

EMWA's Special Interest Groups (SIGs)

The EMWA SIGs allow EMWA and its members to contribute to important conversations around topics that we know will impact on our industry in the coming years.

You may have colleagues interested in joining the EMWA SIGs to debate, and share best practice and resources.

Pharmacovigilance SIG

As part of the growing interest amongst medical writers in safety writing, and also based on the understanding that there are subtle differences between safety writing and medical writing, EMWA is introducing a Pharmacovigilance Special Interest Group (PV SIG).

The PV SIG aims to bring together EMWA members to discuss and share information and best practice in the area of PV and PV writing. The group will aim to increase dialogue within and between the medical writing community and the regulatory authorities (RAs), and will hold an annual PV update session during the EMWA Spring Meeting to discuss current PV-related topics from different perspectives, and to encourage dialogue with the RAs. The group will also act as a resource for medical writers interested in the area of PV by posting guidance and updates to guidance as appropriate, and will liaise with the EMWA Professional Development Committee to advise on additional training for EMWA members in the field of PV writing and PV.

Committee members

- Dr Lisa Chamberlain James (Chair)
- Dr Tiziana von Bruchhausen
- Dr Rohit Pushparajan
- Dr Alison Rapley (EC liaison)

Regulatory Public Disclosure SIG

'Public disclosure' has different meanings for different groups of medical writing professionals.

- Publication professionals understand it to mean the publication of research findings whether the outcomes are negative or positive; the disclosure of funding; disclosure of involvement of medical writers in publication development; disclosure of conflict of interest etc.
- Regulatory professionals understand it to mean the registration, status reporting, and results posting of clinical studies in publicly accessible Internet registries.
- Upon-request or proactive sharing of clinical regulatory documents (eg, synopses, clinical study reports, clinical overviews, clinical summaries) and/or individual patient data.
- Publishing of clinical trial results in journals. The RPD SIG objective is to provide a forum for the discussion and sharing of information, best practices, and ideas with EMWA members.

The concept of 'regulatory public disclosure' is of special interest because of:

- its impact on the content and structure of standard regulatory documents
 - the expectation that the range of regulatory documents affected will burgeon in the coming years
- Public disclosure will create the need for new regulatory documents, which the medical writer will support.