

The Regulatory Public Disclosure Special Interest Group

Who are we and what do we do?

The Regulatory Public Disclosure Special Interest Group (RPD SIG) was first conceived in December 2015 and is a group of EMWA members supporting other EMWA members. The RPD SIG objective is: “to provide a forum for the discussion and sharing of information, best practices and ideas with EMWA members,” as mentioned at the RPD SIG’s launch at the Munich conference in May 2016. The concept of creating SIGs was initiated by EMWA in 2015 with the creation of the first SIG covering pharmacovigilance. The RPD SIG took up the baton shortly afterwards.

Christopher Marshallsay and I jointly chair the RPD SIG and are supported by other eager volunteers – either as part of the committee or as part of the advisory panel, our “global due diligence network” – who support technical and regulatory questions for the SIG.

Current RPD SIG members are:

- Christopher Marshallsay (RPD SIG Co-chair)
- Alison McIntosh (guest editor for this special edition of MEW)
- Holly Hanson
- James Visanji
- Kathy Thomas
- Rafah Alhity
- Sam Hamilton (CORE reference representation)
- Tracy Farrow (RPD SIG Co-chair and CORE Reference representation)

Current additional RPD SIG advisory panel members are:

- Art Gertel (CORE Reference representation)
- René Allard

Why have an EMWA SIG on regulatory public disclosure?

The focus by industry and the general public on improving transparency around the drug development process has driven the industry and regulators to develop ever-expanding process steps and regulations to ensure transparency needs are met. The idea of being able to share

clinical trial data across multiple trials for research organisations to expand and speed up the drug development process is a noble one that strives to get treatments to patients faster. It is, however, challenging to deliver meaningful data and documents for reuse while protecting individual clinical trial participants’ personal data according to globally variable data privacy laws. This, coupled with rapidly changing regulations, has resulted in a complex minefield to traverse when dealing with regulatory public disclosure. It is therefore logical to have a forum where professionals can work together to understand the implications of data sharing.

Medical writing is increasingly involved in all forms of regulatory public disclosure with its impact on the structure and content of standard regulatory documents. The expectation is that the range of regulatory documents affected will burgeon in the coming years and that public disclosure will create the need for new regulatory documents, such as layperson summaries, which medical writers will support.

Various EMWA members involved in the field of public disclosure have been learning the hard way how to navigate through the new regulations and wanted to share their understanding and have a forum in which they could seek the advice of other experts in this area of medical writing – including what they have learnt and the challenges they have faced and overcome. The RPD SIG is a perfect forum for like-minded medical writers working in the field to impart knowledge, trade experiences, and develop best practices on a platform where they can share it more widely with EMWA members.

RPD SIG activities to date

So far, the RPD SIG’s committee members have delivered and supported many activities, such as creating the RPD SIG website, which can be accessed from within the EMWA members-only section of the EMWA website. The website includes useful resources including a glossary, key references, background reading and videos, and a question and answer section.

Last year the RPD SIG delivered a successful full-day symposium on regulatory public

disclosure at the Spring conference in Birmingham where various presenters, including Juan García Burgos from the European Medicines Agency, gave interesting updates on their experiences to date. As follow-ups at subsequent conferences, the RPD SIG has provided topic updates and continues to deliver workshops on the various aspects that affect RPD from foundation-level introductions to advanced levels on specific areas such as redaction and layperson summaries.

Our latest efforts have been realised with this issue of *Medical Writing* dedicated to the topic of regulatory public disclosure with several of the committee members and other volunteers devoting time to write articles. We are pleased to announce that future editions of *Medical Writing* will include a regular RPD section with Sam Hamilton as the RPD SIG section editor. Hence, upcoming issues of the journal will feature additional articles on public disclosure, which we hope will continue to interest EMWA members.

What next for the RPD SIG?

We welcome your ideas about what would be useful, and we continue to explore areas that will be helpful for EMWA members. We would welcome new, interested volunteers to support the RPD SIG. This support can range from committee membership to simply using the website, asking your questions, sharing your own experiences or suggesting ideas for future initiatives and areas requiring expansion. If you are interested in supporting us, please reach out to any of the current committee members for further information.

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