EMWA Newsblast- June 2021

Nick Thompson Fellowship Award

The Nick Thompson Fellowship Award is a recognition of service to EMWA above and beyond the regular responsibilities of the membership or elected offices. It confers lifetime free EMWA membership on the elected fellows. Fellow 2021 is Phil Leventhal for his outstanding contribution to Medical Writing as Editor-in-Chief from 2011 to 2020, we are honoured to award Phil the Nick Fellowship Award and name him Editor Emeritus of its journal.

EPDP Badges – have you got yours already?

Have you gained a foundation or advanced certificate at EMWA and want to more prominently display it as electronic certificate on LinkedIn, your website and emails?

Then contact EMWA Head Office at info@emwa.org .

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.

Let's Meet Up in Switzerland

Are you based in Switzerland/Schweiz/Suisse/Svizzera (no, not Suez) and working as a medical writer/medical communicator or curious about the field/ medical writing and communications or maybe even interested in trying it out? Do you want to network with others in the field?

Let's meet up and get to know each other! Contact Raquel Billiones or Laura Kehoe via LinkedIn for more details.

Update from the vetSIG

The vetSIG's April meeting featured a talk by Louisa Marcombes entitled Sweet Secrets of Honey in the Air: Anatomy of an evidence-based veterinary medicine report. This talk was the first in our series of "tasters of veterinary medical communication" ... Want to know more? Download the observer report here.

Check out our site for more details on past and future meetings/activities, or mail vets@emwa.org for more details.

Meet&Share Session with the MedComms-SIG

Have you ever faced a situation when authors or sponsors of a publication did not want to acknowledge you as medical writer? Have you ever been asked to add an author who has not participated in the study and the article's preparation? Have you ever had issues with publication conclusions that are not substantiated with clinical data?

In our first Meet & Share session, we will discuss strategies and experiences when communicating with investigators and sponsors of biomedical publications. Any other challenges you would like to discuss? Please email info@emwa.org and we will add it to the agenda. Please also email any other topic you would like to see in the MedComms Meet&Share Sessions. The session will be held on Wednesday, July 14, 2021, from 5 to 6 pm CEST. Email info@emwa.org to receive the Zoom link.

EMWA's RPD SIG 'Meet & Share' – Friday 02 July 2021, 13:30 CET

The EMWA Regulatory Public Disclosure Special Interest Group (RPD SIG) are holding their first Meet & Share event on Friday 02 July at 13:30 CET. Topics for discussion include two new requirements once the European Clinical Trials Regulation EU No 536/2014 becomes fully applicable:

1) Lay person summaries of clinical trial results;
2) Redaction of key clinical trial documents which will be made publicly available, e.g., protocol, IB, CSR.

Please join this session to share information and learn from each other.

Closer to the date, registration details for the Zoom meeting will be shared.

Communicating with the Public SIG

We are delighted to announce the formation of a new EMWA SIG. This group will aim to:

- educate and inform EMWA members about this important and expanding area of medical writing
- advance the interaction with Regulatory Agencies on this topic to highlight the importance and value of trained medical writers to do this work
- establish interaction with patient advocacy groups and specialists from organisations focused on engagement with the public to help to highlight the need and value-add that medical writers can bring to this area of medical writing

We will reach out to those EMWA members who have already asked to be involved, but if any other EMWA member would like to be part of the SIG, please contact Lisa Chamberlain James via email or through LinkedIn - the more, the merrier!

Biotechnology Special Interest Group

There is no EMWA Biotechnology Special Interest Group. Yet, biotechnology plays a large part in our world.

Biotechnology uses biological systems and living organisms in production processes. For example, yeast to make bread and DNA to make medical treatments.

For European medical writing, the European medical biotech industry definition should be at the core of this EMWA Special Interest Group. This definition refers to Advanced Therapeutic Medicinal Products (ATMPs). ATMPs are gene, cell and tissue products.

The Biotechnology SIG Proposal needs 5 putative sub-committee members:

- ATMP regulatory writing and medical communication experience
- In vitro/molecular diagnostic regulatory writing and medical communication experience
- Academic spin-out biotech company experience
- Bioinformatics experience
- Robotics/AI experience

Here are some biotechnology statistics:

- Earliest example of biotechnology is c. 9,000 years old
- Global biotechnology sector market size was $449.06 billion in 2019
- Global biotechnology sector market size is expected to be $727.1 billion by 2025
- Molecular diagnostics market size is likely to exceed $25.2 billion by 2025
- 50+% of Industry executives anticipate large-scale AI use in healthcare by 2025

EMWA Special Interest Groups allow EMWA and its members to contribute to important conversations around topics that will impact our industry in the coming years. A SIG is a vehicle for EMWA members to meet, discuss and share information and best practice on a hot topic in the world of medical writing.

This is achieved through the EMWA journal, EMWA website, and events at conferences.

Please contact JenBellWS@outlook.com to be listed on the Biotechnology Special Interest Group proposal to the EMWA Executive Committee as a putative sub-committee member.

PV SIG updates

- Monitoring of medical literature and the entry of relevant information into EudraVigilance by EMA
- EMA pharmacovigilance system manual
- EU Individual Case Safety Report (ICSR) implementation guide
- EMA's news related to COVID-19 vaccines:

o EMA's latest updates on COVID-19 vaccines
o EMA's overview on vaccines currently undergoing evaluation, being authorized, and undergoing safety review in the EU
o First COVID-19 vaccine approved for children aged 12 to 15 in EU
o Direct healthcare professional communication (DHPC): COVID-19 Vaccine Janssen and Vaxzevria (previously COVID-19 Vaccine AstraZeneca)
o AstraZeneca's COVID-19 vaccine: benefits and risks in context

- EMA's "Human Medicines Highlights" Newsletter
- US FDA: Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Unique Device Identification (UDI) Helpdesk has been launched

A Unique Device Identification (UDI) system has been introduced under Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), which become applicable from 26 May 2021 and 26 May 2022 respectively.

The UDI system enhances the identification of medical devices and makes it easier to trace them when necessary. It also increases the effectiveness of post-market safety-related activities for devices, improves incident reporting, enhances targeting of field safety corrective actions, reduces medical errors and helps the fight against counterfeit devices.

On 17 May 2021, the European Commission launched a new helpdesk to support economic operators in implementing the obligations and requirements introduced by the new UDI system. You can access the helpdesk here.

The helpdesk provides support on UDI assignment, labelling and registration of devices. It also provides support on the use of the European Medical Devices Nomenclature (EMDN), which the European Commission has made available to manufacturers and other natural or legal persons required by the MDR and IVDR to use it.

Call for Publication of Unredacted CSRs

The International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO) are urging pharmaceutical companies to publish clinical trial reports for new medicines and vaccines without redactions to ensure that research results are publicly accessible to all those involved in healthcare decision-making. In a joint statement, they stress that systematic transparency can increase trust in regulatory decision-making, reassure the public about data integrity and can stimulate research and development.

FDA adopt E9(R1)

FDA have, in May 2021, adopted E9(R1) 'ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials'. Final FDA Guidance is here.

One of the major topics of the E9(R1) guidance is estimands. CORE Reference - which has been downloaded over 32,000 times to date - references E9(R1) and the topic of estimands. Further, in this publication authored by our team, we present a downloadable worked clinical study example including estimand. The importance of intercurrent events and estimands in clinical trials has received recent attention because trials running through the COVID-19 pandemic must consider these important statistical concepts. Medical writers can better understand the concept behind 'estimand' from this paper published in MDW.

Read more about:

Transparency and Vaccine Hesitancy
eCF Implementation Guide
Video on ICH Guideline Development Process
Regulations, standards, and guidance documents for medical devices that provide information on T&D requirements. Here.

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