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Are clinical trial data shared sufficiently today? Yes

The AllTrials campaign asks for all trials to be registered and their results published. **Ben Goldacre** (doi:10.1136/bmj.f1880) says we need the evidence to make informed decisions about medicines. **John Castellani** says mandatory disclosure could affect patient privacy, stifle discovery, and allow competitors or unscrupulous actors to use the information

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Clinical trials are essential for the successful development of new medicines that save and improve lives and provide hope for millions of patients. Biopharmaceutical companies are committed to the continuous improvement of clinical trials to bring innovative medicines to the patients who need them. This includes protecting the safety of study participants, overcoming barriers to greater participation, and fostering new medical discoveries.

The biopharmaceutical industry is firmly committed to enhancing public health through responsible reporting and publication of clinical research and safety information. In the process of drug development, companies routinely publish their research, collaborate with academic researchers, and disclose clinical trial information at the time of patient registration, drug approval, and for medicines whose research programs have been discontinued. In addition, PhRMA has set out voluntary principles to fortify biopharmaceutical companies' commitment to the highest standards for ethics and transparency in the conduct of clinical trials. PhRMA's *Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results*[1] are designed to help ensure that clinical research conducted by biopharmaceutical research companies continues to protect patients and provide meaningful medical research results to healthcare professionals and patients.

The biopharmaceutical sector may provide more information about its research and products than any other industry. As expected by the healthcare professionals that prescribe innovative medicines, the current biomedical research system includes wide sharing of trial results with government regulators, academic and medical communities, and physicians through submissions to the US Food and Drug Administration (FDA) and other international regulatory bodies, presentations at medical conferences, and publication in peer reviewed journals.

Information on clinical trials for potential new medicines is already required by US law to be posted on ClinicalTrials.gov, the publicly accessible clearing house maintained by the National Institutes of Health (NIH). As of May 2013, ClinicalTrials.gov has information on 146 213 studies in all 50 states and in 185 countries. NIH reported last year that ClinicalTrials.gov "receives more than 95 million page views per month and 60 000 unique visitors daily."[2]

While these efforts are working, the biopharmaceutical industry is engaged in a dynamic ongoing process to improve on all aspects of clinical trials and is committed to taking part in a multi-stakeholder dialogue to advance responsible data sharing that protects patient privacy, maintains the integrity of the regulatory review process, and preserves incentives for biomedical research. We are reaching out to groups such as the Institute of Medicine, the Harvard Multi-Regional Clinical Trial Center, Project Data Sphere of the CEO Roundtable on Cancer, and the European Alliance for Personalized Medicine.

Processes for data sharing or disclosure must take account of patients' informed consent and the reality that re-identification of patients based on anonymized information is possible.[3] Threats to patient privacy will jeopardize patient willingness to participate in clinical trials, which would delay the availability of new therapies.

Dumping millions of pages of clinical trial information into the public domain without providing appropriate scientific and clinical context or guidelines for meta-analysis could lead to second guessing of the expert decisions of national regulators worldwide, undermining patient trust and confidence in the safety and effectiveness of approved medicines.

Mandatory public disclosure of intellectual property, confidential commercial information, and proprietary scientific methods found in clinical trials could stifle discovery and open the possibility of competitors or unscrupulous actors using the information for their own products in other markets or countries. Without appropriate protection for intellectual property to incentivize the enormous investment risk involved, biopharmaceutical companies will be discouraged from investing in the next generation of new medicines, leading to patients and

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physicians being deprived of innovative therapies to tackle the serious and life threatening diseases of the 21st century.

The modern clinical trial system and associated sharing of information led to more than 340 new medicines approved by the FDA over the past decade, with 39 new medicines in 2012 alone. It contributed to over 30 new medicines approved for HIV in the past three decades—based on the work of 2400 completed trials—turning what was once a death sentence into a treatable, chronic condition.

Since 2000, PhRMA member companies have invested about $550bn (£330bn; €390bn) in research and development, including clinical trials, in the search for new treatments and cures. No government or academic institution has the resources or multidisciplinary expertise to conduct the clinical trials needed to develop the new medicines patients need. Only the biopharmaceutical industry can take on this considerable risk at such a scale, and only a carefully balanced regulatory and competitive environment can foster the future investments in this research necessary to produce new treatments to benefit current and future patients.

Competing interests: I have read and understood the BMJ Group policy on declaration of interests and have no relevant interests to declare.

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1 Pharmaceutical Research and Manufacturers of America. Principles on conduct of clinical trials and communication of clinical trial results. 2011. www.phrma.org/sites/default/files/pdf/042009_clinical_trial_principles_final.pdf.
2 US National Institutes of Health. Clinicaltrials.gov. www.clinicaltrials.gov/ct2/about-site/for-media.
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