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EMWA's Responses to ICMJE Proposals 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 (http://annals.org/article.aspx?articleid=2482115). 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.

An EMWA team (Christopher Marshallsay and Tracy Farrow for Regulatory Public Disclosure Special Interest Group; Art Gertel, Sam Hamilton, Tracy Farrow for the Budapest Working Group, Developer of CORE [Clarity and Openness in Reporting: E3 based] Reference) provided feedback on 09 May 2016 direct to Dr Taichman. Dr Taichman replied to Sam Hamilton, thanking the EMWA group for their thoughtful comments and explaining that '…although they cannot be included with those posted prior to the deadline (that site is closed), they will be shared with the other members of the ICMJE'.

Further EMWA contributions to the discussion on this topic can be seen at Retraction Watch (http://retractionwatch.com/2016/01/28/sharing-data-is-a-good-thing-but-we-need-to-consider-the-costs/), on EMWA's LinkedIn page (https://www.linkedin.com/grp/post/2717752-6102832116159049732) and on the LinkedIn page of 'The Publication Plan' group (https://www.linkedin.com/groups/1886265/1886265-6130063859827957764).

EMWA's comments are displayed below.

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EMWA Response to the ICMJE Proposals

Feedback

"As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the deidentified individual patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material)…" (see editorial for further details)

☑ I agree with this general approach (check if applicable, and/or provide additional comments below)

EMWA Comments:

This should be a basic expectation for all data forming the basis of the results and analyses published in journals. The sharing of data would also allow analyses to be performed that answer questions that go beyond the needs of the company that performed the clinical trial. Many of the ICMJE proposals are already anchored in the PhRMA/EFPIA *Principles for Responsible Clinical Trial Data Sharing.*

The ICMJE proposals should expressly require compliance with applicable data protection laws and should allow exceptions from the sharing requirement or delayed sharing if suitable consent from trial participants is not available or if legal or contractual restrictions apply.

Proposed 6 month timeframe following publication for sharing deidentified individual patient data (see editorial for further details)

☐ I agree with this general approach (check if applicable, and/or provide additional comments below)

EMWA Comments:

The ICMJE proposes that authors share all data forming the basis of the results and analyses no later than 6 months after publication. The PhRMA/EFPIA principles foresee data sharing only after approval of marketing authorization applications in the US and EU for new medicines or for new indications. Since the publication of clinical trials is an important instrument to prepare the market for new medicines, the ICMJE proposal creates a dilemma. Combined with the differences between national and regional regulatory deadlines for the posting of results from clinical trials in publically accessible registries, these divergent deadlines linked to publication further complicate publication planning. The ICMJE proposals should be used to support a harmonization of the sharing deadlines, e.g., by reinforcing the deadlines proposed by the existing PhRMA/EFPIA principles, and not to increase the differences.

"The ICMJE will also require that authors include a plan for data sharing as a component of clinical trial registration." (see editorial for further details)

☐ I agree with this general approach (check if applicable, and/or provide additional comments below)

EMWA Comments:

The proposal from ICMJE that plans for data sharing should be publically posted and to use trial registries with mechanisms for the registration of data sharing plans (e.g., *ClinicalTrials.gov*) is not well thought out. ICMJE '…encourage other trial registries to similarly incorporate mechanisms for the registration of data-sharing plans'. For trials that are not registered on ClinicalTrials.gov, (e.g. on EudraCT) how can data sharing plans be posted? Until all registries create the process for capture of this information, registrants cannot post the required information and will therefore find themselves

unable to publish their trial results in ICMJE journals. Predicating such an important publication criteria on external parties' adoption of a process that suits ICMJE, is somewhat questionable. The ICMJE proposals should be clear to equally apply to companies and researchers in academia and in the government.

"…those who generate and then share clinical trial data sets deserve substantial credit for their efforts. Those using data collected by others should seek collaboration with those who collected the data. However, because collaboration will not always be possible, practical or desired, an alternative means of providing appropriate credit needs to be developed and recognized in the academic community. We welcome ideas about how to provide such credit." (see editorial for further details)

☑ I agree that an alternative means of providing credit to those who generate and share clinical trial data sets needs to be developed (check if applicable, and/or provide additional comments and ideas below)

EMWA Comments:

None

Other Comments:

EMWA Comments:

The ICMJE proposal applies to clinical trials defined as "any research project that prospectively assigns human subjects to intervention or comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Trials designed for other purposes, such as to study pharmacokinetics or major toxicity (e.g., Phase 1 trials), would be exempt". The PhRMA/EFPIA principles only apply for clinical trials in patients submitted as part of approved marketing authorization applications in the US and EU for new medicines or for new indications. The WHO defines a clinical trial as "any experimental study which prospectively allocates humans to a medical intervention … the WHO definition of a clinical trial for reporting purposes also includes non-randomized assignments, for example in Phase I trials". These divergent definitions complicate publication planning. The ICMJE proposals should be used to support a harmonization of the clinical trials considered within scope and not to increase the differences.

Christopher Marshallsay and Tracy Farrow for the European Medical Writers Association (EMWA) Regulatory Public Disclosure Special Interest Group; Art Gertel, Sam Hamilton, Tracy Farrow for the EMWA-American Medical Writers Association (AMWA) Budapest Working Group, Developer of CORE [Clarity and Openness in Reporting: E3 based] Reference.