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Background Reading / Viewing

Recent articles on public disclosure of regulatory documents from “Medical Writing” Journal

Regulatory Writing: New developments in public disclosure of clinical trials. Gregory Morley. Medical Writing Volume: 24, Issue: 3, Sep 2015, pp. 153 – 154.

Transferring regulation into practice: The challenges of the new layperson summary of clinical trial results. Kamila Sroka-Saidi, Barbara Boggetti, Thomas M. Schindler. Medical Writing. Volume: 24, Issue: 1, Mar 2015, pp. 24 – 27.

The EMWA Budapest Working Group: A 2-year collaboration to make recommendations for aligning the ICH E3 guideline with current practice and developing clinical study protocol guidance. Sam Hamilton, Walther Seiler, Art Gertel. Medical Writing Volume: 23, Issue: 4, Dec 2014, pp. 281 – 288.

Full publication of clinical trial data: Opening Pandora's box? Greg Morley. Medical Writing Volume: 22, Issue 4, Dec 2013, pp. 301 – 303.

Recent discussion articles on public disclosure from a publications perspective

Taichman DB. Annals of Internal Medicine. Editorial: Sharing clinical trial data: A proposal from the International Committee of Medical Journal Editors. 26 Jan 2016. Doi: 10.7326/M15-2928.
http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf.

If adopted, the proposals described in this editorial would impose additional prerequisites for publication in ICMJE member journals.

See also:

- Drazen's follow-on editorial: http://www.nejm.org/doi/full/10.1056/NEJMe1601087?query=TOC

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- Liz Wager's cautionary statement on escalating associated costs, and the ensuing Retraction Watch discussion thread, which includes a statement by the EMWA RPD SIG Chairs: http://retractionwatch.com/2016/01/28/sharing-data-is-a-good-thing-but-we-need-to-consider-the-costs/
- See also EMWA LinkedIn discussion thread including RDP SIG Chairs' comment: https://www.linkedin.com/grp/post/2717752-6102832116159049732

Recent presentations

EMWA members can view presentations from EMWA's One-Day Symposium on 'Transparency of Clinical Trial Data – Where Does Medical Writing Fit In?' held in May 2014 by going to:

http://www.emwa.org/EMWA/Home/EMWA/News_Items/EMWA_s_Second_One-Day_Symposium.aspx

The Association Perspective – Sue Forda

The European Medicines Agency Perspective – Martin Harvey

Medical Writer's Perspective – Kathy Thomas-Urban

The Industry Perspective – Hans-Jürgen Lomp

The Patient Perspective – David Gilbert

Patient perspective – David Gilbert