# BIO PRINCIPLES ON CLINICAL TRIAL DATA SHARING

**Reaffirming and Broadening Our Commitment to Transparency and Clinical Trial Data Sharing**

The member companies of the Biotechnology Industry Organization (BIO) 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.

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. Moreover, most BIO member companies are small, pre-revenue enterprises that operate with limited resources. While evaluation of requests for additional data will divert resources from their core mission of directly developing innovative therapies, BIO members recognize the value of supporting, to the extent possible, qualified external medical and scientific research.

We are, therefore, committed to building upon our routine publication of clinical research results and ongoing collaborations with academic and government researchers in order to support additional efforts to improve public health.

**How Do We Currently Promote Transparency and Access to Clinical Trial Data?**

BIO and its member companies supported the provisions of the Food and Drug Administration Amendments Act (FDAAA) of 2007 that expanded the registration and summary data requirements for *ClinicalTrials.gov*. In compliance with FDAAA, BIO member companies currently register, at minimum, all clinical trials beyond Phase I on *ClinicalTrials.gov*. BIO also provided recommendations to the National Institutes of Health

(NIH), which was tasked with overseeing the expansion of *ClinicalTrials.gov* to include summary clinical trial data for certain unapproved products.[1]

In addition, BIO member companies already routinely publish their clinical trials in peer-reviewed scientific journals and present their results at scientific meetings and workshops. A growing number of BIO member companies also voluntarily share patient-level clinical trial data through their own company-specific initiatives, as well as innovative public-private partnerships and consortia.

**How Will We Increase Access to Clinical Trial Data, Moving Forward?**

As we explore new opportunities to broaden scientific discourse related to drug development, it is critical to ensure that studies designed to evaluate 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. We will ensure that all fulfilled requests have scientific merit, protect patient privacy, and promote biomedical innovation.

Toward these ends, BIO member companies will honor, <u>at minimum</u>, the following commitments:

1. **Registering Clinical Trials:** BIO member companies will register all company-sponsored clinical trials conducted in patients in an appropriate public registry, such as *ClinicalTrials.gov* or the European Clinical Trials Database (EudraCT).

2. **Summarizing the Results of Clinical Trials:** BIO member companies will post technical summary results in a clinical trials database as follows:

   (a) *For approved products*, all company-sponsored clinical trials testing both safety and efficacy in patients, regardless of whether their outcomes are positive or negative; and

   (b) *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, regardless of whether their outcomes are positive or negative.

3. **Publishing Clinical Trials:** BIO member companies will submit for publication in the scientific literature, or otherwise make available to the scientific community (*i.e.*, on a company-sponsored website, at an appropriate scientific conference, *etc.*), the results of all company-sponsored Phase 3 clinical trials and clinical studies of significant medical importance regardless of whether their outcomes are positive or negative.

4. **Providing Factual Summaries of Clinical Trials to Research Participants:** BIO member companies will work with regulators to adopt a framework for developing and sharing factual summaries of clinical trial results with research participants.

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[1] BIO Comments on Expansion of the Clinical Trial Registry and Results Data Bank (2009) http://www.bio.org/sites/default/files/20090622.pdf

5. **Responsibly Sharing Additional Clinical Trial Data:** For their approved medicines, each BIO member company will fulfill qualified requests from medical and scientific researchers for additional clinical trial data (*e.g.*, Clinical Study Reports, patient-level clinical datasets, clinical study designs and protocols, *etc*.) beyond those shared proactively with the public. To facilitate this process, each BIO member company will develop and make available to the public its own criteria, procedures, and timelines for determining the qualification of specific requests for clinical trial data.

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 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. We view the commitments outlined in these Principles as the opening of a dialogue that will grow and evolve with shared experience.