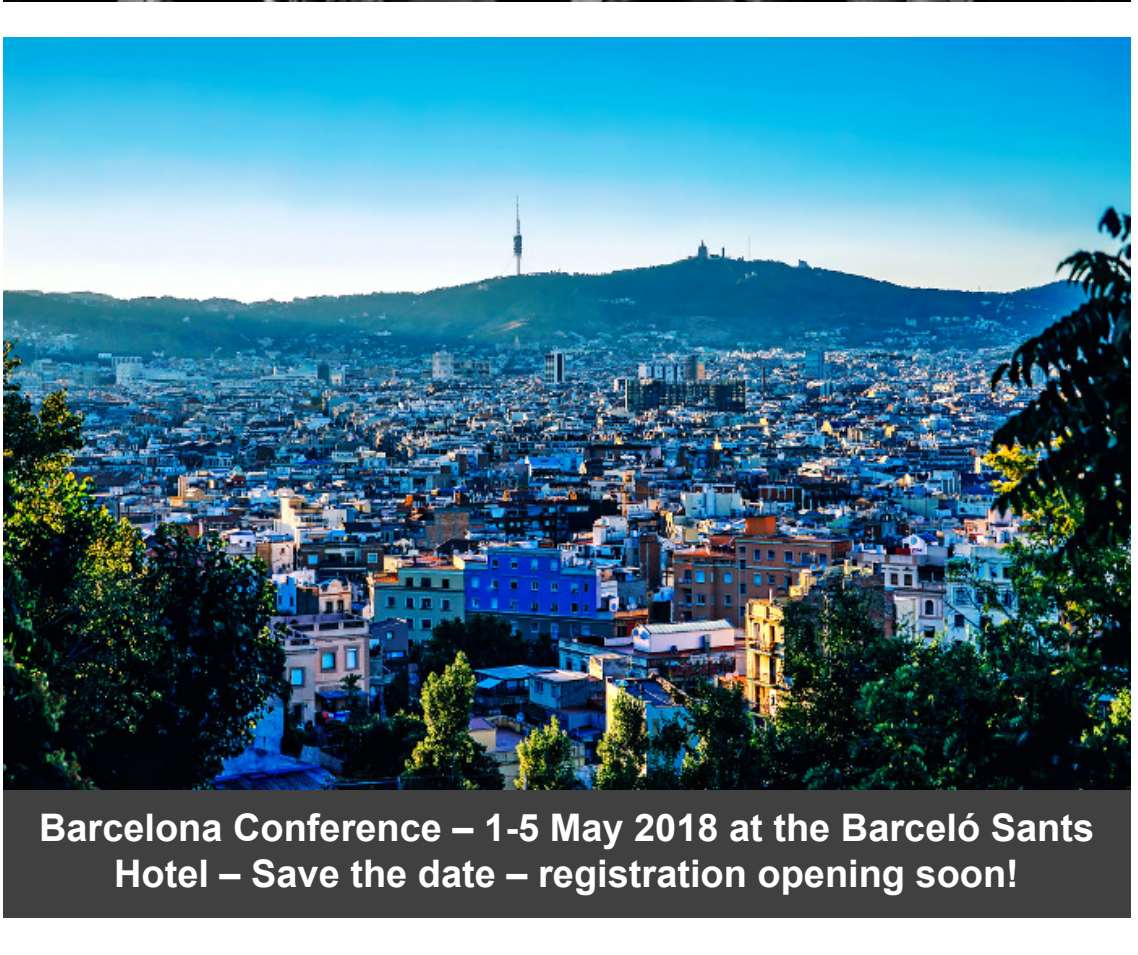
EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA NEWS-BLAST
February 2018

CONFERENCE UPDATES



Barcelona Conference – 1-5 May 2018 at the Barceló Sants Hotel – Save the date – registration opening soon!

Workshops for Barcelona

We will be running 52 workshops in Barcelona, including 5 new topics. They cover a broad range of topics, with about one third of workshops at advanced level.

A preview of the workshops running at the May conference is now available for EMWA members. The preview lists the workshop schedule to help you plan for the conference and discuss training opportunities with your employer. **This preview is for your information only. Head Office CANNOT take advance reservations or bookings before the conference programme is launched in February.**

As well as workshops, there will be lots of other opportunities for learning, including 4 Expert Seminar Series sessions on a range of topics and the 1-day Symposium on medical devices.

EMWA Expert Seminar Series

The EMWA Expert Seminar Series (ESS) is for experienced medical writers, heads of medical writing departments, and industry leaders from other disciplines who want to learn about the latest developments affecting the medical writing industry and play a role in shaping the world of medical writing. This year, EMWA's ESS comprises a range of topics led by international experts. The topics are:

- Pharmacovigilance
- Orphan drugs and rare disorders
- General Data Protection Regulation and Regulatory update: Clinical Trial Registries and Public Databases, and use of Clinical Study Reports for Cochrane Reviews
- Medical journalism

Pharmacovigilance

In March 2017 the European Medicines Agency (EMA) published a major revision of the guidance on Risk Management Plans (RMPs). Five years of experience with GVP Module V, as well as the ongoing dialogue between stakeholders and Regulators, have been taken into consideration.

The revised guidance aims to streamline RMPs, focusing on important risks and missing information (i.e., safety concerns) that have benefit-risk impact and require prospective planning or risk minimisation. In parallel with GVP Module V Rev. 2, the EMA announced an upcoming revision of the guidance on Periodic Safety Update Reports (PSURs) (GVP Module VII) and published updated explanatory notes to GVP Module VII. The new RMP and PSUR will have different focuses and, likely, different lists of safety concerns, thus bringing new challenges to pharmacovigilance writing. Put your questions directly to our PV experts.

On Wednesday, 2nd May during the lunch break there will be a pharmacovigilance roundtable discussion for all medical writers interested or involved in pharmacovigilance.

Orphan drugs and rare disorders

Medical publications and regulatory requirements for rare disorders and orphan drug applications, and other documents (e.g. patient management guidelines) relating to this field may present an authoring challenge.

The most important epidemiological, etiological, and clinical aspects of orphan diseases will be reviewed, and topics such as developing a publication plan, communicating clinical trial data, writing manuscripts and regulatory writing will be discussed.

For regulatory writing, a thorough understanding of marketing authorisation processes; regional differences in incentives; and the implications of potential fast-track designation are essential.

Furthermore, authors of regulatory documents should understand the importance of bringing patients into the co-creation process or the review of regulatory or medical information documents. Attend this ESS for expert "orphan" insight.

General Data Protection Regulation and Regulatory update

Rules governing patient data protections are evolving. Being well informed about EMA Policy 0070, the General Data Protection Regulation (GDPR), and understanding where these requirements overlap is necessary when working in the world of clinical regulatory writing.

Forthcoming additions to the complex disclosure environment expected in 2018 include Health Canada's clinical data disclosure policy guidance. Awareness of the whole is a must for all medical writers.

In this session, 'jobbing' MWs as well as a Pharma disclosure expert and a major CRO's legal expert will help you navigate current requirements.

Medical journalism

What skills are needed for good medical journalism? In this session, the different professional paths between scientific writing and medical journalism, ethical aspects of journalism, and much more will be discussed. You will hear about how journalists' criteria for selecting news have evolved and how these apply to medicine in particular. The session will also include an interactive talk, analysing the mechanics of recognising a story, researching it, and producing cogent editorial material. Finally, you will hear about how writers in medicine can save time by using tools that are readily available on the Internet.

Read more about it

If you like the sound of the Barcelona 2018 ESS programme and want to know more, click here to access the online conference brochure for detailed ESS abstracts and the biographies of the experts delivering your ESS programme. We hope to see you - our experienced contingent - in Barcelona for a stimulating Expert Seminar Series.

Brought to you by EMWA's ESS Committee

Sam Hamilton, Maria Kołtowska-Häggström, Eva-Maria Damsgaard Nielsen, and Tiziana von Bruchhausen.

NEWS OF INTEREST

PV SIG Update

All EMWA members with a deep interest in pharmacovigilance are warmly invited to attend the expert seminar on pharmacovigilance on 2nd May (see ESS programme above).

We gained real experts in the field who will talk about the recent RMP and the upcoming PSUR guidance revision and will answer your questions:

- Martin Huber, PRAC member Germany
- Val Simmons, EU QPPV Eli Lilly & EFPIA Pharmacovigilance Committee
- Jerry Parker, Head of Periodic Safety Reporting Novartis

At lunch break there will be a roundtable discussion on pharmacovigilance. We aim to get together the pharmacovigilance writers within EMWA and offer them an opportunity to network and share their practical experience in an informal way. Don't miss this event!

Regulatory update

The EMA has published the following advice / guidance documents:

- Explanatory note to GVP Module VII (PSURs) and Q&A for assessors
- Pre-authorisation procedural advice for users of the centralised procedure and post-authorisation procedural advice for users of the centralised procedure
- Revision 5 of the "Guideline on the evaluation of anticancer medicinal products in man" (effective in April 2018)

The EMA has published the following material / communication for the public:

- Three video animations (see EMA YouTube channel) to explain how the EMA ensures that medicines are effective and safe for citizens across the European Economic Area
- An updated brochure on the EU regulatory system for medicinal products that provides a high-level overview to the public
- A fact sheet on orphan medicines
- A press release regarding a defect reported with oral plastic syringes pre-filled with Buccolam (epilepsy medicine for children)

The Ukraine published guidance (similar to the EU GVP) on RMPs (Annex 14) and PSURs (Annex 12).

Indian regulators have published a Pharmacovigilance Guidance Document for MAHs (effective in January 2018), which has a major impact on companies in India (e.g. requirements for a pharmacovigilance system master file [PvMF], similar to the EU PSMF, and a PV officer in-charge [PvOI], similar to the EU QPPV).

The Japanese Health Authority has instituted Conditional Early Approval System for Pharmaceuticals in October 2017, which is similar to the Accelerated Approval by the FDA and will allow early approval of drugs intended to treat serious conditions.

The final ICH guideline E17 on general principles for planning and design of multi-regional clinical trials (effective 14 Jun 2018) is available here.

The ICH guideline Q3D on elemental impurities became effective in the EU in December 2017 for authorised medicinal products.

CORE Reference

Background
CORE Reference is a freely available resource for the reporting of human medicinal trials. Explore the website (www.core-reference.org), and key articles

- Non-technical article: 'Safeguarding the privacy of clinical trial patients': http://blogs.biomedcentral.com/on-medicine/2016/05/27/safeguarding-privacy-clinical-trial-patients/

- Technical publication: 'Developing the Clarity and Openness in Reporting: E3-based (CORE) Reference user manual for creation of clinical study reports in the era of clinical trial transparency': http://dx.doi.org/10.1186/s41073-016-0009-4

to understand how CORE Reference came about, and how it can facilitate reporting of modern clinical trials so as to retain the data utility needed to support regulatory decision-making, whilst safeguarding the privacy of participants.

Breaking News

Ten thousand downloads
In January 2018, the CORE Reference **download counter** hit and **exceeded 10,000**. The sheer numbers of individuals downloading CORE Reference means that understanding and awareness of appropriate reporting in an era of data disclosure is taking hold, as can be seen from the groups publicly declaring their support at: http://www.core-reference.org/adoption-and-use/

Plans for Public Disclosure of CSRs In Canada
Health Canada's plans for an autumn 2017 release of guidance to support their **Policy on public release of clinical information** have fallen behind, with no new planned release date indicated. The responsible Health Canada team are aware that CORE Reference is the only known freely-available resource that pinpoints the sections in an ICH E3-compliant CSR that are potentially affected by public disclosure.

To read more about the status of development of guidance to support Health Canada's policy see:

https://www.canada.ca/en/health-canada/programs/consultation-public-release-clinical-information-drug-submissions-medical-device-applications.html

FDA joins the global push towards publication of trial data through CSRs
In January 2018, the FDA made the following announcement https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592566.htm detailing plans to publish CSRs in a pilot scheme "…to evaluate whether disclosing certain information included within CSRs following approval of a NDA improves public access to drug approval information." The plans indicate that the CSR body, protocol and statistical analysis plan will be shared. When the pilot is concluded, public feedback will be sought. Keep watching this space for further developments.

Finally, despite large numbers of you downloading CORE Reference, we need you to tell us about its adoption and use via the dedicated page http://www.core-reference.org/adoption-and-use/. We know from your personal emails that support is widespread, but we need your public declaration of support. Thank you.

Sam Hamilton and Art Gertel
Chair and Strategist for http://www.core-reference.org

MEDICAL DEVICES

The 6th EMWA symposium day will focus on medical devices in general, the recent changes in the European legislations, and opportunities for medical writers.

For more details, check out the programme of the medical device symposium at https://www.emwa.org/media/2531/barcelona-symposium-flyer.pdf

Want to learn more about the medical device special interest group? See https://www.emwa.org/members/special-interest-groups/medical-devices-sig/

WEBINAR NEWS

General Info

EMWA is looking for 3 or 4 volunteers to join the Webinar volunteer team. If you have experience running or presenting webinars, or developing eLearning materials, we would love to hear from you.

This is a concrete opportunity to make meaningful and significant progress in this area as well as make your voice heard. Interested, or any questions please contact Carolina Rojido at webinar@emwa.org.

This Month Info

Our first 2018 webinar will be available on the Webinar archive from Monday 19th February.

Amy Whereat´s presentation on "Writing tips that will change the way you write in English" is a practical and step-by-step guide on sentence building, introductory phrases and link words, comparing and contrasting, as well as some `language myths'.

Please send your questions to webinar@emwa.org before Thursday 11th February and we will endeavor to answer them.

From 19th February - Please go to https://www.emwa.org/training/emwa-webinars-programme-archive/. (nb - this is a pre-recorded session)

EMWA NEWS

As you already know we have been celebrating our 25th Anniversary as an organization and have sent out a specially designed buttons with the December issue of the MEWs. We are planning to have a contest for the best pictures of delegates wearing these buttons so go out and take some pictures and send them to our PR Officer Maria Almeida. The winners will be announced at the conference in Barcelona.

The monthly EMWA NewsBlast has been receiving positive reviews from our members We are now planning to archive all of the past NewsBlasts on the members section of the website.

We have now launched the Ambassador's program where experienced EMWA members will be speaking at career events at universities, career planning days or seminars in Europe. Our first speakers have presented and will present at universities in Reading and London (Alison Rapley), Zurich Switzerland (Raquel Billiones), at clinical development training academies in Rome and Berlin (Tiziana von Bruchhausen), and at the National Clinical Research Conference in Bucharest Romania (Abe Shevack).

The momentum is growing and we are spreading the word about medical writing and EMWA across Europe. If you would be interested giving an official EMWA presentation please contact the Executive Committee.

EPDP news

We are delighted to welcome Alison Rapley, Carolina Rojido and Laura Collada Ali as members of the EMWA Professional Development Committee (EPDC). Alison will be focusing on supporting the workshop programme, while Carolina and Laura will be working together on the webinar programme.

New Webeditorial

Read this before bombarding your next web article.
https://www.emwa.org/news/new-webeditorial-how-to-write-an-unsuccessful-web-article/

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