



EMWA News

Spring conference in Vienna

Last year, the November conference in Warsaw reached a record of attendees. Now, we are two months away from the annual spring conference in the beautiful city of Vienna, and we are beyond excited. This time, the 7th EMWA Symposium will focus on “Real-World Evidence: A Central Role for Medical Communicators”, and there will be an offering of more than 50 workshops, including many on new topics. Check out the Vienna conference minisite (<http://vienna.emwa.org>) for detailed information.

Joint Position Statement on the Role of Professional Medical Writers

We also have some exciting news regarding the Joint Position Statement on the Role of Professional Medical Writers (JPS). Over the past several months, the 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. Moreover, the recognition of the JPS has been underscored by endorsements and communications from organisations around the globe including:

- The Enhancing the QUALity and Transparency Of health Research (EQUATOR) Network
- European Association of Science Editors (EASE)
- Australasian Medical Writers Association (AusMWA)
- Association of Regulatory and Clinical Scientists (ARCS Australia)
- The Council of Science Editors (CSE) and Board of Editors in the Life Sciences (BELS)

Clinical trial transparency and data disclosure

On another note, PhUSE has released a paper developed by industry experts with the goal of highlighting the evolving global landscape of clinical trial transparency and disclosure with

special focus on individual study and submission-related requirements, which you can find on EMWA's website.

Additionally, three new resources on data sharing have recently been released:

1. Schmidt H, Caldwell B, Mollet A, Leimer HG, Szucs T. An industry experience with data sharing. *N Engl J Med*. 2018 Nov 22;379(21):2081–2. <https://www.nejm.org/doi/full/10.1056/NEJMc1805610>.
2. EMA Data anonymisation – a key enabler for clinical data sharing Workshop report. 4 December 2018. EMA/796532/2018. https://www.ema.europa.eu/documents/agenda/agenda-data-anonymisation-workshop_en.pdf
3. European Medicines Agency policy on access to documents POLICY/0043 updated. <https://www.ema.europa.eu/en/about-us/how-we-work/access-documents>



Veterinary medical writing

Since the last conference in Warsaw, there has been a rising interest in veterinary medical writing, which has led to the introduction of a new regular section in the journal and a Veterinary Medical Writing Special Interest Group.

Journal themes for 2019 and 2020

Finally, the following are the themes for journal issues planned for 2019, and we are already thinking about the topics for 2020. The editors are always looking for fresh ideas, so, please contact the journal office (MEW@emwa.org) if you think of a topic that should be covered.

- June 2019: Generics and Biosimilars
- September 2019: Trends in Medical Writing
- December 2019: Artificial Intelligence & Digital Health

Webinars in 2019

If you haven't checked them out yet, we have an amazing lineup of webinars for this year. Register on the website and don't miss them!

- **April:** "Checking House Styles: Customising PerfectIt for Advanced Users" by Daniel Heuman
- **June:** "Covering your first medical advisory board meeting: tips and tricks" by Laura Carolina Collada Ali
- **July:** "Nutrition basics" by Carolina Rojido
- **August:** "Writing your first white paper for the medical devices industry" by Laura Collada Ali
- **September:** "Pharmacovigilance writing: monitoring and enhancing patients' safety throughout the life-cycle medicinal products" by EMWA President Tiziana von Bruchhausen
- **October:** "Whole foods plant based (WFPB) science" by Carolina Rojido
- **December:** "Personal experience from transitioning from Pharma to Medical Devices" by Sarah Choudhury

Special Interest Groups

Regarding EMWA's Special Interest Groups (SIG), the new Medizinprodukte-Sicherheitsplanverordnung (MPSV) for Germany has been released end of November 2018.

Interested in volunteering for EMWA?

Keep in mind that EMWA is run by volunteer medical writers just like you. So, if you would like to contribute to any of our teams (congress planning, journal, website, social media team, conference advertisement, webinars team, internships project, workshop leaders, pharmacovigilance special interest groups, freelance business group, finance, etc.), don't hesitate and contact us (info@emwa.org)! We would love to hear from you.

Open Access Clinical Study Report (CSR) Template

In November 2018, TransCelerate Biopharma – an alliance among some of the world's prominent biopharmaceutical organisations - released a clinical study report (CSR) template.

TransCelerate's CSR template was developed using the two "well-known standards" – ICH E3 and CORE Reference (www.core-reference.org). The EMWA-AMWA CORE Reference development team was not involved in the TransCelerate CSR template development work.

Read our Press Release on TransCelerate's CSR template and use of CORE Reference in its development: <https://www.core-reference.org/news-summaries/core-reference-statement-on-transcelerate-csr-template/>

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