From the Editor

Making responsible decisions – every day

I am writing this message, Lisbon (Portugal) just went back into a lockdown, the United Kingdom (UK) reports an increasing number of COVD-19 cases, whereas other European countries are just doing fine.

As it is very difficult for the EC to foresee where we will be in November, and we always prioritise the health of our EMWA members, we announced a new conference format for the upcoming November conference. Now is the time to take the first step into a new reality. We aim to offer our first hybrid conference. All EMWA workshops will be offered in the virtual format only. However, we aim to run a 1-day, London-based, hybrid conference day on November 4, 2021. Why London? We aim to avoid cross-country travels of EMWA members and evaluate the feasibility of EMWA hybrid conferences for which we need our UK-based Head Office support.

However, networking is a major pillar of EMWA conferences, and we would like to offer local medical writers and communicators groups the possibility of organising networking events on this day. In accordance with country-specific COVID-19 regulations, we aim to live-stream the conference day from the UK, provide local face-to-face networking opportunities, and discuss urgent topics with our local peers. If you would like to support a local networking event in your area, please get in touch with us (info@emwa.org).

Additionally, we will offer PR support for the local networking events through our newly formed EMWA Creative Team. The creative team aims to support not only conferences and networking events with promotional material but also offers the creation of visuals, infographics, and slide decks for any EMWA-related activities. If you need support for social media postings, your next article for *Medical Writing*, or for the website, please email president@emwa.org.

I hope you see the opportunities the new hybrid conference brings to EMWA and to all our members.

Carola Krause
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For me, the most difficult task of medical writing is clicking that "SEND" button. After more than15 years in this field, the decision to send out and share a document with colleagues, regulatory authorities, even the public, is always accompanied by a knot in the pit of my stomach. This simple act comes with questions ranging from the mundane "Is this document good enough or do I need another round of QC?" to the profound "Did I write this document according to Good Clinical Practice guidelines to the best of my ability?" Decision-making is part of our private and professional lives. Should I get vaccinated? Should I quit my job and go freelance? Should I work from home? Should I share this on social media? Should I try something new?

We want to make the right choices and dichotomy looks good on paper but in practice, it is not always binary; reality is seldom black or white, yes or no.

So how do I cope with the anxiety of decision making?

- Pause. Step back if we must. Boldness and spontaneity are great but leaping without looking is irresponsible.
- Talk it over. Have a sounding board, a discussion partner(s), or a second pair of eyes to look over your document.
- Do not procrastinate. Pausing is important but putting off too long is counterproductive. Reflect but do not overthink.
- Be responsible. As medical writers and communicators, our professional decisions sometimes have some far-reaching consequences, be it on a project deliverable, corporate goals, or the outcome of a global pandemic. Acting responsibly and with integrity is therefore important.
- Forgive yourself. No document is perfect. Things can go wrong. Deviations happen. Non-compliance events occur. Keep to the quality tolerance limits but learn from your mistakes.

This issue contains articles highlighting the challenges and rewards of decision-making in the healthcare industry. The first half of 2021 marked major regulatory decisions especially in Europe. The Medical Device Regulation 745/2017 came into full force on May 26, 2021, after a 1-year postponement due to the pandemic. On July 31, 2021, the European Commission officially published and confirmed January 31, 2022, as the date of application of the Clinical Trials Regulation 536/214 and the go-live date of the new Clinical Trial Information System. At the time of writing, we are awaiting updates on Plan S, an initiative for open-access science publishing.

In the midst of all these regulatory changes, medical writers and communicators play a vital role in ensuring smooth transitions and compliance. This is where our decision-making skills will stand us in good stead.

Finally, in this issue, you will become aware of the recent decisions taken by EMWA to try something new.

- We have new special interest groups (SIGs, p. 15)!
- The EMWA Executive Committee has decided to try out a hybrid conference format (see p. 4 and p. 7)
- We have decided to give the journal a new look! We also hope to move away from using stock photos and tap into the creativity of our membership. If you have any ideas for covers of our future issues (p. 127), please reach out.

To close, we would like to thank our contributors, our guest editors Maria and Claire, and our editorial team for putting this issue together. Happy reading.

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