

Sandra Götsch-Schmidt gives a broad and detailed overview of the types of generic-specific documents that medical writers can contribute to and elaborates on how such contributions may look. She also presents general information about the development of generics and gives pertinent information about cases where specific types of documents may not apply for certain products.

Tiziana von Bruchhausen, Kerstin Prectel, and Stefanie Rechtsteiner provide best practices for developing pharmacovigilance documents for generics and biosimilars throughout a product's life cycle, with a focus on writing Drug Safety Update Reports, Periodic Safety Update Reports, and Risk Management Plans. They show us how regulatory considerations need to be interpreted by document and by product in order for safety concerns to be appropriately addressed.

David McKinn, Craig Scott, and Baxter Jeffs offer their insights into best practices for writing lay summaries for generics and biosimilars. They provide example language that can be used when developing layperson-orientated materials for generics and biosimilars.

Krithika Muthukumaran offers her views on the development of biosimilar insulins and how their availability (from different competitors) will impact treatment options in patients with diabetes. She addresses the topic from various perspectives, including a discussion of regulatory and market aspects by region, and what the introduction of biosimilar insulins may mean in practice for patients and healthcare industry professionals.

Martin Mewies critically summarises changes, successes, and challenges in biosimilar development from multiple perspectives: a regulatory perspective, a market perspective, and a healthcare industry acceptance perspective (by doctors and patients). He examines the progress made to date in establishing the biosimilar market, challenges in bringing biosimilars to patients, the impact biosimilars have had so far, and potential future trends.

To sum up, I hope that I have passed on some of my excitement for the field of generics and biosimilars through this issue, and that you'll find all nine articles helpful and will enjoy them as much as I have! If this turns out to be the case, please help us spread the word about the articles in the wider medical writing community and beyond and let us know which of them you found most useful in your daily practice.

GUEST EDITORS



Diana Radovan, PhD, ELS
Senior Medical Writer
Trilogy Writing and
Consulting GmbH
EMWA member since 2010
EMWA PV SIG member
since 2017
diana.radovan@
trilogywritng.com



For the last 6 years, James Visanji has volunteered as EMWA's Treasurer and as a member of the Executive Committee. James stepped down from this role at the conference in Vienna this past May, so several of us on the Executive Committee wanted to personally thank him for his many years of service, not to mention his friendship.

James was already well into his treasurership when I joined the Executive Committee and was introduced to the wide range of topics that the committee has to consider. I really appreciated his skill at succinctly outlining the facts and the decisions to be made about EMWA's finances. It was clear that the whole committee benefited from his business knowledge and pragmatic advice on a wide range of issues, and his good humour could lighten the moment and make the long meetings more enjoyable. I will very much miss him on the Executive Committee but, as Education Officer, I'm very pleased he's got no plans to give up as a workshop leader – and who knows, maybe the time freed up might prompt ideas for new workshop topics! Thank you James.

Marian Hodges
Education Officer

When I started serving on the Executive Committee 4 years ago, it felt as if James had been on the EC for ever. While not visible centre stage, he was not only paramount for EMWA's finances, but also when things got turbulent and waters got rough, he was there, solid as a rock; when there were heated discussions, everybody listened when he spoke; and when there were important decisions to be made, everybody was happy to count on him and his knowledge. It is amazing what he has accomplished in the past 6 years. On a personal level, James has always been helpful and fun to be around. He certainly is a character, and this is what makes him so special and likeable. I will sadly miss him on the EC but am looking forward to meeting him as a "private person" at conferences and to continuing our discussions such as on environmental issues (James will know what I mean...). All the best, James, for your "EMWA sabbatical"! Best wishes,

Beatrix Dörr
Honorary Secretary



Before my time in the Executive Committee (EC), what I associated with James' name were financial reports in the Annual Meetings and cheerful ties – what a great hallmark! When I started working on the EC, I strongly felt that James held a large bit of the historical memory of EMWA: regardless of the issue we had to address, he would know whether EMWA had encountered a similar one in the past, the lessons learnt, the do's and don'ts. We all have great respect for James' experience and competence beyond his role as treasurer, and more than once his advice on tricky issues saved time and costs. In my experience, James has been a great person to work with: very firm in his positions, but also open to be convinced by well-grounded arguments. I benefited very much from his advice and learnt a lot from his attitude; although I was not always in agreement with his views, I truly respected and acknowledged them – his arguments were solid, his explanations thoughtful and sensible. The interaction with James has strengthened my ability to convey my point or come to a common agreement. Since he decided to step down from the EC, I think that he has become more laid-back, which added some hilarity to the most intensive meetings. However, dear James, be reassured that even though you have left the EC, you will remain a reference point for all of us – this is a threat that we will put into practice at the bar!

Best wishes,

Tiziana von Bruchhausen
President 2018–2019
Vice President 2017–2018

I had the pleasure of working with James throughout his tenure on the EMWA Executive Committee. All I can say is that the EMWA membership was blessed to have someone with such a laser-sharp mind serving their interests over the past 6 or so years.

Not that I expect you to(!), but anyone who looks at the improvements in our accounts in recent years can clearly see where James had a very positive effect. The organisation is in a much more secure place than it previously was – financially as well as non-financially – and the two are more intertwined than most people realise. Speaking personally, I was happy to have James on my side in the early days of my role as we tackled the labyrinthine internet arrangements (two platforms for one website anyone?) and quickly managed to cut the website-related costs down to a fraction of what they once were. But his impact was not only financial, he also exuded a professionalism which benefited the committee as a whole. (For those of you not in the know, as committee members we also have an input into all areas affecting the organisation). Most of all though, James also brought a fun element to the role. Many's the time his good humour and pleasant company helped to get us through a difficult meeting or to decompress after one. I will miss having him on the committee but am sure that once he has sorted out Brexit(!), he will return to his natural home at EMWA.

Good luck, James, and enjoy your (hopefully short) retirement.

Diarmuid De Faoite
EMWA Website Manager

Like Diarmuid, I have had the chance to see James in action over several years as a volunteer for the Executive Committee. What I have most appreciated is his ability to cut through the BS and rapidly make wise, clear-headed decisions. At the same time, he's always been willing to change his mind when presented with a cogent opposing argument. To add to this, his knowledge of business and legal issues has come in handy and saved us on many occasions. One story that sticks out in my mind was how he negotiated us out of a contract with a former vendor who was not performing (and making my life miserable). He visited them at their offices and laid things out very simply, as in "Let me make you an offer you can't refuse". They were left with no option than to agree to our demands. I could not have accomplished this myself, so I thank him for taking an enormous burden off my shoulders. James will still be around EMWA as a workshop leader and friend, but I will miss his no-nonsense approach and humour, which have been a key part of the smooth functioning of the Executive Committee over the past several years.

Best wishes,

Phil Leventhal
Editor-in-Chief