

# EMWA News

## Editorial

What can I say? I am excited to be writing my first editorial as section editor of EMWA News. With Bea as my predecessor, I know I have some big shoes to fill and hope to be up to the task.

In this issue, we share the latest news from our association. The 44th conference in Birmingham has just finished, and Slavka prepared an overview of all the new features that were offered. As the renewed Freelance Business Group was presented in Birmingham, we asked Satyen to briefly introduce the changes and improvements to both Freelance Business Group and Forum. Diarmuid organized a conference map that allows EMWA members to keep track of past and

upcoming conference sites. Moreover, last March, Abe and Carola attended the 3rd MedComms Meeting in Berlin. Here, they share their experiences. Finally, one year after the CORE Reference was launched, Sam surveyed its practical utility and shares the results in this section. In other news, some EC positions were renewed this year, and we welcome Tiziana von Bruchhausen as the new Vice-President, Maria João Almeida as PR Officer, and Beatrix Doerr as Honorary Secretary; James Visanji, was re-elected as Treasurer. To those leaving their positions, thank you for your outstanding work during the past year.

From the PR office, we are keeping our collaborations with international organisations

## SECTION EDITOR



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as AMWA and ISMPP, as well as constantly building new bonds. Also, this year was the first time since 1966 that the BELS exam took place at the location of the EMWA Conference, and a number of members were able to take the Editor in Life Sciences (ELS) certification exam. We are looking forward to the positive results soon. Last but not least, we kindly remind you to save the date for our November conference in Cascais, Portugal, a wonderful location to balance work and pleasure. Looking forward to meeting you there!

## 44th EMWA Conference in Birmingham

In keeping with EMWA tradition, the 44th Spring Birmingham conference was a huge success. With 373 delegates, this meeting offered a rich educational programme including 31 foundation and 18 advanced workshops. I found it fascinating that delegates came from 28 different countries, many of them outside Europe, such as Argentina, India, Israel, Japan, Russia, Singapore, Taiwan, and Ukraine, among others. The 5th Symposium Day on “Transparency and Disclosure of Clinical Regulatory Documentation” with speakers representing regulatory bodies, the pharmaceutical industry as well as regulatory writers was attended by about a third of conference delegates. Experienced EMWA members enjoyed the 3rd Expert Seminar Series, which covered topics such as pharmacovigilance reporting, the role of medical writers in peer-reviewed publications and responses to regulatory authorities, how to organise a medical conference, and current industry position on clinical trial protocol templates. We were also excited to offer a rich list of non-EPDP activities, including new seminars on Mindfulness and Biosimilars.

The 2nd annual Internship Forum offered not only appointments with the companies but also career coaching for PhDs and post-docs who want to transition to medical writing. As usual, the Annual Meeting and Freelance Business Forum were part of the programme. This year the renewed Freelance Business Group was also introduced (see next article in this section).



Besides the educational programme, the rich social activities included a Balti masterclass, Birmingham walking, canal walk, and literary heritage tours.

Over 140 delegates enjoyed the annual Spring Dinner and Dance that offered a great opportunity to meet new and old friends.

Noteworthy, this year, a new conference minisite replaced the traditional conference PDF brochure, which allowed EMWA members to find information of interest in a fast and comprehensive manner. It also allowed conference organisers to swiftly update the conference information so that delegates were up-to-date with the latest conference news and developments. The new minisite has also influenced the content of the well-known conference mini-

guide; practical information about conference events in the mini-guide helped delegates finding their way around, while detailed information about educational events content as well as the newest updates were available on the conference minisite. The EMWA PR team was present during the whole conference, updating all EMWA members on the latest conference proceedings via social media.

Now that the Spring conference is over, we are already organising our 45th conference, which will be in Cascais, Portugal, next Autumn.

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## Freelance Business Group subcommittee introduced at the 44th EMWA Conference in Birmingham

A fantastic turnout for the Freelance Business Forum (FBF) at the 44th EMWA Conference in Birmingham continues to follow the pattern set at the preceding two conferences and reflects the increasing number of freelancers joining the EMWA community.

The Freelance Business Group (FBG) at EMWA has historically been managed by one or two (and sometimes even three) volunteer Freelance Advocates whose key responsibilities were overseeing the freelancer section (Out On Our Own) of *Medical Writing*, organising the FBF, and conducting periodic surveys. In the past year or so, a number of initiatives have been introduced

by the FBG that expand the benefits available to our freelance members. To continue along these lines and provide added value to our freelance members requires more volunteers and ideas.

To address this requirement and harmonise the operation of the FBG with other EMWA subcommittees covering specific areas, in December 2016, EMWA's Executive Committee recommended the formation of a FBG subcommittee. Comprising of four to five volunteers and headed by a chairperson elected amongst them, the FBG subcommittee was slated to be introduced at the conference in Birmingham.

While I have continued to volunteer for the

FBG, I am now joined by Allison Kirsop (UK), Petra Pachovska (Czech Republic), Paul Wafula (Germany), and George Xinarianos (UK) as fellow subcommittee members. It is our goal to continue running the FBG productively as in the past and to build on these to keep adding value for our members. Last but not most important, your ideas, no matter how big or small, are an essential component to the success of the FBG. Should you wish to share these with us, please get in touch.

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## EMWA Conference Map

Although EMWA provides many benefits to its members, it is safe to say that the bi-annual conferences remain a constant highlight. The very first conference was in Brussels in 1992 and the recent Birmingham conference was the 44th EMWA gathering!

With the natural passage of time, frequent delegates might find it difficult to remember exactly when and where certain conferences happened. To this end – and also as a contribution towards documenting EMWA history – I have created an interactive Google Map of all EMWA conferences, from 1992 to 2018!

You can access this map by going to [www.emwa.org](http://www.emwa.org) -> Conferences -> Past Conferences. Find the page directly by using this shortened URL: <http://tinyurl.com/kcuc9e>.

I hope that your electronic trip down memory lane awakens some nice recollections of previous EMWA conferences. If you have any

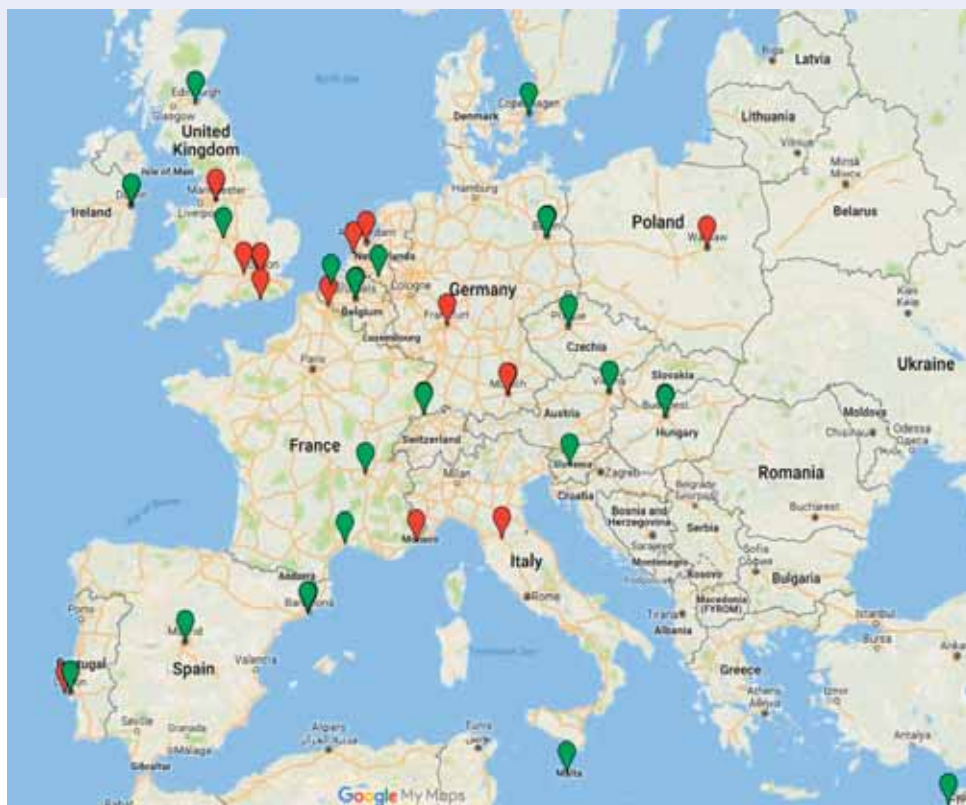
corrections to the map, please just reach out to me. The same applies to any EMWA website-related issues you wish to raise.

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## Call for volunteers

As you all know, EMWA is run by our members and relies on them to develop and support all our initiatives. There are currently a number of vacancies for EMWA members to get involved with various groups. This is a great opportunity to develop your skills and experience at the same time as helping to promote the role of medical writers and strengthen our association. If you

are interested in getting involved or want more information please contact [info@emwa.org](mailto:info@emwa.org).



## CORE Reference One Year On

The year since the May 2016 launch of Clarity and Openness in Reporting: E3-based (CORE) Reference has been a busy one:

- CORE Reference has been downloaded over 7,000 times.
- Pharmaceutical companies, CROs, and freelance medical writers are using CORE Reference as both an official and unofficial resource, and have reported utility at [www.core-reference.org/adoption-and-use](http://www.core-reference.org/adoption-and-use).
- A mailing list was established to share important regulatory and public disclosure updates as they occur. Join via: <http://www.core-reference.org/subscribe>.
- CORE Reference was presented at the EMWA, AMWA and DIA conferences and at other national meetings. See “Publicity” at: <http://www.core-reference.org/publications/>
- Links to regulatory authority public disclosure pages have been added at: <http://www.core-reference.org/disclosure-feedback/>.
- EMWA and AMWA workshops are planned at forthcoming conferences from autumn 2017. See “Coming Soon...” at: <http://www.core-reference.org/publications/>.
- We conducted a Utility Survey and presented the data at the EMWA 2017 Spring Conference.

### Results of the CORE Reference Utility Survey

At the 5th EMWA Symposium “Transparency and Disclosure of Clinical Regulatory Documentation” in Birmingham, UK on May 4, 2017, Tracy Farrow shared data gathered via the CORE Reference Utility Survey (March 22 to April 21, 2017) on how CORE Reference is used in practice.

Eighty-eight individuals responded to the survey. The vast majority (88%) were medical writers. 36% worked on publications, 30% on medical communications, 9% on results posting, 9% on clinical trial disclosure, and 6% on regulatory affairs. CROs were the most common employers (42%), followed by large pharma (18%) and small pharma or biotech companies (19%). Another 17% were freelancers, and 3% were academics. Responders’ clients were most often in Europe (66%) and North America (44%), followed by Asia Pacific (19%) and other locations (6%). 37% responded that they used CORE Reference as an

unofficial reference tool, 34% had incorporated it into their procedures, policies, or templates, and 28% had used it to author clinical study reports (CSRs). Most (80%) found CORE Reference to be very (48%) or somewhat valuable (31%). Just over half (52%) had signed up for the CORE Reference mailing list.

Full results from the CORE Reference Utility Survey are available at:



<http://www.core-reference.org/media/1048/coreref-utilitysurveyresults-bhamsympo-may17.pdf>

### Relationship between CORE Reference and public disclosure of CSRs

Sam Hamilton next explained the relationship between CORE Reference and public disclosure of CSRs. Sam emphasized the following:

- CORE Reference is a complete and authoritative open access resource for authoring CSRs for interventional studies fit for today’s public disclosure environment.
- “Smart authoring” of the regulatory review version CSR – that incorporates proactive anonymisation of sensitive data – maintains high data utility whilst minimising the need for redactions in the public disclosure version CSR.
- CORE Reference highlights hotspots in the CSR where sensitive information may need to be safeguarded in line with European Medicines Agency Policy 0070, and includes links to relevant guidance, making it an all-inclusive resource.



EUROPEAN MEDICAL WRITERS ASSOCIATION



The Resource for Medical Communicators

Before presentation of the survey results, Sam asked audience members about the usefulness of CORE Reference in preparing CSRs fit for public disclosure, based on their understanding of the resource. Similar numbers responded “extremely useful”, “somewhat useful”, or “not sure”, and none considered it “not at all useful”. When Tracy repeated the same poll after she and Sam had presented the Utility Survey results and instructive information on CORE Reference, 58 of 64 audience responders felt that it was extremely or somewhat useful in the context of preparing CSRs fit for public disclosure, and only 6 remained unsure. These results highlighted the importance of continuing to engage with colleagues to raise awareness about the general utility potential of CORE Reference, not least in supporting CSR-related public disclosure requirements.

### Tell us about your use of CORE Reference

Please continue to tell us about your use of CORE Reference via [www.core-reference.org/adoption-and-use](http://www.core-reference.org/adoption-and-use). We know that support is widespread, but we need your public declaration of support on the website.

*This article was written with the support of Tania Kotsokechagia, Lexis Communications Ltd.*

**Sam Hamilton**  
Chair, CORE Reference  
<http://www.core-reference.org>





## Medical writers getting (it) together in Paris

Following the 2016 EMWA Spring conference, a few medical writers decided to meet together to meet, network, and share ideas. The first meeting was held in June 2016, where we passed a pleasant summer evening discussing medical writing issues in France. Since then, the group has continued to meet around every 3 months.

As the word got around, the fledgling, informal, and mostly English-speaking crowd became a rather motivated, French- AND English-speaking group with lots of ideas to share. And so today, the group has approximately 60 medical communication professionals,

including writers, editors, translators and scientists, with about 20 showing up at each meeting.

Our objective going forward is to continue to meet, network, and support each other to improve the quality of medical writing in France and to help French research teams to publish their work. Our first project is to obtain official recognition for the role of the medical writer in France, which is not the case today. This, we hope, will simplify things for freelancers (insurance, employment codes, etc.) but also for academic and pharmaceutical research groups

who depend on government assistance for research support.

So, medical writers are getting it together in France.

Anyone interested should contact Amy Whereat. Meetings are also usually published via [www.eventbrite.fr](http://www.eventbrite.fr) and [www.medcommsnetworking.com](http://www.medcommsnetworking.com).

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## 3rd MedComms Meeting in Berlin

On Friday March 17, 2017 Stgilesmedical issued its third open invitation to an educational networking event in Berlin. In the cosy cinematic DaWanda Snuggery, the local MedComms community came together to network, promote and exchange current advances in the field. Medical Writers and newbies to the profession spent a sociable afternoon, which was framed by a set of diverse presentations.

Abe Shevack, who was EMWA's Vice-President at the time, gave an introduction about EMWA as an organisation and an enthusiastic overview of the events and activities scheduled for the upcoming annual conference in Birmingham. He described the topics for the Expert Seminar Sessions, the theme of this year's 5th Annual Symposium, and the Internship and Freelance Business Forums.

Steven Walker, Scientific Director at

Stgilesmedical, introduced the audience to the role of MedComms professionals as educators. His talk covered the important role of medical writers in organising conventional and digital medical meetings. He pointed out the steps to follow when organizing meetings from developing the content and communication strategy to inviting speakers and giving practical tips about running meetings. From his talk, it became clear that medical writers take a great responsibility in organising, promoting and providing a communication service to distinct audiences in the medical industry.

The involvement of many professions in medical communication became clear through Alice Bergfeld's talk on the impact of medical translations in effectively communicating medical content. As a freelance medical translator, she introduced the audience to the educational prerequisites, intercultural knowledge, and other

soft skills needed to pursue a successful career in medical translation.

How careers are connected to evolving regulatory guidelines was pointed out by Claudia Frumento. As a specialist in medical devices, she has been seeing an increased demand for medical device specialists, which has been going hand in hand with this year's release of the Medical Device Regulation due to replace the old Medical Device Directive.

In short, this event – with its informal character – once again provided participants with a wonderful opportunity to network and discuss current and upcoming MedComms topics.

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