataraja Andrea Palluch Francesca Pirkl

**Thomas Schindler** Walther Seiler Uma Swaminathan Tiziana von Bruchhausen **Beate Wieseler** Douglas Fiebig Debbie Jordan Elise Langdon-Neuner Rita Wellens

### **NEWS OF INTEREST**

### **Regulatory News**

- EMA launches a new secure online portal for sponsors to submit applications for orphan designation and to manage <u>post-designation</u> activities
- EMA published its <u>workshop report</u> on how to better apply the Paediatric Regulation to boost development of medicines for children. A factsheet and a video are also available.
- EMA <u>restricted</u> use of Keytruda (pembrolizumab) and Tecentriq (atezolizumab) as first line-treatments for urothelial cancer
- EMA begins <u>review</u> of medicines containing the painkiller metamizole
- EMA pre-authorisation procedural <u>advice</u> for users of the centralised procedure
- EMA post-authorisation procedural <u>advice</u> for users of the centralised procedure
- FDA <u>published</u> first CSR in <u>pilot program</u>: <u>Erleada</u>
- <u>Draft guidance</u> "Patient-focused drug development: collecting comprehensive and representative input"
- Press Release: Statement from FDA Commissioner Scott Gottlieb, MD, on new policies to reduce the ability of brand drug makers to use REMS programs as a way to block timely generic drug entry, helping promote competition and access
- ICH S9 guideline on nonclinical evaluation for anticancer pharmaceuticals- Qs&As

### **Medical Writing Journal**

Contributing to Medical Writing is an excellent way to enhance your career and grow as a medical writer by providing:

- Visibility within the medical writing community
- The opportunity to demonstrate knowledge and expertise of a subject
- Professional experience that can be listed on a CV Networking with experts

Several options are available to EMWA members who want to volunteer:

- Provide content for regular sections
- Write feature articles
- Serve on the Editorial Board as a Section Editor Serve on the Editorial Board as an Associate Editor
- Serve as Guest Editor for an issue
- Serve as co-Editor or Editor-in-Chief

For further information, write us at <a href="mailto:mew@emwa.org">mew@emwa.org</a>.

# Joint Position Statement

The Russian translation of the Joint Positions Statement (JPS) is now available. EMWA would also like to thank all of the following people for their excellent work in translating the JPS on the role of medical communicators in the preparation of manuscripts for publication.

By joining with AMWA and ISMPP in both developing and publicizing the Joint Position Statement, EMWA is providing a valuable service to publication professionals around the world by enabling them to more easily read, understand, and apply the principles of the JPS.

# **WEBINAR UPDATE**

This month LIVE webinar will be on the 27th of July from 14:00 to 15:00 CET. Andrea Rossi will talk about **Writing guidelines**.

For more information about this webinar and registration please click <u>here</u>

# **OTHER NEWS**

# Assistant web manager position

We are looking for an assistant to our web manager. If you have the skills and are interested in volunteering, please reply to info@emwa.org.

### **NewsBlast instructions to** contributors

We are adapting our format: Contributions to the NewsBlast should be sent to pr@emwa.org until the 22nd of each month to be published in the following month.

Updates should be concise, **150-200** words long, with a separate and detailed piece of information to be included on one of the EMWA webpages (according to the author's input).



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