EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast - November 2019

Malmö Conference: Looking forward to seeing you there!

View your conference registration details in this short video.

Ambassador Group Meeting

As a reminder for those attending the Malmo conference and who would like to attend the lunch time Ambassador group meeting, we plan to meet on Saturday from 11:45-13:15 in the Dialogue room (adjacent to the lunch area in the foyer on the conference floor). You are welcome to bring along any other interested delegates.

Medical Writing News

Interested in Being a Guest Editor for the September 2020 issue on EU Regulations?

Medical Writing is looking for a Guest Editor for the September 2020 issue on EU regulations. This is a great opportunity for increasing your visibility as an expert in this area. Your responsibilities as Guest Editor would be:

Come up with ideas for articles related to EU Regulations. We are looking for 6 to 8 articles.
Find and confirm contributors for each of the articles. Contributors do not need to be EMWA members.

Once you have found authors, communicate the names, email addresses, and topics to our Managing Editor. We will take care of chasing after and communicating with the contributors.

Write the introductory editorial. It should be 400-600 words.

The deadline for the issue will be June 9, 2020.

If you are interested, please write mew@emwa.org.

EMWA/AMWA/ISPP Joint Position

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) recognize the challenges to scientific publishing being posed by predatory journals and their publishers, which employ practices undermining the quality, integrity and reliability of published scientific research. The joint position statement complements several other sets of guidelines that have helped define the characteristics of a predatory journal.

By joining with AMWA and ISMPP in both developing and publicizing the Joint Position Statement on predatory journals, 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 this JPS.

In order to raise awareness among non-English speakers about the responsibilities of medical writers and publication professionals concerning this significant issue, EMWA has initiated the translation of this statement into European languages. We are proud to announce the posting of the first JPS translation into Portuguese by Diana Ribeiro and reviewed by Maria João Almeida. In order to access the translation please click here.

We are currently looking for translators. If you would like to volunteer please contact Abe Shevack (aspscientist@gmail.com) or the EMWA Head Office (info@emwa.org).

Ambassadors Programme News

The EMWA Ambassador Programme's continues to reach out to new audiences to promote medical writing and EMWA.

John Carpenter attended a Network Pharma, Medcomms event in Manchester on 10 Sept. Altogether about 70 students attended with the EMWA banner displayed. John answered students' questions during the general exhibition.

Tiziana von Bruchhausen gave a talk about EMWA and careers in medical writing at the Dr Notghi Academy in Berlin on 13 Sept to a group of clinical professionals in training. The presentation went well and Tiziana will be repeating this talk at regular intervals in the future.

John Carpenter gave a well-received talk on EMWA and medical writing the University of Birkbeck careers fair in London on 28 Sept. He also manned an exhibition table where he answered students' questions and gave out promotional material. In fact one of the students contacted John to say that she will be attending the EMWA Malmo conference.

Anne McDonough gave a presentation at a well-attended career event at the University of Essex in Colchester on 18 Oct. Altogether 60-80 attended the talk where she answered a lot of questions about medical writing. There was a lot of interest in the MEWs issue on careers in medical writing.

In other news, Abe Shevack has initiated a collaboration with the German Scholars Organization (GSO) (https://www.gsonet.org/) headed by Dr. Anne Schreiter. This is a not for profit group with around 5000 members whose main focus is helping young academics to find positions in Germany As part of this collaboration, Abe has been invited to participate in a webinar interview on 25 Nov to talk about medical writing, getting your foot in the door, and how EMWA supports medical writers.

Regulatory Public Disclosure

Docket FDA-2019-N-2012 Update – Perspectives Vary on FDA's Proposed Integrated Review Template

You may recall that FDA Docket "New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication" was opened in summer 2019. Comments were invited on FDA's proposed Integrated Review Template as a possible alternative or addition to the publication of redacted clinical documents adopted by some authorities (e.g. EMA and health Canada). Mine and Art Gertel's comments are posted here on the FDA Docket (as well as on the CORE Reference website).

A total of 22 sets of comments are posted. These make interesting reading; I encourage you to read them for yourself in full. In the meantime, below are my 'take home points' on perspectives of interested stakeholders including:

Industry associations

- PhUSE's Data Transparency Working Group
  - Suggest that reidentification attack risk is higher in the proposed FDA Integrated Review compared to the redaction approach taken by EMA and HC - as applied directly to publication of clinical documents
- PhRMA & Biotechnology Innovation Organization
  - Both support the use of the FDA Integrated Review, and suggest to abandon the publication of redacted clinical documents
- Combination Products Coalition
  - Request publication of discipline-specific review memos, in addition to the proposed FDA Integrated Review

Publications professionals

- Cochrane; BMJ and PLOS (joint comments)
  - All support providing the CSR, protocol and SAP in addition to the proposed FDA Integrated Review document

Pharmaceutical companies

- Leo Pharma
  - Point out the non-alignment of redaction approach with some other health authorities [EMA, HC]. Support the proposed FDA Integrated Review

Data and analytics company interested in real-world data

- Flatiron Health
  - Suggest that totality of evidence, including any consultative reviews, are included in the proposed FDA Integrated Review

Charities

- Lupus Foundation of America & Cancer Support Community
  - Both want patient experience data considered in the decision-making process.

ISO14155 (GCP for Medical Devices) Update

The new ISO14155 GCP update is here and transparency is one of the key additions for medical devices with postings required in a publicly accessible database. Read Raquel Billiones' summary here of this critical update.

Generation of Synthetic Clinical Trial Data

I am pleased to share Replica Analytics' Webinar materials from 4th October 2019 on the generation of synthetic clinical trial data. Please find below the links to the webinar materials:
The complete set of slides can be downloaded, together with a recording of the webinar.
Feel free to distribute this information to your colleagues and others in your network. Spread the word about synthetic data, how it is generated, and its benefits.

Given the necessary protections around 'real' clinical trial data, we should understand about upcoming alternatives.

Recent Clinical Trial Transparency Publications

Baronikova et al remind us that improvements in clinical trials disclosure are needed in their publication. Commitments by the biopharmaceutical industry to clinical trial transparency; the evolving environment in BMJ Evidence-Based Medicine.

Nature Medicine aligns with International Committee of Medical Journal Editors guidelines in requiring prospective registration of interventional trials in a publicly available database as a pre-requisite to publishing papers on clinical trials in this October 2019 Editorial 'Raising the bar on Clinical Research'.

MHRA Updates

The MHRA is currently publishing numerous documents in anticipation of a possible Brexit on 31-Oct-2019. An update to their Pharmacovigilance webpage can be found here.

Substantial document describing how UK pharmacovigilance will deviate from EU GVP is 70 pages of a Module by Module, paragraph by paragraph description of where UK pharmacovigilance will deviate from EU GVP modules

The document can be found here.

Pharmacovigilance news

- Exceptions and modifications to the EU Guidance on Good Pharmacovigilance Practice in case of a no-deal Brexit
- Mandatory use of eCTD format expanded for regulatory activities by Health Canada
- PRAC recommends four-week limit for use of high-strength estradiol creams
- New Zealand's regulatory authority have extended their timeline for reporting medical device-related adverse events
- Monthly PDF editions (including the October 2019 edition) of the Drug Safety Update newsletter from MHRA and its independent advisor the Commission on Human Medicines available

EMWA News Archive

You can access older EMWA news here.

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