

# Medical Writing

## Generics and biosimilars

When I first stepped into the biosimilar world as part of my medical writing career development, I was both excited and surprised. I was entering this fascinating setting with an originator mindset, as many of us do, and discovered that there are many aspects to be considered for biosimilar documents, not all of which are entirely obvious.

Later, from chats with other writers during coffee breaks at EMWA conferences, it became clear to me that more conversations across different areas of development (originators, biosimilars, and generics) were needed. While general information on biosimilars and generics is increasingly available, there aren't many hands-on resources for medical writers who have broad medical writing experience but who don't have any experience specifically in these areas.

This MEW issue aims to bridge this information gap. The nine feature

articles included here address both the 'bigger picture' and provide hands-on tools for developing fit-for-purpose documents throughout a biosimilar/generic product's life cycle.

Regulatory pathways in the EU and the US in the generic and biosimilar industries are critically discussed in detail by **Yousuf Mohiuddin Mohammed**, with real-life examples when available. He focuses on clinical development requirements for generics and biosimilar in order for region-specific regulatory requirements to be met, but also covers the impact of such requirements on other parts of the respective submission dossiers.

The particulars of biosimilar development are further developed by me (**Diana Radovan**). My feature article provides information about biosimilar-specific terminology, addresses the typical challenges of writing biosimilar dossiers and how medical writers can provide strategic support in overcoming them, and summarises future directions in biosimilar development in the context of a changing competitive landscape.

Statistical considerations for biosimilar development are outlined by **Alison Balfour** and **Susanne Schmitt**. These considerations include clinical trial design, covering choice of endpoints, types of required analyses, choice/justification of equivalence margin (based on statistical and clinical considerations), and imputing missing data for efficacy.

**Katharina Brauburger** and **Sabrina Heisel-Stöhr** provide best practices for developing clinical biosimilar documents, paying close attention to a number of typical challenges, and how fundamental biosimilar concepts, such as immunogenicity and extrapolation, must be used in writing fit-for-purpose documents. The authors also run the only EMWA workshop on biosimilars, which is always fully booked in no time; so keep an eye out for it when registering for the next EMWA conference!

While general information on biosimilars and generics is increasingly available, there aren't many hands-on resources for medical writers who have broad medical writing experience but who don't have any experience specifically in these areas.



**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 Prechtel, 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@trilogywriting.com](mailto:diana.radovan@trilogywriting.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 Hedges**  
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