EMWA News

EMWA team responds to ICMJE requirements on sharing clinical trial data

In January 2016, the International Committee of Medical Journal Editors (ICMJE) proposed requirements on sharing clinical trial data, in Darren Taichman's editorial, Annals of Internal Medicine.[1] The ICMJE stated its belief "…that there is an ethical obligation to responsibly share data generated by interventional clinical trials because participants have put themselves at risk. In a growing consensus, many funders around the world – foundations, government agencies, and industry – now mandate data sharing". The editorial outlined ICMJE's proposed requirements to help meet this obligation, and encouraged feedback on the proposed requirements at www.icmje.org by 18 April 2016.

In May 2016, comments on the ICMJE's proposal were provided directly to the corresponding author, Dr Taichman, by an EMWA team that included members of the EMWA Regulatory Public Disclosure Special Interest Group (Christopher Marshallsay and Tracy Farrow) and the Budapest Working Group, developer of CORE (Clarity and Openness in Reporting: E3-based) Reference (Art Gertel, Sam Hamilton, and Tracy Farrow). Dr Taichman confirmed that 'EMWA's thoughtful comments …will be shared with the ICJME group.' EMWA's comments are available at: http://www.emwa.org/Documents/EMWA comments-ICMJE proposals-09may16.pdf.

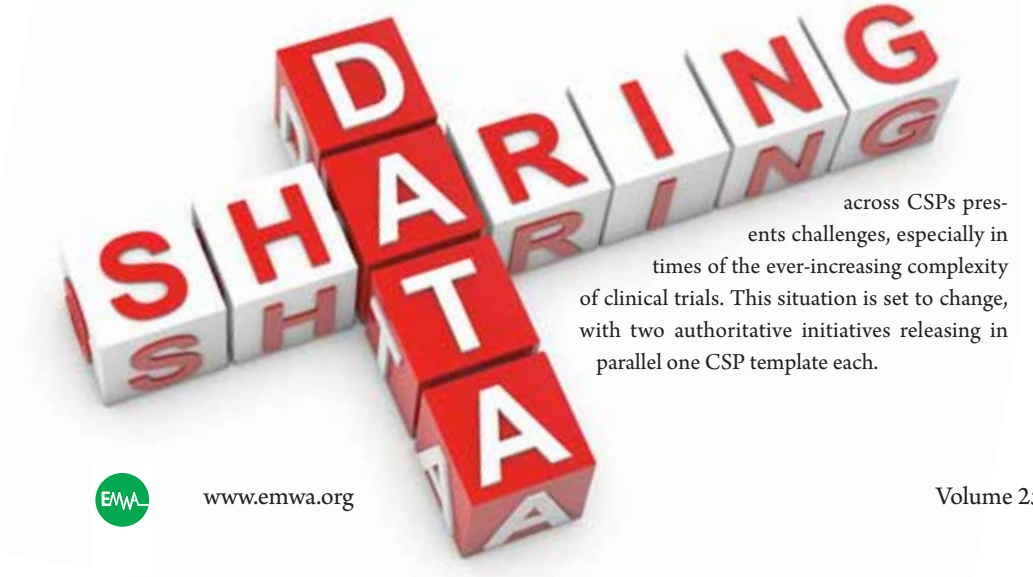
Further EMWA contributions to the discussion on this topic can be seen at Retraction Watch[2] and on the LinkedIn pages for EMWA[3] and The Publication Plan.[4]

References

1. Taichman DB, Backus J, Baethge C, Bauchner H, de Leeuw PW, Drazen JM, *et al.* Sharing clinical trial data: A proposal from the International Committee of Medical Journal Editors. Ann Intern Med. 2016;164(7): 505-506.
2. Retraction Watch. Sharing data is a good thing. But we need to consider the costs. [cited April 2016]. Available from: http://retractionwatch.com/2016/01/28/sharing-data-is-a-good-thing-but-we-need-to-consider-the-costs/
3. LinkedIn. European Medical Writers Association. Available from: https://www.linkedin.com/grp/post/2717752-6102832116159049732
4. LinkedIn. The Publication Plan. Available from: https://www.linkedin.com/groups/1886265/1886265-6130063859827957764

Templates for clinical study protocols: Where are we?

In contrast to clinical study reports, hardly any formal guidance for document structure has been available for clinical study protocols (CSPs). The resulting lack of consistency across CSPs presents challenges, especially in times of the ever-increasing complexity of clinical trials. This situation is set to change, with two authoritative initiatives releasing in parallel one CSP template each.



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Early in 2016, TransCelerate BioPharma launched its "common protocol template",[1] which provides a heading structure and common text expected to be used across CSPs. This initialcore template is accompanied by a set of text libraries for specific areas (e.g. diabetes, asthma). TransCelerate views its common protocol template as a foundational element in the longer-term movement towards an electronic protocol. As stated on TransCelerate's web site, recommendations for modifications in future releases of the common protocol template can be submitted at any time and will be reviewed on a routine basis.

Members of the Budapest Working Group (Tracy Farrow, Art Gertel, Walther Seiler, and Sam Hamilton) have already submitted preliminary comments.

Only a few weeks later, on 18 March 2016, the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) jointly released their own draft CSP template for public comment.[2] The template contains instructional and sample text; its heading structure differs from TransCelerate's common protocol template. The open comment period for this draft version closed on 17 April 2016.

This parallelism of two major initiatives on the same complex topic was unexpected. Yet, any medical writer interested in the challenging subject of CSP structure should keep an eye on both initiatives.

References

1. TransCelerate BioPharma Inc. Common Protocol Template [cited 2016 Apr 1]. Available from: http://www.transceleratebiopharmainc.com/initiatives/common-protocol-template/
2. U.S. Food and Drug Administration. FDA and NIH release a draft clinical trial protocol template for public comment [cited 2016 Apr 1]. Available from: http://blogs.fda.gov/fdavoice/?s=protocol