



April 18, 2016

Darren B. Taichman, M.D., Ph.D.  
Secretary, International Committee of Medical Journal Editors  
c/o American College of Physicians  
190 N. Independence Mall West  
Philadelphia, PA 19106

**Re: Comments on *Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors***

Dear Dr. Taichman:

The Biotechnology Innovation Organization (BIO) is pleased to offer the following comments on *Sharing Clinical Trial Data: A proposal from the International Committee of Medical Journal Editors* ("ICMJE") ("the Proposal").<sup>1</sup>

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products.

**General Comments**

BIO member companies are committed to improving human health through the development of innovative therapies. We strongly support research that aims to improve human health through better drug development and recognize that responsibly sharing our clinical trial data can help to advance such research, while reinforcing public confidence in the safety and efficacy of our medicines. As such, we share the underlying goals of ICMJE in setting forth a policy to "increase confidence and trust in the conclusions drawn from clinical trials," "enable the independent confirmation of results," and "foster the development and testing of new hypotheses."<sup>2</sup> Even though most BIO member companies are small, pre-revenue enterprises that operate with limited resources, and evaluation of requests for data may divert resources from their core mission of developing innovative therapies, BIO members recognize the value of supporting qualified external medical and scientific research via data sharing.

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<sup>1</sup> ICMJE, *Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors*, *Annals of Internal Med.* (Jan. 26, 2016). Available: <http://www.icmje.org/news-and-editorials/M15-2928-PAP.pdf>

<sup>2</sup> *Id.*



Drug development is a highly complex, costly, lengthy, and competitive endeavor. The interests of all participating stakeholders must, therefore, be carefully balanced when considering increased access to clinical trial data. Foremost, study participants themselves must have confidence that their personal medical information and privacy will be respected in accordance with the terms of their informed consent and in compliance with relevant laws and regulations. Additionally, in order for innovative biotechnology companies to successfully attract the investment necessary to fund a drug or biologic program over the decade or more required for its development, it is imperative that data not be disclosed prematurely or in a manner that does not protect confidential and proprietary information.

In 2014, BIO and its member companies adopted the *BIO Principles on Clinical Trial Data Sharing* ("BIO Principles"), which we believe to be largely consistent with ICMJE's proposed data sharing policy.<sup>3</sup> Under the BIO Principles, BIO members have committed to posting technical summary results in a clinical trials database 1) for approved products, all company-sponsored clinical trials testing both safety and efficacy in patients, and 2) for products discontinued in development for all indications because of safety concerns, all pivotal company-sponsored clinical trials testing both safety and efficacy in patients. In addition, for their approved products, BIO members have committed to reviewing and, as appropriate, fulfilling qualified requests from medical and scientific researchers for additional clinical trial data (e.g., patient-level clinical datasets, Clinical Study Reports, clinical study designs and protocols, etc.) beyond those shared proactively with the public. To facilitate this process, each BIO member company is committed to developing and making available to the public its own data sharing plan (*i.e.*, its general policy on data sharing for all clinical trials), outlining the criteria, procedures (including data sharing agreement requirements), and timelines for managing specific requests for clinical trial data.

As we explore new opportunities to broaden scientific discourse related to drug development, it is critical to ensure that analyses of clinical data outside the expert review processes of health authorities have scientific merit and can enhance the treatment and safety of patients. BIO member companies are committed to responsibly, consistently, and transparently providing qualified researchers with clinical trial data beyond those normally shared proactively with the public. BIO members are also committed to ensuring that fulfilled requests have scientific merit, protect patient privacy, and promote biomedical innovation.

## Specific Comments

Given the degree of alignment between the BIO Principles and the ICMJE Proposal, we are generally supportive of ICMJE's efforts to facilitate responsible sharing of clinical trial data with qualified researchers. We offer the following comments and suggestions to clarify and improve the Proposal, and to strike the appropriate balance between advancing the scientific discourse through the sharing of data, protecting the privacy of patients, and promoting investment and innovation.

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<sup>3</sup> Biotechnology Innovation Organization, *BIO Principles on Clinical Trial Data Sharing* (March 2014). Available: <http://www.bio.org/articles/bio-principles-clinical-trial-data-sharing>



- Sponsors Are Responsible for Clinical Trial Data

BIO recommends that ICMJE clarify that, when referring to requirements for “authors” to share data or include a data sharing plan as part of clinical trial registration, it actually means the trial Sponsor that controls the data and/or is responsible for submitting information for clinical trial registration. Authors of a publication may not have the legal authority or indeed the ability to share data or post a data sharing plan.

Similarly, the proposal states that data sharing plans provided by authors should address “where researchers will house data and, if not in a public repository, the mechanism by which they will provide others access to the data.” Authors may not be able to address these points, as the Sponsor may house their own data sets.

- Application of Legal Obligations to the Data Sharing Requirements

ICMJE should recognize that any proposed data sharing policy will have to comply with all applicable laws relating to patient privacy and informed consent. Sponsors have to comply with a range of privacy and informed consent legislation around the globe that depends on the countries in which clinical trials have been conducted. For example, Sponsors may be required to withhold individual patient data from sharing programs when the patient withdraws consent or may not be able to obtain IRB approval for informed consent forms that include data sharing in regions that do not have transparency policies. It is important that Sponsors are able to continue to comply with these legal obligations.

- Data Sharing Requirements Should Apply Only After Regulatory Approval

BIO member companies recognize that responsible clinical trial data sharing advances public health and scientific discourse, honors research participants’ expectations of privacy as outlined in their terms of informed consent, and promotes biomedical innovation. As such, we are committed to the responsible sharing of individual patient data with qualified researchers in a manner that meaningfully advances the scientific and medical discourse while balancing the interests of all stakeholders.

BIO believes that requirements regarding individual patient data sharing should only apply to approved medicines and indications. This would serve to protect proprietary information, ensure continued investment in biopharmaceutical research, and maintain the integrity of the regulatory review process. Such requirements would not in any way preclude a Sponsor from sharing individual patient data at an earlier time.

Requiring sharing of patient level data while regulatory approval is still being pursued may force disclosure of competitive, proprietary information at a highly sensitive time in product development. This risks negatively impacting not only the incentive for biopharmaceutical companies to continue to invest in research and clinical development programs, but also the willingness of clinical trial sponsors to publish results prior to regulatory approval.

Additionally, premature disclosure of patient-level clinical trial data could undermine the regulatory review process. National regulatory authorities are empowered to make



important public health decisions based upon their review of the data for unapproved medical products. The release of secondary analyses of clinical trial data by independent researchers before or during regulatory review could potentially impose external pressure or influence on regulators in a manner that compromises the integrity of the review process.

- Six Month Time Frame

BIO recommends that data sharing requirements not apply to unapproved medicines until six months after regulatory approval. This should provide Sponsors sufficient time to publish and prepare de-identified data for sharing to protect patient privacy.

In addition, BIO understands this paragraph to mean that Sponsors should be prepared to accept data sharing requests from external researchers beginning six months after regulatory approval, or six months after publication for an approved medicine.

- Exceptions to Data Sharing Policy

The ICMJE Proposal states that there may be “rare situation[s] in which compliance with [the proposed] requirements is impossible.”<sup>4</sup> BIO agrees with this statement, and notes that there may be instances in which legal, public health, or patient privacy concerns would outweigh the potential benefit of making individual patient data available to other researchers. Clinical trials in rare diseases, for instance, may bear a greater risk, or a reasonable likelihood that individual patients could be re-identified from individual patient data. Accordingly, BIO recommends that ICMJE explicitly state that exceptions to the data sharing policy will be granted when necessary to protect the privacy of patients, for legal reasons, or ethical or public health rationales.

- Implementation Questions

BIO agrees with the recommendation that the policy only apply to clinical trials that enroll their first patients one year after adoption of the policy.

Additionally, while BIO shares the goal of ICMJE in facilitating responsible sharing of patient-level clinical trial data with qualified researchers, we note that the Proposal raises a number of questions regarding implementation of the proposed data sharing requirements. We request that stakeholders be given additional opportunity to comment on the Proposal after ICMJE has reviewed stakeholder comments and revised or clarified its proposal.

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BIO member companies recognize that responsible clinical trial data sharing advances public health and scientific discourse, honors research participants’ expectations of privacy as outlined in their terms of informed consent, and promotes biomedical innovation. We are

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<sup>4</sup> Id.



and will remain committed to working with the broader scientific community to develop knowledge that will improve drug development, enhance public health, and reinforce public confidence in the safety and efficacy of our medicines.

BIO appreciates this opportunity to provide comments on the Proposal. We would be pleased to provide further input or clarification of our comments, as needed.

Sincerely

/S/

Cartier Esham, Ph.D.  
Executive Vice President, Emerging Companies Section &  
Vice President, Science & Regulatory Affairs  
Biotechnology Innovation Organization