

Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors



The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January, 2016, we published a proposal aimed at helping to create an environment in which the sharing of de-identified individual participant data becomes the norm.¹ In response to our request for feedback we received many comments from individuals and groups. Some applauded the proposals, while others expressed disappointment they did not more quickly create a commitment to data sharing. Many raised valid concerns regarding the feasibility of the proposed requirements, the necessary resources, the real or perceived risks to trial participants, and the need to protect the interests of patients and researchers.

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, the ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

- 1 As of July 1, 2018, manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as described below.
- 2 Clinical trials that begin enrolling participants on or after Jan 1, 2019, must include a data sharing plan in the trial's registration. The ICMJE's policy regarding trial registration is explained on the ICMJE website.

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For ICMJE's website see www.icmje.org
For ICMJE's policy regarding trial registration see www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after de-identification	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices)	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices)	Not available
What other documents will be available?	Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code	Study protocol, statistical analysis plan, analytic code	Study protocol	Not available
When will data be available (start and end dates)?	Immediately following publication; no end date	Beginning 3 months and ending 5 years following article publication	Beginning 9 months and ending 36 months following article publication	Not applicable
With whom?	Anyone who wishes to access the data	Researchers who provide a methodologically sound proposal	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose	Not applicable
For what types of analyses?	Any purpose	To achieve aims in the approved proposal	For individual participant data meta-analysis	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (link to be included)	Proposals should be directed to xxx@yyy; to gain access, data requestors will need to sign a data access agreement Data are available for 5 years at a third party website (link to be included)	Proposals may be submitted up to 36 months following article publication After 36 months the data will be available in our university's data warehouse but without investigator support other than deposited metadata Information regarding submitting proposals and accessing data may be found at (link to be provided)	Not applicable

*These examples are meant to illustrate a range of, but not all, data sharing options.

Table: Examples of data sharing statements that fulfil the ICMJE requirements*

For ClinicalTrials.gov see
<https://prsinfo.clinicaltrials.gov/definitions.html#shareData>

If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript, and updated in the registry record.

Data sharing statements must indicate the following: whether individual de-identified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc); when the data will become available and for how long; by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Illustrative examples of data sharing statements that would meet these requirements are in the table.

These initial requirements do not yet mandate data sharing, but investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions. These minimum requirements are intended to move the research enterprise closer to fulfilling our ethical obligation to participants. Some ICMJE member journals already maintain, or may choose to adopt, more stringent requirements for data sharing.

Sharing clinical trial data is one step in the process articulated by the World Health Organization (WHO) and other professional organisations as best practice for clinical trials: universal prospective registration; public disclosure of results from all clinical trials (including through journal publication); and data sharing. Although universal compliance with the requirement to prospectively register clinical trials has not yet been achieved and requires continued emphasis, we must work towards fulfilling the other steps of best practice as well—including data sharing.

As we move forward into this new norm where data are shared, greater understanding and collaboration among funders, ethics committees, journals, trialists, data analysts, participants, and others will be required. We are currently working with members of the research community to facilitate practical solutions to enable data sharing. The United States Office for Human Research Protections has indicated that provided the appropriate conditions are met by those receiving them, the sharing of de-identified individual participant data from clinical trials does not require separate consent from trial participants.² Specific elements to enable data sharing

statements that meet these requirements have been adopted at ClinicalTrials.gov. WHO also supports the addition of such elements at the primary registries of the International Clinical Trials Registry Platform. Unresolved issues remain, including appropriate scholarly credit to those who share data, and the resources needed for data access, the transparent processing of data requests, and data archiving. We welcome creative solutions to these problems at ICMJE's website.

We envision a global research community in which sharing de-identified data becomes the norm. Working towards this vision will help maximise the knowledge gained from the efforts and sacrifices of clinical trial participants.

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DBT is employed as an Editor by the *Annals of Internal Medicine* and the American College of Physicians. LP is Chief Editor of *PLOS Medicine* and receives a salary and benefits from Public Library of Science, a non-profit publisher and advocate of open access research, has received travel reimbursement from WHO to attend consultations on data sharing, and has received travel reimbursement from the Association of Healthcare Journalists to speak on data sharing. CL is employed as an Editor by the *Annals of Internal Medicine* and the American College of Physicians. AH is an employee of Jimma University in Ethiopia and the Editor of *Ethiopian Journal of Health Sciences*. LG is employed by WHO. PS, AP, AJ, S-TH, FG, FAF, FF, JMD, HB, CB, and JB declare no competing interests. PS's affiliation as representative and past president of the World Association of Medical Editors

(WAME) does not imply endorsement by WAME member journals that are not part of the ICMJE.

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- 1 Taichman DB, Backus J, Baethge C, et al. Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors. *Ann Intern Med* 2016; **164**: 505–06.
- 2 Menikoff J. Letter from Jerry Menikoff, MD, JD, Director, Office for Human Research Protections, to ICMJE Secretariat. March 7, 2017. http://icmje.org/news-and-editorials/menikoff_icmje_questions_20170307.pdf (accessed June 5, 2017).