RPD SIG
Regulatory Public Disclosure
Special Interest Group
(meeting date 10 May 2019)
CHAIRS’ INTRODUCTION

Tracy Farrow and Christopher Marshallsay
RPD SIG
Regulatory Public Disclosure
Special Interest Group

RESOURCES GUIDE

Sam Hamilton – RPD SIG Committee

Vienna 7 – 11 May 2019
Resources (1)
Must be logged in as a member on www.emwa.org to access

• EMWA RPD SIG web page (new location):
  https://www.emwa.org/sigs/regulatory-public-disclosure-sig/

• Explanatory and introductory content PLUS this button at end of page

  RPD-related News - EMWA Newsblast

• This is archived RPD content from the NewsBlast that you receive to your inbox monthly
Resources (2)

- [www.core-reference.org](http://www.core-reference.org) active and resource-rich website:
  
  **ESTABLISHED RESOURCES**
  - Downloadable PDFs of CORE Reference + Mapping Tool (counters)
  - Multiple publications with direct links

  **CONTINUING PROFESSIONAL DEVELOPMENT**
  - In ‘real time’ clinical trial disclosure-related news direct to your inbox
    - [https://www.core-reference.org/subscribe](https://www.core-reference.org/subscribe)
  - Periodic ‘News Summaries’ dedicated page
  - External links: Japanese language blog, TransCelerate CSR template
  - Links to EMA, FDA, Health Canada disclosure regulations and portals
Resources (3)
Must be logged in as a member on www.emwa.org to access RPD Section content

• Medical Writing (MEW) journal website: https://journal.emwa.org
• Volume 27(2) June 2018 – “Public Disclosure” issue, guest editor Alison McIntosh
• Volumes 27(3) Sep 2018 onwards – RPD Section, editor Sam Hamilton
  • The issue’s RPD open access ‘Feature Article’ is linked in the RPD editorial
  • Short summary articles
  • Box information – e.g. status updated from …regulatory regions, …journal editors, …resources etc.
  • EMA named senior within ‘Medical and Health Information Service’ to contribute regular content ‘Direct from EMA’ – planned for late 2019
• Brussels-based Lawyer – expert on CTR, GDPR, Pol 0070 interplay (Opinion 03/2019 + EC guideline Q&A (Apr 19)], legal aspects, application to pharmaceuticals research. Regular content (?)
Planned MEW RPD Feature Articles 2019 & 20

Articles in progress

• Publication of CTPs and SAPs on www.clinicaltrials.gov (S Eibert)
• Medicinal products and medical devices in clinical trials conduct and disclosure: and never the ‘twain shall meet! (R Billiones, K Thomas)

Planned article topics [final titles pending]

• Summary of Health Canada’s 20-Mar-19 Final Regulation on “public access to clinical information on drugs and medical devices” (S Eibert)
• Clinical trial disclosure: A CRO medical writer’s perspective (V Fagan)
Planned External Publication

- Review of the TransCelerate template for clinical study reports (CSRs) by the developers of Clarity and Openness in Reporting: E3-based (CORE) Reference
- Hamilton S, Bernstein AB, Blakey G, Fagan F, Farrow T, Jordan D, Seiler W, Gertel A
- Submitted for publication via BMC portal on 07 May 2019
- On publication, we will share the open-access link widely, including in MEW’s RPD Section; forward the link to your colleagues
How you can help

Contact sam@samhamiltonmwservices.co.uk with:

• Content ideas, suggestions of content providers - for RPD Section in MEW

• Offer to write articles – FAs, short pieces
  • As the RPD field matures, we all gain experience. Writing is free exposure, and showcases your writing ability and knowledge
  • Example 1: Are you attending a T&D conference – e.g. DIA in Dec 2019?
  • Example 2: Are you/your company considering/assessing commercial clinical trial disclosure software platforms?

• Did you read an interesting article or find a resource – tell me so I can disseminate

• Sign up to https://www.core-reference.org/subscribe

Contact Tracy.Farrow@ppdi.com or Christopher.Marshallsay@grunenthal.com

• What other resources would you like to see made available?

• Want to join the RPD SIG Committee?

SPREAD THE WORD AND SUPPORT YOUR RPD SIG
Thank you!