EUROPEAN MEDICAL WRITERS ASSOCIATION

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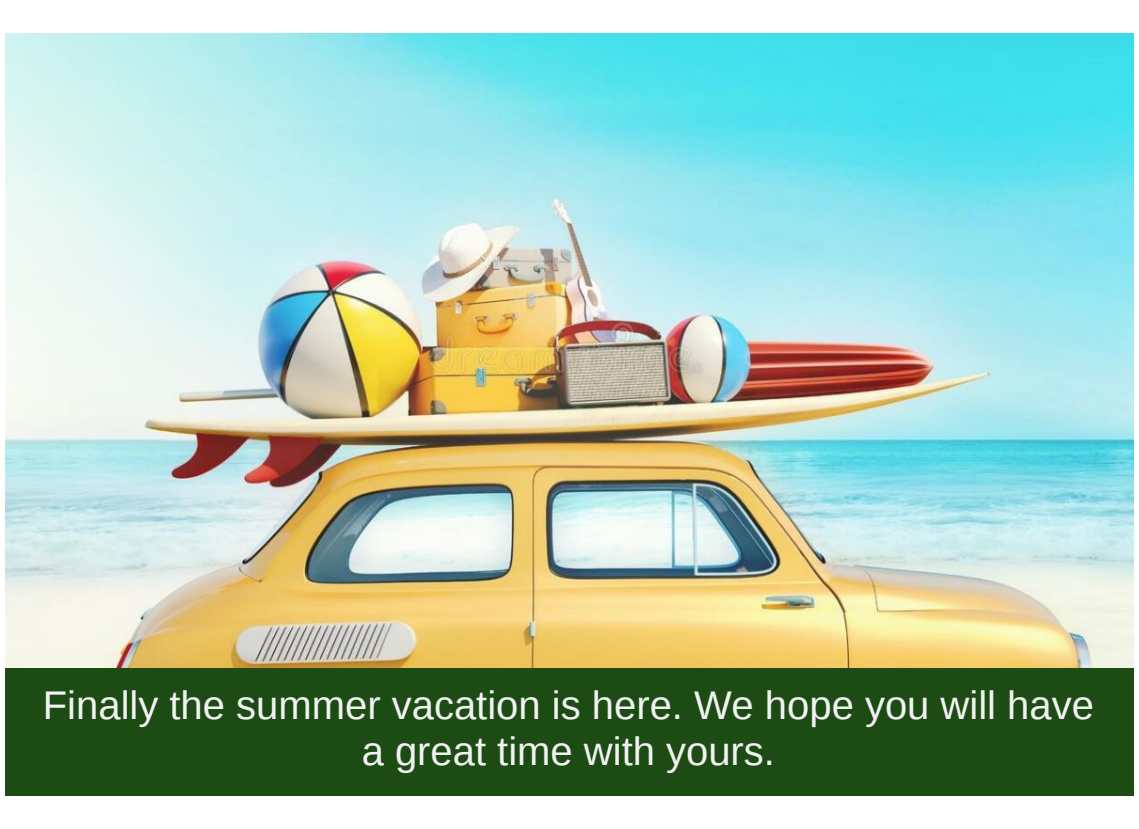

Finally the summer vacation is here. We hope you will have a great time with yours.

Winner of the Nick Thompson Fellowship 2022

The Nick Thompson Fellowship Award is intended as recognition of service to EMWA above and beyond the normal responsibilities of the membership or elected offices.
It is a pleasure to recognize a 26-year member, Raquel Billiones, as one who has contributed to the evolution of EMWA in many ways, since becoming a member in 2006. She has worn many different hats: including, as co-founder and co-chair of the medical device special interest group, which led to establishing the medical device education track. Medical device training has become an integral part of EMWA's curriculum, and nearly all workshops are fully- booked, demonstrating the recognition of the value of training in this discipline.
Raquel marshals her energy and dedication to embody the very spirit of the Nick Thompson Fellowship, and it is with great pleasure that we welcome Raquel to the Band of Fellows.

Freelance Business Group subcommittee: come join the team!

The freelance business group (FBG) focuses on all things freelance. We have a subcommittee of 5 people and are looking for new volunteers. We have several new initiatives that we want to push forward this year and are seeking for proactive freelancers who can dedicate some time every month to these projects. If you are a freelancer, enthusiastic to volunteer for EMWA and have some time to spare, please contact the FBG chair Laura A. Kehoe at freelance@emwa.org

First EMWA translators' meet-up!

Claire Harmer and Aurélie Gobet will be holding the first EMWA translators' meet-up on Zoom on 7th July at 10am BST (11am CEST). The idea is for EMWA's translators to meet, get to know each other and share ideas/skills/advice. It could end up becoming a regular event in future (if there's enough interest!).
We sent out an email invite on Monday 20th June and did our best to include any EMWA members listed as translators, but we're sure there are some people we have missed! If that includes you and you're interested in attending this event or another meet-up in future then please let us know via info@emwa.org. We can then add you to our mailing list, which you can unsubscribe from at any time.

Upcoming July Webinar

The 10 Most Common Misconceptions New Freelance Medical Writers Have & Why They're Wrong
by Sophie Ash, BSc (Hons), DipION

Tuesday 19th July 2022, 17:00 CET

It's not uncommon for fresh-faced freelancers to feel overwhelmed when embarking on entrepreneurship for the first time. Suddenly faced with the prospect of self-promotion, branding, sales, and negotiation, it's easy to lose momentum, or get stuck before you're even out of the gate. "How much should I charge?", "Is networking essential for my success?", and "What should I put in my portfolio?" are just a handful of the questions that are probably running through your jittery mind. Rest assured, this is totally normal. If you act now, you can get back on the straight and narrow, well on your way to increased freedom and flexibility in your freelancing business. It's time to show up for yourself and quit floundering. Avoid making the ten most common mistakes that new freelance medical writers make by learning from others' business blunders.
Learning Objectives:
- List the top ten most common misconceptions that new freelance medical writers make
- Create an action plan to help you and your freelance medical writing business thrive

Contact EMWA to register.

Ambassadors Programme News

The EMWA Ambassador Programme's is continuing its efforts to reach out to new audiences to promote medical writing and EMWA.

On 11 June, Sally Hill gave an introduction to medical writing and EMWA for a group of 18 translators, interpreters, editors and copywriters in Utrecht. These language experts were attending a workshop organized by SENSE, the Society of English-language professionals in the Netherlands. Like EMWA, SENSE has special interest groups (SIGs) and the full-day workshop on medical translation, medical editing, and medical writing was organized by the SENSE Medical SIG. Some attendees were old hands while others were at the early stages of their careers. Several expressed an interest in EMWA, and one medical editor based in Germany has already become an EMWA member!

On 19 Sept Sarah Choudhury will represent EMWA at the Network Pharma Medcomms Career Event at the **at the Radisson Hotel & Conference Centre at London Heathrow.** Around 400 participants including employers from Medcomms agencies and new comers seeking career information are expected. If you have medical writing experience in either MedComms or HEOR/market access and would like to serve as a panel discussion moderator or if you would like to volunteer to help man the EMWA exhibitor table at this event please contact Abe Shevack (aspscientist@gmail.com).

In October 2022, Beatrix Doerr will present an online webinar in German to young scientists who are members of the German Association for Epidemiology, Biostatistics and Medical Informatics (GMDS). The topic and date of the webinar will be announced.

If you are an experienced medical writer and EMWA volunteer and are interested in becoming an EMWA Ambassador or if you know of any upcoming career events in your locality please contact Abe Shevack (aspscientist@gmail.com).

SUS SIG and PV SIG joint webinar – Thursday, Sep 15, 2-3 pm CET

Title: *Joint PV SIG / SUS SIG Webinar: Assessing and Reporting Environmental Risk for Human Medicinal Products throughout Development*
Speakers:

- Diana Radovan PhD ELS, *Head of Regulatory Affairs Europe* at *Plusultra pharma GmbH* and *PV SIG Committee Member*
- Liron Sarid-Krebs PhD, *Senior Consultant/Team Lead* at *Biopharma Excellence, a PharmaLex Company*

Time: Thursday, Sep 15, 2-3 pm CET

How and Where to register: Please contact EMWA's Head Office (info@emwa.org)

Save the date! SUS SIG and PV SIG joint webinar – Thursday, September 15, 2-3 pm CET

Assessing and Reporting Environmental Risk for Human Medicinal Products throughout Development ***by Diana Radovan, Plusultra pharma GmbH and Liron Sarid-Krebs, Biopharma Excellence***

Read more details in EMWA's webinar programme webpage.

Biotechnology Section contributions wanted
Contact the EMWA journal Biotechnology Section editor, Jennifer Bell (JenBellWS@outlook.com), with contributions for upcoming quarterly columns in EMWA's journal, Medical Writing. Contributions are wanted that reflect medical writing at different stages of a biotechnology product lifecycle and services that support product development, including and not limited to education, research and development, bioinformatics, manufacturing, packaging, supply chain, AI, and bio-banking.

EMWA PV SIG Meet&Share on Developmental Risk Management Plans (dRMPs) Monday 26th September 2pm CET

Email: info@emwa.org to receive your registration invite

We look forward to lively discussions and exchange!

Clinical medical writers and pharmacovigilance writers, you are welcome to join!

Thank you,

The EMWA's PV SIG

Regulatory news

Medicines and Vaccines

ICH
1. The International Council for Harmonisation (ICH) held a successful hybrid Meeting in Athens on 21 to 25 May 2022. Reports were received from all the ICH Working Groups on their activity status, there was a report from the MedDRA Management Committee, and updates on important ICH activities in relation to training and communication. A summary of the meeting is on the ICH Official website.

CTR and CTIS

1.Clinical Trials Highlights Issue 9 (May 2022) is out now.

2. An EMA CTIS webinar will take place on 01 July 2022, 09.30 to 13.30 CET. There is no need to register – the event will be broadcast live. The event will look back at 6 months of CTIS and will also look to the future.

EU Regulatory

1. A new Brookwood webinar is planned for 28 June 2022 at 13.00 UK time: 'Overview and impact of ICH E8(R1) on clinical trials'.

2. The European Commission's Q&A document on EU CTR 536/2014 is at Version 6.1 , last updated May 2022; there is a new Q&A on complex clinical trials ; and a Q&A on the interface between the CTR and Regulation EU 2017/746 (which covers in vitro medical devices). All are available as 'Latest updates' at the bottom of this page.

3. Draft EMA Guidance titled "Guidance document on how to approach the protection of personal data and commercially confidential information in documents uploaded and published in the Clinical Trial Information System (CTIS)" is open for public consultation until 08 September 2022.

4. A list of metadata for real-world data catalogues is published on the Big Data EMA webpage to help pharmaceutical companies and researchers to identify and use such data to investigate the use, safety and effectiveness of medicines.

5. Publicly available clinical data are published on EMA's Clinical Data webpage for COVID vaccines Nuvaxovid, Spikevax ,and Cominarty – all in June 2022.
6. The EMA and Health Canada co-chaired the latest global regulatory workshop on COVID-19 observational studies and real-world data on 20 May 2022 and discussed collaboration on observational research during the pandemic.

7. The EMA, EC, and HMA have jointly issued a Q&As document on conducting complex clinical trials (CCTs) on 23 May 2022. It provides guidance to support sponsors, clinical trialists, and applicants regarding scientific aspects and the planning, set-up, submission for obtaining CT authorisation, conduct, reporting and transparency, analysis and interpretation of CCTs under the EU CTR as well as their use in submissions for marketing authorisation.

UK and MHRA News

1. MHRA has joined three international partnerships to set global standards for medicines and medical devices regulation. The partnerships are with ICH , IMDRF and MDIC .

2. The wide-reaching effect of the COVID-19 pandemic on healthcare resource has led the UK's National Health Service (NHS) Health Research Authority (HRA) to ask sponsors and funders of research within the NHS to urgently review their study portfolios, with the aim to make changes or close 'unviable' studies in order to release resource and funding for other studies. Guidance has been issued by the HRA on how to manage changes to studies, stop recruitment or close studies, with the necessary assessments of risk-benefit and ethics, and also how to make the data available.

FDA Guidance and News

1. The FDA continues oversight of trials during the COVID-19 pandemic and has released the 2021 data of its annual inspection metrics for the compliance programs within the Bioresearch Monitoring (BIMO) program.

2. FDA will run 2 public meetings on patient-focussed drug development (PFDD) 'Using Methods from PFDD Guidance 1 and Guidance 2 as Tools for Including Patient Experience Data in Clinical Trials: Who to Ask and How to Ask ' – dates 30 June and 25 July 2022.

3. A joint study published in Therapeutic Innovation & Regulatory Science on 24 May 2022 , authored by representatives from the FDA and EMA stresses value of EU-US ongoing collaboration on GCP inspections. GCP inspection findings between the 2 agencies were comparable, providing support for continued FDA-EMA GCP collaboration.

Real-World Data

1. eHealth Network (a voluntary network set up under article 14 of Directive 2011/24/EU who provides a platform of Member States' competent authorities dealing with eHealth) released a "Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU " in Jun 2022.

2. The Clinical Trials Transformation Initiative (CTTI) held a multi-stakeholder Expert Meeting on 11 May 2022 to discuss recommendations for embedding elements of clinical trials into routine care . More resources are expected to be released in late 2022.

Transparency and Disclosure Resources and News

1. In the previous CORE Reference News Summary of May 2022 , we cited the TranspariMED article and report by Prescrire on the alleged decline in access to information on drug trials in Europe in recent years. As reported in an update to the TranspariMED article, EMA has pushed back against Prescrire's criticisms. EMA has also responded to articles on transparency published in the BMJ .

2. Issue 9 of EMA's Clinical Trials Highlights newsletter reports that as of 30 April 2022, 56 clinical trial applications have been submitted for evaluation via CTIS, and 4 clinical trials are authorised and publicly viewable through the CTIS public search function.

3. Reminder of PHUSE's Data Transparency Summer Event – on 28-30 June 2022. Agenda here; register here.

4. Dormer et al. published an article on plain language summary "A practical 'How-To' Guide to plain language summaries (PLS) of peer-reviewed scientific publications: results of a multi-stakeholder initiative utilizing co-creation methodology".

5. The CPDP2022 workshop "State-of-Play of De-Identification Techniques " took place in Belgium on 25 May 2022, and a recording of the workshop is available on YouTube.

Development Strategy News

1. This LinkedIn Group 'Protocol Development' issues interesting articles on the topic. Issue 8 (27 May 2022) includes links to a number of useful papers, on for example, basket trials and platform design trials . There are many more papers in this issue that caught my eye, so I suggest that you sign up to join the group to access all the materials in this issue and others.

2. The WHO published a draft resolution (proposed by Argentina, Peru, and the UK) 'Strengthening clinical trials to provide high-quality evidence on health interventions and to improve research quality and coordination '. A call is made to strengthen national capabilities to comply with international standards of trial design and to strengthen policy frameworks. There is also the suggestion that publicly available protocol design critiques should be made available by regulators, as well as other transparency initiatives.

News from Asia Regulators

1. The Drug Regulatory Authority of Pakistan (DRAP) has published the final guidelines on clinical trials applications for therapeutic goods in Pakistan, which provides advice on new applications for clinical trials, subsequent submissions, regulatory requirements, procedure for submission, review, evaluation and approval of applications for the conduct of clinical trial.

Medical Devices

Medical devices information is kindly compiled by Raquel Billiones.

1. MCDG 2022-10 Q&As on the interface between EU CTR and IVDR issued on 25 May 2022
The Q&As aim to clarify certain interfaces between the CTR and the IVDR and to support the conduct of clinical trials using diagnostic assays, including combined trials for the development of companion diagnostics.

2. In Switzerland (26 May 2022), clinical trials with in vitro diagnostic medical devices will be regulated by the Ordinance on Clinical Trials with Medical Devices instead of the Ordinance on Clinical Trials. This came into effect concurrent with application of Regulation (EU) 2017/746 on in vitro diagnostic medical devices in the EU (see next point).

3. European Federation of Pharmaceutical Industries and Associations (EFPIA) has issued a statement on the Regulation (EU) 2017/746 for in vitro diagnostics. The new regulation aims to ensure a high level of public and patient safety, but the EFPIA highlight that there are still some aspects of use of these devices in clinical trials that have not been addressed.

Opportunites for Medical Writers in the UK

The Health Research Authority in the UK has an exciting opportunity for more members to join their Research Ethics Committees (RECs). They are looking for people who are passionate about health and social care research to review applications for research studies Committees are made up of volunteer members who give their time to make a difference. The work is varied but includes some of the biggest challenges we face in health and social care today, from cancer to dementia, and more recently COVID-19.
You'll gain a wealth of skills which can help with your career including an understanding of research ethics, an increased knowledge of research including methodology and statistics, an understanding of relevant legislation, specialised knowledge in areas such as paediatric research or adults lacking capacity to give consent, enhanced committee skills including summarising, debating, evaluating and decision making.
In return you will need to commit to attend at least six REC meetings a year virtually via zoom, take part in sub-committee work via email, review research applications and amendments electronically through the members' portal or email, take part in relevant training.
Interested? There is a lot more information at #StepForward Become a REC member - Health Research Authority (hra.nhs.uk) or you can contact member.recruitment@hra.nhs.uk.