


Acknowledgements
The author would like to thank the reviewer and editorial board of Medical Writing for their invaluable assistance.

Author information
Silvia Paz Ruiz is a physician, researcher, health science and regulatory writer; consultant in real world evidence generation, patients engagement, health outcomes and pharmacoeconomics research for the pharmaceutical and medical device industries across Europe and North America. She collaborates with CROs, regulatory agencies and pharmaceutical and medical device companies.

ICMJE to mandate data sharing statements

Those of us who attended the 2017 spring conference in Birmingham were treated to an excellent symposium on transparency in clinical trials, where EU Policy 00701 on disclosure of clinical data was a key focus. A month later, the ICMJE (International Committee of Medical Journal Editors) announced that beginning in July 2018 they will require that submitted manuscripts based on clinical trials carry a data sharing statement. Data sharing statements will be expected to describe the following: whether data will be shared; what will be shared; and when and for how long the data will be available. Also, from 2019 new trials will have to include a data sharing plan in their registration information.

As the ICMJE themselves point out, these requirements – tellingly referred to as “minimum requirements” – do not mandate data sharing itself, only statements relating to data sharing. However, they warn that “editors may take into consideration data sharing statements when making editorial decisions” and that some journals “already maintain, or may choose to adopt, more stringent requirements for data sharing”.

Complementing the ICMJE’s stick approach, the authors of a recent Sounding Board article in the New England Journal of Medicine propose offering “data authorship” as a carrot to encourage data sharing. According to the proposal, people who gather clinical trial data should be given credit that can be used to support applications for tenure and funding. The hope is that this would serve as an incentive to share data with others.

References

Stephen Gilliver
stephengilliver@gmail.com