EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast- February 2021

|MC:TOC|

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Webinar Programme News - Preview for 2021

March 2021 (exact date to be confirmed)
The impact of COVID-19 on the content of clinical trial documentations: new requirements!
Raquel Billiones

April 2021 (exact date to be confirmed)
Transitioning from Medical Translation to Medical Writing
Laura C Collada Ali & Paz Gómez-Polledo

2021 (exact date to be confirmed)
MedCom via video? Veterinary medicine on YouTube as an example of communicating medicine to a lay audience.
Karim Montasser

Regulatory News

Click here to read this month's Pharmacovigilance SIG news:

- Invitation to webinar on Real world research on medicines: contribution of the European Network of Centres in Pharmacoepidemiology and Pharmacovigilance (ENCePP) on 8 March 2021
- Direct healthcare professional communication (DHPC): Metamizole: Risk of drug-induced liver injury
- Article on "The European Medicines Agency's EU conditional marketing authorisations for COVID-19 vaccines"
- Recent EMA's communications on COVID-19 vaccines
- Adverse reactions, medical device incidents and health product recalls in Canada: 2019 summary report available
- Health Canada releases Notice of clarification to drug manufacturers and sponsors: Canadian-specific considerations in risk management plans
- FDA Guidance on Providing Regulatory Submissions in Electronic Format - Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling released
- FDA Final Guidance on Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products released
- FDA Draft Guidance on Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act released
- FDA's Center for Drug Evaluation and Research (CDER) lays out 2021 agenda
- Public consultation open for EMA's Guideline on good pharmacovigilance practices (GVP) - Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 3)
- Public consultation open for EMA's Guideline on good pharmacovigilance practices (GVP) - Module XVI Addendum II – Methods for effectiveness evaluation

Regulatory Public Disclosure:

Click here to read this month's Regulatory Public Disclosure news:

- EMA "CTIS Highlights" Issue 02; CTIS Training; CTIS Rollout Dec 2021
- PHUSE COVID-19 Impact on May 2020 Clinical Trial Transparency Update
- Final FDA Guidance: Research Participant Confidentiality
- PHUSE Data Transparency Meeting
- EPA Rule - transparency in developing regulatory guidances
- 14th ISCR Annual Conference 2021: Virtual Medical Writing Workshop

Check out the Latest edition of Medical Writing

available online and in print

here!

Want to help run a webinar?

It's not too late to let us know if you are interested in joining the webinar team and learning how to run an EMWA webinar. We will be providing training soon on using the webinar software and the procedures we use on the day. You will need to be available to run webinars live on the day a few times a year.

For more information, contact webinar@emwa.org

EMWA workshops

Congratulations to everyone who gained credits from the workshop programme in November. The EMWA Professional Development Committee is now planning a workshop schedule for the May conference. More information soon!

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