

# Leading medical journals propose mandate on clinical data sharing

January 20 2016

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The International Committee of Medical Journal Editors (ICMJE) proposes new rules that will require authors to share clinical trial data as a prerequisite for their manuscripts to be considered for publication. The goal is to improve the benefit to society from the efforts of patients who volunteer to participate in clinical trials. The ICMJE proposal is outlined in an editorial published simultaneously today in *Annals of Internal Medicine* and 13 other ICMJE member journals.

“Enabling responsible data sharing is a major endeavor that will affect the fabric of how [clinical trials](#) are planned and conducted and how their data are used,” writes lead author Darren Taichman, MD, PhD, Secretary, ICMJE and Executive Deputy Editor of *Annals of Internal Medicine*. “By changing the requirements of the manuscripts we will consider for publication in our journals, editors can help foster this endeavor.”

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention to study the cause-and-effect relationship between a health-related intervention and a health outcome. The ICMJE believes there is an ethical obligation to share data generated by interventional clinical trials because participants put themselves at risk. They say that sharing data should increase confidence and trust in the conclusions drawn from clinical trials, enable independent confirmation of results, and foster the development and testing of new hypotheses. If done well, data sharing will benefit patients, investigators, sponsors, and society.

The ICMJE is seeking and will consider feedback before it adopts new data sharing requirements. Comments are welcome at [www.icmje.org](http://www.icmje.org) and should be received by April 2016. It anticipates that new data-sharing requirement will go into effect for clinical trials that begin to enroll participants beginning 1 year after the ICMJE adopts the new policy.

Provided by Annals of Internal Medicine

Citation: Leading medical journals propose mandate on clinical data sharing (2016, January 20) retrieved 6 May 2024 from

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