Data Sharing Statements for Clinical Trials by ICMJE

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Who is ICMJE

• International Committee of Medical Journal Editors
• Committee of 15 members
• Editors of leading journals in general medicine
• Began in Vancouver, 1978
• Directing strategy for editing of medical journals
• Available at http://www.icmje.org
Members Representing

- Annals of Internal Medicine
- BMJ
- Bulletin of WHO
- Deutsches Arzteblatt
- Ethiopian Journal of Health Science
- JAMA
- Journal of Korean Medical Science (JKMS)
- The Lancet
- National Library of Medicine (NLM)
- New England J of Medicine
- The New Zealand J of Medicine
- PLOS Medicine
- Revista Medica
- Ugeskrift for Laeger
- WAME
Website of ICMJE

Data Sharing

ICMJE INTERNATIONAL COMMITTEE OF MEDICAL JOURNAL EDITORS

Recommendations
Conflicts of Interest
Journals
About ICMJE
News & Editorials

Read the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

Use the ICMJE Form for Disclosure of Potential Conflicts of Interest to generate a disclosure statement for your manuscript.

Announcements

ICMJE Announces Requirement for Clinical Trial Data Sharing Statements – June, 2017

READ THE EDITORIAL

SHARE YOUR FEEDBACK

Up-dated ICMJE Recommendations – December, 2016

Quick Links

- Clinical Trial Registration
- Who is an Author?
- FAQs
- Request to receive an E-mail when the Recommendations are updated.

About ICMJE

The ICMJE is a small group of general medical journal editors and representatives of selected related organizations working together to improve the quality of medical science and its reporting. ICMJE meets annually to refine its Recommendations for the Conduct, Reporting.
ICMJE Guidelines

• International Committee of Medical Journal Editors Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals
• ICMJE Form for Disclosure of Potential Conflicts of Interest
• Requirement for Clinical Trial Data Sharing Statements
• Following journals: > 4,000
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 deidentified individual participant data becomes the norm. In response to our request for feedback we received many comments from individuals and groups (1). 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, ICMJE will require the following as conditions of consideration for publication of a clinical trial report in our member journals:

1. As of 1 July 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 1 January 2019 must include a data sharing plan in the trial’s registration. The ICMJE’s policy regarding trial registration is explained at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html. 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 deidentified participant data (including data dictionaries) will be shared; what data in particular will be shared; whether additional, related documents will be available (e.g., study protocol, statistical analyses plan, etc.). 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 organizations 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 toward 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 deidentified 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 (https://prsinformation.clinicaltrials.gov/definitions.html#shareData). The 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 www.icmje.org.

We envision a global research community in which
Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Journal Editors

Darren B. Taichman, Peush Sahni, Anja Pinborg, Larry Pelpel, Christine Laine, Astrid James, Sung-Tae Hong, Abraham Halamek, Laraghi Gololy, Fiona Godlee, Frank A. Fristle, Fernando Florenzano, Jeffrey M. Drazen, Howard Bauchner, Christopher Beethge, and Joyce Backus

Secretary, ICMJE, Executive Deputy Editor, *Annals of Internal Medicine*.  
Representative and Past President, World Association of Medical Editors.  
Scientific Editor-in-Chief, *Ugskrifter for Læger* (Danish Medical Journal).  
Chief Editor, *PLOS Medicine*.  
Editor-in-Chief, *Annals of Internal Medicine*.  
Deputy Editor, *The Lancet*.  
Editor-in-Chief, *Journal of Korean Medical Science*.  
Enterprising Editor, *Ethiopian Journal of Health Sciences*.  
Editor-in-Chief, *The British Medical Journal (BMJ)*.  
Editor-in-Chief, *New Zealand Medical Journal*.  
Editor, *Revista Médica de Chile* (Medical Journal of Chile).  
Editor-in-Chief, *Journal of the American Medical Association (JAMA)* and the JAMA Network.  
Chief Scientific Editor, *Deutsches Ärzteblatt (German Medical Journal)* & *Deutsches Ärzteblatt International*.  
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Data Sharing Statements

- Ethical obligation to share data by interventional clinical trials
- Data sharing of deidentified participant data becomes the norm
- Conditions of publication in member journals
  - 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.
  - Clinical trials that begin enrolling participants on or after January 1, 2019 must include a data sharing plan in the trial's registration.
- Details at www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
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<th>Example 1</th>
<th>Example 2</th>
<th>Example 3</th>
<th>Example 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will individual participant data be available (including data dictionaries)?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>What data in particular will be shared?</td>
<td>All of the individual participant data collected during the trial, after deidentification.</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).</td>
<td>Not available</td>
</tr>
<tr>
<td>What other documents will be available?</td>
<td>Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code</td>
<td>Study protocol, statistical analysis plan, analytic code</td>
<td>Study protocol, statistical analysis plan, analytic code</td>
<td>Not available</td>
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Table 1. Examples of data sharing statements that fulfill these ICMJE requirements

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<td><strong>When</strong> will data be available (start and end dates)?</td>
<td>Immediately following publication. No end date.</td>
<td>Beginning 3 months and ending 5 years following article publication.</td>
<td>Beginning 9 months and ending 36 months following article publication.</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>With whom?</strong></td>
<td>Anyone who wishes to access the data.</td>
<td>Researchers who provide a methodologically sound proposal.</td>
<td>Investigators whose proposed use of the data has been approved by an independent review committee (“learned intermediary”) identified for this purpose.</td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>For what types of analyses?</strong></td>
<td>Any purpose</td>
<td>To achieve aims in the approved proposal.</td>
<td>For individual participant data meta-analysis.</td>
<td>Not applicable</td>
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ICMJE = International Committee of Medical Journal Editors.
*These examples are meant to illustrate a range of, but not all, data sharing options.*
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<td>By what mechanism will data be made available?</td>
<td>Data are available indefinitely at (<a href="#">link to be included</a>).</td>
<td>Proposals should be directed to xx@yyy. To gain access, data requestors will need to sign a data access agreement. 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.</td>
<td>Not applicable</td>
<td>Data are available for 5 years at a third-party website (<a href="#">link to be included</a>). Information regarding submitting proposals and accessing data may be found at (<a href="#">link to be provided</a>).</td>
</tr>
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Where are the data?

As the research community embraces data sharing, academic journals can do their bit to help. Starting this month, all research papers accepted for publication in Nature and an initial 12 other Nature titles will be required to include information on whether and how others can access the underlying data.

These statements will report the availability of the 'minimal data set' necessary to interpret, replicate and build on the findings reported in the paper. Where applicable, they will include details about publicly archived data sets that have been analysed or generated during the study. Where restrictions on access are in place — for example, in the case of privacy limitations or third-party control — authors will be expected to make this clear.

The new policy (full details of which are available at go.nature.com/2bf4vqn) builds on our long-standing support for data availability as a condition of publication. It also extends our support for data citation, the practice of citing data sets in reference lists in a similar way to citing papers. Authors are encouraged to cite data sets that have digital object identifiers (DOIs) assigned to them.

The introduction of data-availability statements follows a trial at five Nature journals — Nature Cell Biology, Nature Communications, Nature Geoscience, Nature Neuroscience and Nature Physics — that began in March 2016. The pilot confirmed differences in the culture of data sharing and access between different disciplines, and that the lack of obvious, public, community repositories can pose a significant barrier to public data deposition. Nevertheless, even in disciplines that are not yet so able to embrace openness and sharing, there is increasing awareness and appreciation that data deposition can enhance the visibility and reuse of published research, and that data citation can increase the recognition of those who create and share data.

This new policy will be implemented across the diverse range of Nature journals by early 2017. We expect that its implementation will shed more light on the reasons for disciplinary differences in data sharing, identify challenges and help to promote the practice more widely.

It's not just journals. A broad drive across the research, funding and publishing communities is under way to make the availability of research data more transparent. Funders, for example, are also introducing data-availability statements. The seven UK research councils require their grant holders to include them. And the US National Institutes of Health is asking researchers to provide management plans for their research data.

We expect that offering consistent information on data availability in our papers will promote data reuse by future researchers. And where public data archiving is a mandatory requirement of journals, there is some evidence that including data-availability statements with persistent links to data in published articles is an effective approach to ensuring public data availability and policy compliance (T. H. Vines et al. FASEB J. 27, 1304–1308; 2013).

This new policy follows the launch, in July 2016, by our publisher Springer Nature of an ambitious project to introduce and standardize research data policies across all of its journals (see go.nature.com/2by6l6x). The project sets out a defined common framework for data policy — which Nature policies align with — that enables different journals to encourage data sharing in a way that reflects the circumstances of respective specialist communities.
What Should We Do?

- Educate researchers and editors
- Make a registration system for data of clinical trials in each country: standardized data required by the ClinicalTrials.gov (https://prsinfo.clinicaltrials.gov/definitions.html #shareData)
- Government registry of clinical trials at KCDC website: https://cris.nih/go/krcris/index.jsp
- Country system for their own researchers
- Consider how to share and be shared
Thank you!
Let’s go together for our medical science!