EUROPEAN MEDICAL WRITERS ASSOCIATION

EMWA Newsblast- May 2021

EMWA virtual conference 4-25 May

Some days left until the end of our 2nd Virtual Conference, and we can already anticipate its success! We thank all the members, workshop leaders and participants for making this possible!

EMWA upcoming seminar on lay language summaries - Friday 28 May

We are pleased to invite you to the following seminar on lay language summaries organized by Parexel (BRONZE sponsor of the 51st EMWA conference)

All those who registered for the 51st EMWA conference will receive the Zoom details for this seminar automatically. If you were not able to attend the conference but would like to attend this seminar please email emwaconference@emwa.org in order to receive the details.

Date: Friday 28 May

Time: 12:00-13:30 CEST

Breaking through the regulatory ropes and scientific shackles – thinking "patients first" in lay language summary development

Presenters:

Shruti MP, Associate Director, Medical Writing, Parexel

Sarah Yelling, Account Manager, Patient Communications, Parexel

Beware of a phishing emails

We want to reassure you that no data breach has occurred due to an email that has been circulated to some members. Please never click on a link from an email you suspect may not originate at EMWA.

Have you updated your EMWA profile?

We are working on an improved Member Directory. We request you to opt-in if you want to be listed on the new Member Directory. Stay tuned for more information!

Call for volunteers

The PR team is looking for some volunteers to help with posting in social media, and preparing this Newsblast. If you want to be part of the team, email pr@emwa.org.

New Joint Position Statement on Medical Publications, Preprints, and Peer Review

The American Medical Writers Association (AMWA), the European Medical Writers Association (EMWA) and the International Society for Medical Publication Professionals (ISMPP) have collaborated in preparing a Joint Position Statement on Medical Publications, Preprints, and Peer Review. The purpose of this document is to advocate the adaptation of standards by researchers/authors, qualified peer reviewers, and journals editors to ensure the integrity of published scientific and medical information. The document contains suggestions and an extensive checklist to ensure data integrity and quality as well as transparency in medical publications.

In order to raise awareness among non-English speakers about this important initiative EMWA has begun the translation of this statement into European languages.

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).

MedComms Day is 9 June

The plans are now set out at https://medcommsday.com/ and Peter hopes you will join in and encourage your own communities to participate in whatever ways and however much you/they like. There will be several free meetings and it would be great to see others running their own activities.

Despite the strange times we live in, hopefully once again we'll see people from across the globe, starting in New Zealand and ending over on the West Coast USA, contributing stories and photos and videos and so on that reflect their #MedComms Day.

EudraCT and EU Clinical Trial Register - Updated FAQs

EudraCT & EU CTR Frequently Asked Questions were updated on 16 April 2021. There is plenty of interest about publication in the CTR, and on results postings.

CTIS Major Milestone

EMA confirmed that the clinical trial EU Portal and Database, one of the main deliverables of the Clinical Trial Regulation and the key component of the Clinical Trial Information System (CTIS), is now fully functional and on track to go live by 31 January 2022. Read all about it in this press release.

ICH E6 R3 Draft Guidelines

On 19 April 2021, the International Council for Harmonisation (ICH) Management Committee released the first draft document from the ICH's GCP E6(R3) renovation process. The GCP principles document (dated March 2021) is not issued for public consultation but has been published as a work in progress in order to facilitate transparency and understanding. The document states that the "overarching principles provide a flexible framework for clinical trial conduct. They are structured to provide guidance throughout the lifecycle of the clinical trial. These principles are applicable to trials involving human participants, i.e., healthy volunteers or patients. The principles are interdependent and should be considered in their totality to assure ethical trial conduct and reliable results". The ICH E6(R3) Expert Working Group is organising a web conference on 18–19 May 2021 to present the current draft of the GCP principles and E6(R3) development.

Public Web Conference to Provide Progress Update on ICH E6 Guideline for Good Clinical Practice

Regional regulators are to be present at a free public web conference convened by the ICH E6 Expert Working Group on 18 and 19 May 2021. The meeting will provide a status update on revisions to the ICH E6 Guideline for Good Clinical Practice. Registration is now open for Tues 18 May 2021 or Wed 19 May 2021.

FDA Name and Shame for ClinicalTrials.gov Postings Failures

FDA announced that action is being taken for Sponsor failures to submit the required summary clinical trial results postings on ClinicalTrials.gov.

The first 'Notice of Noncompliance' was issued to Acceleron Pharma on 27 April 2021.The Sponsor has 30 days to submit results for a study of dalantercept and axitinib in patients with advanced renal cell carcinoma. Interestingly, there is a link to a publication on ClinicalTrials.gov under results for this study (NCT01727336). The FDA reiterate that they are authorised to seek civil money penalties if Acceleron do not comply.

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