

**Yale University Open Data Access (YODA) Project  
Public Comment Response to ICMJE's Proposal for Sharing Clinical Trial Data**

The ICMJE is seeking feedback on its proposed requirements for sharing clinical trial data. Read our editorial, "Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors" and tell us what you think.

Please tell us your thoughts below by April 18, 2016. Note that your name, comments and the information you provide below (except for your email address) will be posted at our website. Submitted comments will be posted within one business day.

See posted comments [here](#).

\* Required field

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**Institution / Affiliation** \* Yale University

**I am a (check all that apply):** \*

X Researcher

X Clinician

Clinical trialist

Clinical trial sponsor / funder

Clinical trial participant

Patient

Other

**Requirement To Share Data Agreement**

**"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)

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

**Comments (200 word limit)**

We support and applaud the ICMJE's proposal for sharing clinical trial data as a condition of publication. While the proposal clearly states that all deidentified IPD underlying the results presented in the article are required to be shared, as well as any related metadata, we believe this proposal could be strengthened by more explicitly defining the metadata. The metadata needed to understand and make

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use of data includes, but is not limited to, blank case report forms, data definitions and specifications, trial protocols with any amendments, analysis plans, and clinical study reports.

We also believe that the ICMJE proposal could be further strengthened if it were broadened to include all deidentified IPD associated with the conduct of the published clinical trial – the complete and final trial data – not just the deidentified IPD underlying the published results. We are concerned that as investigators publish multiple articles, multiple data sets for the same trial will be shared, creating version control issues and potential confusion. Furthermore, sharing the complete and final trial data will best enable this shared resource to be used for additional research on secondary endpoints and subgroup populations, not just to validate findings published in the ICMJE member journal.

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**6 Month Time Frame Agreement**

**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)**

**Comments (200 word limit)**

We support and applaud the ICMJE’s proposal to require sharing of clinical trial data within 6 months of publication. This represents a reasonable timeframe that allows investigators sufficient time to prepare the deidentified IPD and metadata. However, it is worth noting that interest in a clinical study is never higher than at the time of its publication and the ICMJE could consider capitalizing on this interest by requiring sharing of clinical trial data upon publication. Absent this, we would strongly encourage the ICMJE to require submission of a clear and detailed data sharing plan to be considered by the editors that would in turn be publicly-disseminated at the time of article publication. Investigators will vary in their ability to adequately prepare and share deidentified IPD and metadata associated with their clinical study. ICMJE member journals are in the best position to provide advice, oversight and assurance of data sharing compliance at 6 months if the data sharing plan is reviewed as part of the article submission process and is published as part of, or in coordination with, article publication.

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**Require a Data Sharing Plan Agreement**

**“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)**

**Comments (200 word limit)**

We support and applaud the ICMJE’s proposal that authors include a plan for data sharing as a component of clinical trial registration and include a description of the data sharing plan as part of the

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submitted manuscript. However, we believe this proposal could be strengthened by more explicitly defining the aspects of the data sharing plan that will be a component of clinical trial registration and described in the publication. The use of free text fields by clinical trial registries will likely lead to data sharing plans of limited specificity, with no clear party responsible for compliance. Similarly, given word limit requirements for many ICMJE-member journals, published data sharing plans are likely to be brief, without clear details. Specific aspects of any data sharing plan that should be described include the data repository to be used (if any), process for requesting shared data, materials to be shared, and mechanism by which data access will be provided to external investigators, as well as other data-sharing plan elements outlined in the 2015 Institute of Medicine Report. As noted earlier, the data sharing plan should be reviewed by the editors as part of the article submission and publication process.

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**Providing Credit Agreement**

**“...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)**

**X 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)**

**Comments (including, if you wish, ideas on how to provide credit) (200 word limit)**

We strongly agree with the ICMJE that a means of providing appropriate credit for generating and sharing clinical trial data needs to be developed and recognized in the academic community. We would suggest the following ideas for providing such credit. First, any published article that was made possible through shared data should include explicit acknowledgement, including a statement to the effect of “This study used data from CLINICAL TRIAL (NCTXXXXXXXX) that was made available by INVESTIGATORS through DATA SHARING PLATFORM; data can be requested by BRIEF DIRECTIONS.” Second, the ICMJE should work with the National Library of Medicine of the U.S. National Institutes of Health to develop a mechanism that would allow citations to data, perhaps using NCT numbers (or another unique identifier), thereby allowing all investigators who contributed to the collection of the data to receive credit for the number of articles that were published using the shared data. Finally, any “trial citation index” should be taken into account by the academic community when making promotion decision, so that investigators receive credit not only for the number and prestige associated with articles they have authored, but also for articles that were made possible by data they shared.

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**Other Comments (200 word limit)**

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Currently lacking from the ICMJE's proposal is specification of penalty(ies) for investigators who do not share deidentified IPD within the 6 month timeframe. We believe this proposal could be strengthened by explicitly defining penalty(ies), such as exclusion of all associated trial authors from publishing articles in ICMJE member journals for a 3 year period.

We would also like to raise the following issues for consideration. First, as investigators will be responsible for preparing data to be shared, which includes protecting patient privacy, resources will be required for best-practice deidentification (<http://dx.doi.org/10.1136/bmj.h1139>; <http://dx.doi.org/10.1136/bmj.c181>). The ICMJE should advocate that clinical trial funding organizations provide budgetary support for data sharing efforts.

Second, the ICMJE should advocate that Institutional Review Boards adopt Informed Consent forms that explicitly permit data sharing, ensuring that trial participants are aware of data sharing plans.

Finally, the ICMJE noted that authors of secondary analyses must explain completely how theirs differ from previous analyses as a safeguard. While we agree that such discussion is critical to any published article using shared data, we anticipate frequent differences among authors in analysis and interpretation of the same data source, which will enhance, not diminish, understanding of the clinical trial.

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