



# Data Sharing Statements for Clinical Trials by ICMJE

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***Journal of Korean Medical Science***

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# ICMJE Guidelines for Member Journals

- 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

# What is ICMJE (<http://www.icmje.org>)

The screenshot displays the ICMJE (International Committee of Medical Journal Editors) website. At the top, the ICMJE logo and name are visible, along with a search bar. Navigation tabs include Recommendations, Conflicts of Interest, Journals, About ICMJE, and News & Editorials. The main content area is divided into two columns: 'Recommendations' and 'Conflicts of Interest'. The 'Recommendations' section features a box titled 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals' with links to 'Browse' and 'Download'. The 'Conflicts of Interest' section features a box titled 'ICMJE Form for Disclosure of Potential Conflicts of Interest' with a link to 'Access the Form'. Below these, there are sections for 'Announcements' (including a notice about clinical trial data sharing) and 'Quick Links' (with links to clinical trial registration, author information, FAQs, and email updates). The 'About ICMJE' section describes the committee's mission. At the bottom, a section titled 'Member Publications & Organizations' displays a grid of logos for various journals and organizations, including Annals of Internal Medicine, BMJ, Bulletin of WHO, Deutsches Arzteblatt, JAMA, JKMS, The Lancet, National Library of Medicine, PLOS Medicine, Revista Médica de Chile, and WAME.

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

## Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

**T**he 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](http://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, statis-

tics) 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://prsinfo.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](http://www.icmje.org).


We envision a global research community in which


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Journal Information

 PubMed

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Table of Contents > Full Text

## Editorial

[ARTICLE](#) [PDF](#) [PUBREADER](#) [ePUB](#) [REFERENCES](#)

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## Data Sharing Statements for Clinical Trials: A Requirement of the International Committee of Medical Journal Editors

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<sup>12</sup>Editor, *Revista Médica de Chile (Medical Journal of Chile)*.

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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.
- Registry details at [www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html](http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html)

**Table 1.** Examples of data sharing statements that fulfill these ICMJE requirements

Element	Example 1	Example 2	Example 3	Example 4
Will <b>individual participant data</b> be available (including data dictionaries)?	Yes	Yes	Yes	No
<b>What data</b> in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What <b>other documents</b> 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

**Table 1.** Examples of data sharing statements that fulfill these ICMJE requirements

Element	Example 1	Example 2	Example 3	Example 4
<b>When</b> will data be available (stating publication 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
<b>With whom?</b>	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
<b>For what types of analyses?</b>	Any purpose	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable

ICMJE = International Committee of Medical Journal Editors.

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



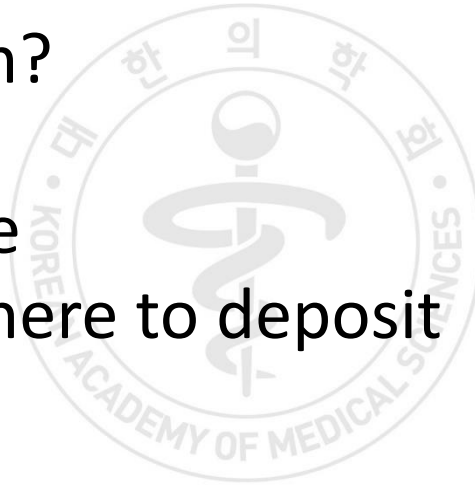
**Table 1.** Examples of data sharing statements that fulfill these ICMJE requirements

Element	Example 1	Example 2	Example 3	Example 4
By <b>what mechanism</b> will data be made available?	Data are available indefinitely at (link to be included).	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.	Not applicable
		Data are available for 5 years at a third-party website (link to be included).	Information regarding submitting proposals and accessing data may be found at (link to be provided).	

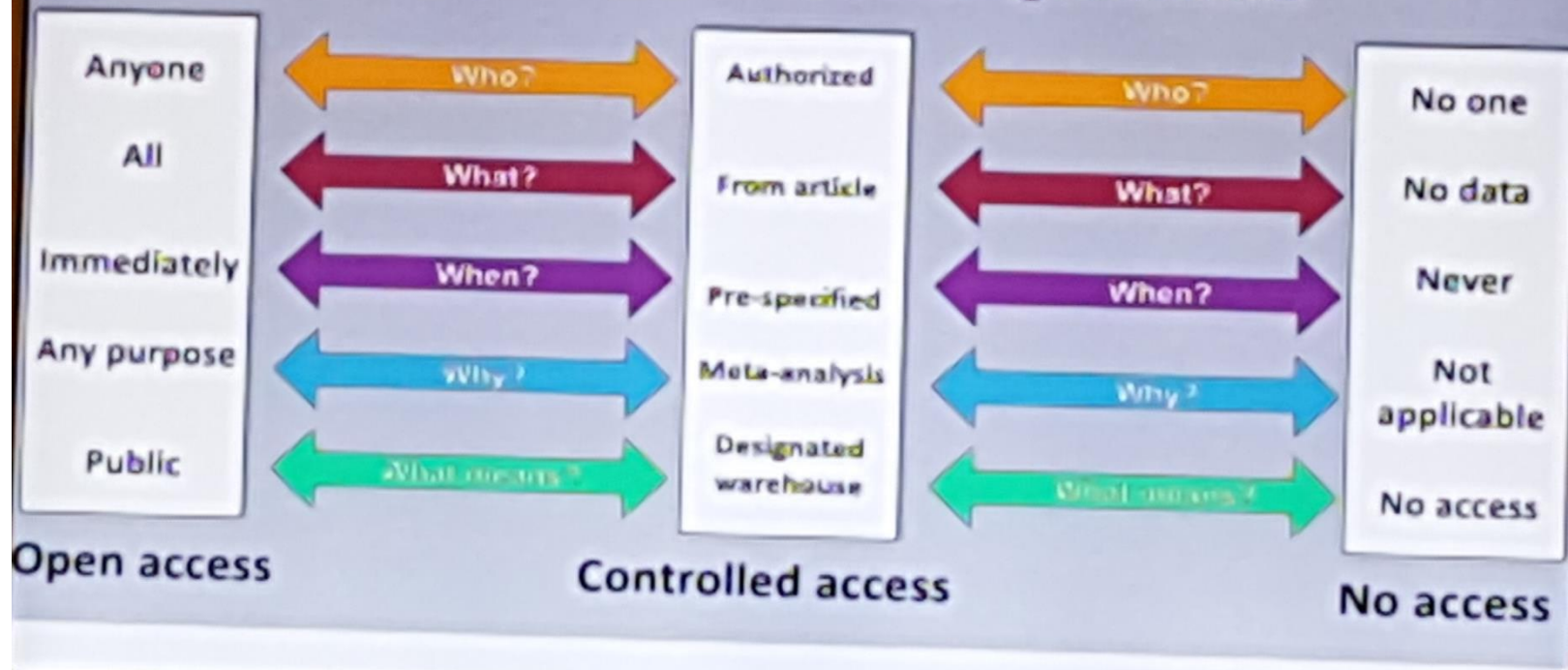
ICMJE = International Committee of Medical Journal Editors.  
 \*These examples are meant to illustrate a range of, but not all, data sharing options.

# Data Sharing Plan

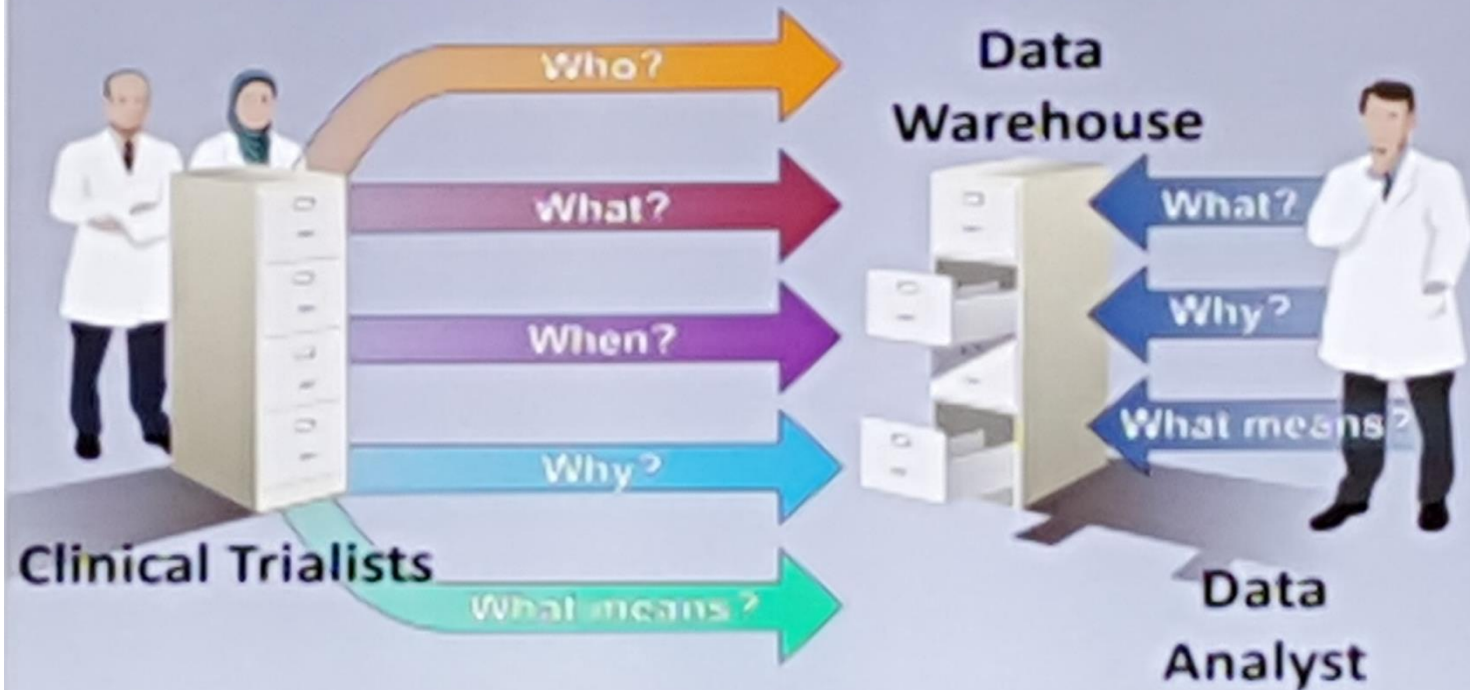
- Level of sharing data: What?
- With other data?
- Share with whom?
- Share when?
- For what purpose
- How to share: where to deposit



## Examples of Public Data Sharing Statements

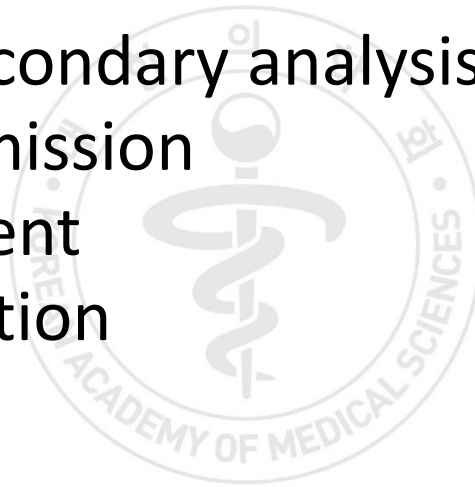


# Public Data Use Statement



# Issues Challenged

- Protection of privacy
- Ownership of data
- Authorship of secondary analysis
- Plan only at submission
- Sponsor agreement
- Data standardization



# What Should We Do for Data Sharing?

- Educate researchers
- Educate editors
- Make a registration system for data of clinical trials: 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/kr/cris/index.jsp>
- Consider how to share and be shared