ICMJE Proposes Mandatory Clinical Trial Data Sharing

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Last month, the International Committee of Medical Journal Editors (ICMJE) proposed requiring authors to share de-identified patient data underlying the results presented in their articles. The proposal is available here.

If you are a clinical trial sponsor, you may wish to comment on this proposed data sharing policy. Your company works hard to obtain its trial data, and the proposed policy will impact your clinical trial operations.

Timing of disclosure:

No later than 6 months after publication of the article.

Scope of data:

The de-identified patient data required to reproduce the article's findings, including necessary metadata, tables, figures and appendices or supplementary material.

Effective date:

This would go into effect for clinical trials that begin enrolling one year after the ICMJE adopts the requirement.

Data sharing plan:

Authors would have to include a data sharing plan as part of the clinical trial registration. They would need to indicate where researchers would house the data and, if not in a public registry, how they would provide others with access. Other data sharing plan elements from the 2015 Institute of Medicine report would also apply, such as (a) whether data would be freely available upon request or only after application to and approval by a learned intermediary, and (b) whether a data use agreement would be required.

IRB and ICF:

Sharing clinical trial data would require planning to include IRB approval and informed consent of participants.

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Attribution and restrictions:

The ICMJE would require authors to reference the data source, explain how their secondary analyses differ from the previous analyses, and – our personal favorite – "seek collaboration with those who collected the data." In a nod to the likelihood that many sponsors will (legitimately, in our opinion) view these secondary researchers as "data parasites," "data stealers" or "data socialists," the ICMJE states, "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." ICMJE welcomes suggestions.

Rationale:

In support of its position, among other things, the ICMJE explains that requiring data sharing will (a) increase transparency in the conduct and reporting of clinical trials; (b) increase confidence and trust in the conclusions drawn from the trials; (c) enable independent confirmation of the trial results; and (d) foster the development and testing of new hypotheses. Further, many funders around the world mandate data sharing, and there is a moral imperative to share data because patients put themselves at risk to generate the data.

Reactions:

There are a whole host of concerns raised by this proposal. A New England Journal of Medicine editorial addresses two concerns:

"The first concern is that someone not involved in the generation and collection of the data may not understand the choices made in defining the parameters. Special problems arise if data are to be combined from independent studies and considered comparable. How heterogeneous were the study populations? Were the eligibility criteria the same? Can it be assumed that the differences in study populations, data collection and analysis, and treatments, both protocol-specified and unspecified, can be ignored?

A second concern held by some is that a new class of research person will emerge…characterized as 'research parasites.'" This editorial goes on to give an example of – and to offer support for – symbiotic collaboration rather than parasitic use.

Because this issue is a hot potato, one author of this NEJM editorial partially recanted here.

If you can't beat 'em, join 'em:

In the US, companies and academia have been engaging in data sharing initiatives for a few years. GlaxoSmithKline launched a data sharing system in 2013, which now includes 13 companies. Rather than waiting for the regulators to mandate data sharing, these companies took the matter into their own hands perhaps in a proactive effort to exercise some control over the data sharing process. Other companies have also started providing curated access to clinical trial data.

Yale launched the YODA project (no, this is not Star Wars Episode XIII).

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The proposed ICMJE policy also falls in line with initiatives at NIH and the White House to promote data sharing.

The European Medicines Agency's policy on clinical trial data sharing requirements went into effect on January 1, 2015.

In other words, clinical trial data sharing is where industry, academia and government are headed.

Comments due by April 18, 2016:

The ICMJE is seeking feedback here. The feedback form includes 4 topics with checkboxes to indicate whether you agree, and you can add comments. There is also a freeform comment box. You have an opportunity to impact the ICMJE proposal, and we encourage you to weigh in.

If you have any questions or would like more information about these developing issues, please contact the following:

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