

# EMWA News

## Editorial

A lot was going on from April to June this year. Certainly the main event was our spring conference in Munich. Aside the established workshops, Freelance Business Forum, Expert Seminar Series, and updates on Special Interest Groups – it included an outstanding Symposium Day, the launch of the Internship Forum, and a poster exhibition.

Mainly, but not only, based on the very interesting symposium theme, EMWA was asked to present at the Brunch Club meeting of the MedComms Networking group (<http://www.medcommsnetworking.com>). Also, EMWA has been presented during talks at a careers fair at 'The Organisation for Professionals in Regulatory Affairs' (TOPRA) in London, at the Max-Planck Institute in Munich and EMWA attended the CTrials conference in Tel Aviv.

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## Spreading the word – EMWA's presence at the CTrials conference

In a new departure, EMWA took a stand at the CTrials conference in Tel Aviv in April 2016. This conference is organised by The Israeli Association for the Advancement of the Biomedical Research Community and covers hot topics in the field of clinical trials. Two members of the EMWA Executive Committee, Barbara Grossman, a fluent Hebrew speaker, and Diarmuid De Faoite voluntarily manned the stand during the conference. Approximately 400 people attended the CTrials conference and more than half of them visited the EMWA stand to find out more about what EMWA has to offer. A targeted follow-up email was sent to all those who registered their interest.

EMWA was also invited to give a 20 minute talk to the conference attendees and Diarmuid De Faoite gave a well-received presentation on Important Documents in Clinical Research. Of course, EMWA

already has members in Israel and we are indebted to Sharon Furman-Assaf and Miriam Aghassi-Ippen for their help in making this event such a success.

The EMWA Executive Committee will carefully assess the impact of this initiative with a view to further expanding the organisation's scope of actions.

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## SECTION EDITOR



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## Elsa Lewis from Lioness Writing Ltd reports on presenting at the TOPRA careers fair on 17 April 2016

More than 100 students and young professionals in Regulatory Affairs in the pharmaceutical industry attended the inaugural TOPRA (The Organisation for Professionals in Regulatory Affairs) careers fair called 'Regulatory Careers Live' at the Royal Pharmaceutical Society in central London.

Presenters included representatives from pharmaceutical companies, regulatory agencies, and contract research organisations. Elsa presented 'What colour is your paraglider' as an interactive introduction to Medical Writing within Regulatory Affairs and for the wider industry. Within this presentation, EMWA was introduced as an organisation for Medical Writers. During the networking sessions there was enthusiasm from participants to learn more about EMWA and careers in Medical Writing.

The second TOPRA career fair is planned for 2017.

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## Munich: A report on EMWA's record-breaking conference



What a record-breaking conference it was! Some 419 participants enjoyed a short stay in picturesque Munich, the main city of Bavaria, Germany. The delegates were mostly drawn from Germany and the UK, but some also came from as far away as Argentina, Australia, China, India, South Korea, Singapore, Japan, the US, Lebanon and Israel! They chose what to attend from a total of 50 workshops – 34 at foundation and 16 at advanced level.

At the opening session, Beatrix Dörr, EMWA's PR Officer, gave a great insight into the region with a talk titled 'Servus Bavaria: The Land of Beer, Crazy Kings and Medical Writers'. She was followed by an invited speaker, Stefanie Weber from the Audi Accident Research Unit, who gave a stimulating talk on how it is possible to learn from road accidents by integrating technical, medical and psychological perspectives.

EMWA is always working hard to make the conference experience as rich as possible. New medical writers were particularly well served this year with two new features that look set to become staples at future conferences. The first-ever internship forum attracted over 50 participants and was a

matching exercise par excellence. Medical writers seeking internships had the unique opportunity to present themselves to companies open to taking on internees. Allied to this, a new seminar by Philip Leventhal, the Editor-in-Chief of EMWA's *Medical Writing* journal, imparted many valuable tips in his talk, *Getting Your Foot in the Door: How to Build Experience to get a First Medical Writing Job*. There was also a stimulating poster session in the exhibition area during the duration of the conference.

For more experienced medical writers there was also an array of offerings to avail of. The six Expert Seminars presented as part of EMWA's second Expert Seminar Series (ESS) were suited to senior and experienced medical writers. International experts held lectures with either a panel or participant discussion or demonstration on topics including automated authoring systems, building medical writing teams in the Far East and India, and how transparency and disclosure initiatives will impact clinical document structures.

The Symposium Day, entitled *Scientific and Medical Communication Today* focused on the evolving field of medical

communications, focusing on the importance of medical writers as medical communicators.

The Pharmacovigilance Special Interest Group (PVSIG) held its first session with presentations from Industry and Regulators on the latest aspects of Pharmacovigilance. The CORE Reference team also held an open session. Since the CORE Reference launched open access on 03 May 2016, resources are available at the dedicated website: [www.core-reference.org](http://www.core-reference.org). EMWA also launched the Regulatory Public Disclosure SIG (RPD SIG), as a natural follow-up to CORE Reference at the conference.

At the Annual Meeting we said goodbye to outgoing EMWA President Sam Hamilton who drove many initiatives in the course of her time on the Executive Committee. Alison Rapley is the new EMWA President, supported by Abe Shevack as Vice-President. Education Officer Barbara Grossman also stepped down from her role and will be sorely missed. Marian Hodges will step into Barbara's shoes on the EMWA Executive Committee. Slavka Baronikova was re-elected as Conference Director for another two years and we congratulate her on her success.

Of course, EMWA conferences are also about networking, meeting old friends and making new ones. Apart from the coffee and lunch breaks, the organised events are a great way for delegates to mingle. All of the social events were fully booked. The outdoor events such as the walking tour and bike ride were all a great success, despite the inclement weather. Over 150 people signed up for the Bavarian spring dinner and dance which showcased many elements of Bavarian culture.

Don't miss out on the next EMWA experience! The 43rd EMWA Conference in Brussels, Belgium, will be held from 3-5 November 2016 at The Sheraton Brussels Hotel.

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## The 4th EMWA Symposium “Scientific and Medical Communication Today”

The 4th EMWA Symposium focused on the ever-changing field of medical communications and the importance of medical writers as medical communicators.

After the welcome from Symposium moderators and introductory polling questions to characterise the audience, Prof. Nico Pitrelli (Scuola Internazionale Superiore di Studi Avanzati – Sissa – Trieste, Italy) set the ground with a wide and thoughtful view on the evolving environment of scientific communications facing the challenges to the professional functions as well as working practices of scientific and medical writers. During the second engaging and inspirational presentation by Chris Colaço (Initiate Training & Development, Switzerland), focus was oriented on the importance of medical writers’ reputation, branding, brand promise and value. Moving from paradigmatic examples of brand, Chris explained the principles and significance of building a medical writer’s brand.

After the first coffee break, different perspectives on what scientific communications means have been discussed. Jan Geissler (European Patients’ Academy on Therapeutic Innovation, EUPATI, Germany) presented the patients view: the need to see patients as centre of any healthcare service and communicate to them appropriately. As the new EU Clinical Trials Regulation (<http://www.ema.europa.eu>) requires that

clinical trial communications will also include lay person, medical writers have to be able to prepare these documents and communicate scientific data to patients as well. An example of effective communication of medical data to patients and lay public was reported by Fabienne Huebener (inword.de, Germany) that narrated a story that emotively involved the audience and inspired writers on the difference between ‘writing’ and ‘communicating’ medicine. The morning was closed by the EMWA past-president Laurence Auffret (CINETIQUE Translations, UK) that highlighted the concept of effective translation. This cannot be ensured by the application of translation’s standards but needs to be targeted to cultural environment.

The role of regulatory authorities and their initiatives on communication and transparency were presented by Juan Garcia Burgos (European Medicines Agency, UK), highlighting the importance and benefits linked with their effective development and use. Hartwig Buettner (Eli Lilly, Germany) shared industry’s expectations and issues through some examples on the importance of high quality disclosures and their link with the status of drug development. Hartwig highlighted industry appreciation of medical writers as a key figure in communication about addressing unmet medical and patient’s needs by clinical

development. This session was closed by Chris Winchester (Oxford PharmaGenesis, UK) experience from medical communication agency point of view, highlighting that planning and high quality delivery are the constants that ensure successful collaboration with the medical communications agency for achieving high quality scientific communications.

Past, present and future trends for communicating scientific and clinical research were the natural conclusion of the day. Andrea Bucceri (Dove Press, UK) described new technologies and methods of communicating scientific data and facilitating access to information highlighting their crucial role in the present and future scenario. Jan Seal-Roberts (Adis, Springer Healthcare, UK) predicted the possible development of scientific articles and their management in the next 5, 10 and 20 years according with the evolving reading habits of healthcare professionals and technical evolution. The day had its natural conclusion with the presentation on extending the impact and reach of science publications by Martin Delahunty (Springer Nature Publishing Group, UK). Martin exacerbated the central role of scientific journals for future high-quality research disclosure in an environment where open access to content and data will extend the reach and impact of publishing beyond the traditional research communities to anyone who has an interest, need or wants to advance better medical practice and health outcomes.

Each session ended with a Q&A session where presenters answered questions from the audience.

Description of the contents presented are available also at <https://www.gkm-therapieforschung.de/emwa16/>. All presentations are available at EMWA website and some of the presenters will write an article on their presentation to be published in the 2016 December issue of EMWA’s *Medical Writing* journal.

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### EMWA at the Max Planck Institute of Psychiatry

On behalf of EMWA Christopher Marshallsay and Beatrix Doerr joined invited speakers from a broad spectrum of areas to introduce the career option “medical writing” at the 2nd Career Day of the Max Planck Institute of Psychiatry held on May 11th, 2016. They presented an introduction to the medical writing profession which included the different type of medical writers, what medical writers do, the ‘typical’ medical writer profile, career progression in medical writing, and the pros and cons of the role. They also introduced the new EMWA Internship Forum and the advantages of EMWA membership. The audience, largely BSc, MSc and PhD students, posed many questions and – as so often – were not aware of the role. One excited attendee reported “that’s me”, obviously a budding medical writer, subsequently attended the open sessions at the EMWA Spring Conference and was thrilled to be able to talk with medical writers and to learn about the profession, the opportunities it offers, and how best to apply.

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## RPD SIG – Launch meeting May 2016

The Regulatory Public Disclosure Special Interest Group (RPD SIG) launched at the EMWA Spring conference and held an introductory session on 12th May, alongside the launch of CORE Reference. The session was very well attended and was received enthusiastically by the audience.

Tracy Farrow, Senior Director of Medical Writing at PPD, introduced the session by taking the audience through some background to the current regulatory public disclosure environment and why it is important and of interest to medical writers. She described the objectives of the EMWA RPD SIG in providing a forum for the discussion and sharing of information, best practices, and ideas with EMWA members, and named the proposed advisory panel who will be supporting this important SIG by freely sharing their knowledge and expertise.

Dr Christopher Marshall, Head Medical Writing and Public Disclosure at Grünenthal, described the new RPD SIG website and the available resources that include a glossary of terms, a library of key references and background reading as well as a question and answer log. He finished off discussing the next steps and request that volunteers share ideas and experience. This will be a key component of RPD SIG.

The session was brought to a close with an opportunity for the audience to ask questions and pleasingly many of the conversations continued into the refreshment area after the session. The interest in the RPD SIG and the fluid nature of topic in general should generate an informative and interesting session at the Spring conference in 2017 when the RPD will have its first formal session as part of the Symposium Day.

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## PV SIG – Meeting update May 2016

The pharmacovigilance special interest group (PV SIG) held its first session at the EMWA Spring conference. The session title was 'Are we ready for the patient's voice through social media in the benefit-risk assessment of drugs?' and despite being held late on Friday afternoon, was very well attended.

The participants were given the latest update on the MHRA's WebRADR initiative, which is collecting and collating adverse event data. The MHRA's Special Projects Officer for Vigilance and Risk Management of Medicines, Dr Alicia Ptaszynska-Neophytou, outlined the project and explained the problems involved in dealing with the huge amount of data available and the approaches that the MHRA are taking. Alicia described what had been learnt in the 21 months since WebRADR was launched, and the progress that the WebRADR consortium are making, along with their plans moving forwards.

Dr Ulrich Vogel, Head of Strategic Data Analysis and Global Pharmacovigilance at Boehringer Ingelheim then described the collection of data from patient support programmes (PSPs) – an alternative source of Pharmacovigilance data that many medical writers are less familiar with, but that has gained importance in the periodic safety update report (PSUR) assessment of some products. Ulrich explained what kind of information writers could expect from a PSP database, and how these data could be analysed and described. Ulrich explained his company's approach and the challenges faced when dealing with this kind of information.

To round of a very interesting and informative session, there was an excellent discussion, and both presenters took a variety of questions, covering topics from how to address quality versus quantity, audit ramifications and why 'death' had been classified as a 'non serious event'! The session was enjoyed by all and we are looking forward to the next one in Spring 2017.

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## CORE Reference news, June 2016

Sam Hamilton wrote a Guest Blog at BioMed Central's invitation in late May 2016: 'Safeguarding the privacy of clinical trial patients': <http://blogs.biomedcentral.com/on-medicine/2016/05/27/safeguarding-privacy-clinical-trial-patients/>.

This clear and nontechnical article shows patients, doctors and researchers how this important topic relates to them. The blog is expected to receive 2000-3000 hits a day, and should drive up traffic to <http://www.core-reference.org> as well as the technical publication: <http://dx.doi.org/10.1186/s41073-016-0009-4>

Perhaps more importantly, the Blog helps those outside the sphere of regulatory medical writing understand that CORE Reference is a **freely available resource for the reporting of human medicinal trials**. Increasing awareness in the pharmaceutical research sector of the availability of CORE Reference means that just one month after its release, CORE Reference downloads reached 1,000 and this number is increasing exponentially, as a look at the download counter on the website will tell you. **Principal Investigator-led clinical trial units in universities, hospitals and medical charities should also know that this free resource is available for them.** Please use Sam's Blog to help spread the word, and also outside your professional circles. Let's encourage patients and the public generally to be better informed.

The open comment period on CORE Reference ended on 14 June 2016. Comments and responses are shared via [http://www.core-reference.org/Comments and Responses](http://www.core-reference.org/CommentsandResponses) page.

EMWA and AMWA workshops are planned at forthcoming conferences from autumn 2016.

Finally, despite the encouraging numbers downloading CORE Reference, we need you to tell us about its adoption and use via the dedicated page on <http://www.core-reference.org>. We know from your personal emails that support is widespread, but we need your public declaration of support.



EUROPEAN  
MEDICAL  
WRITERS  
ASSOCIATION



We would also like you to tell us if you have submitted CSR(s) redacted for public disclosure to regulators, and share any feedback that you may have received via the Contact page.

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We continue to develop the resources to help you use CORE Reference effectively:

Resource	Where and When	Presenter
<p><i>Webinar:</i> CORE Reference: A Medical Writer's Guide to Preparing CSRs in an Evolving Context</p>	<p>AMWA (online) 27 July 2016 13.00-13.45 EDT</p>	<p>Aaron Bernstein</p>
<p><i>Presentation:</i> CORE Reference: A Medical Writer's Guide to Preparing CSRs in an Evolving Context</p>	<p>11-12 July 2016 3rd ExL Clinical Medical Writing Forum Sonesta Hotel Philadelphia, Philadelphia, PA, USA</p>	<p>Aaron Bernstein</p>



# Brussels 2016 – save the date

See page 54 for more details

## Call for Companies

The 2nd Medical Writing Internship Forum will be held at our May 2017 Conference in Birmingham, UK. Please contact [internship@emwa.org](mailto:internship@emwa.org) for more information.

