EUROPEAN MEDICAL WRITERS ASSOCIATION

RPD SIG

Regulatory Public Disclosure Special Interest Group

(meeting date 10 May 2019)

CHAIRS' INTRODUCTION

Tracy Farrow and Christopher Marshallsay

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RPD SIG
Regulatory Public Disclosure Special Interest Group

RESOURCES GUIDE

Sam Hamilton – RPD SIG Committee

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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

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RPD-related News - EMWA Newsblast

- This is archived RPD content from the NewsBlast that you receive to your inbox monthly

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Resources (2)

- 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 CPD
  - https://www.core-reference.org/subscribe
- Periodic 'News Summaries' dedicated page CPD
- External links: Japanese language blog, TransCelerate CSR template CPD
- Links to EMA, FDA, Health Canada disclosure regulations and portals CPD

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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 (?)

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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)

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Planned External Publication

BMC Part of Springer Nature

- **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

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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!