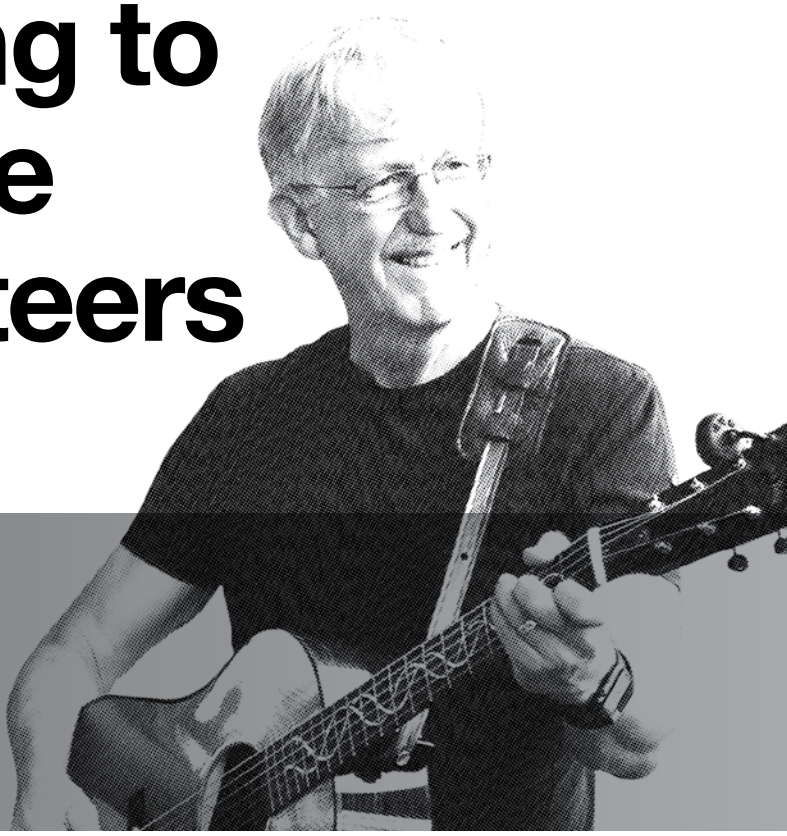
Sharing Trial Data Is the Right Thing to Do for Science and for Volunteers



Francis Collins
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The broad sharing of research information is not only a core value of NIH but also necessary to improve the growing body of biomedical knowledge.

With all of the exceptional opportunities facing biomedical research today, partnerships and team science are more important than ever. The combined efforts of many different scientific disciplines — and many different sectors of society — are absolutely essential if we are to make the most of the many exciting possibilities that lie before us.

One outstanding example is the Accelerating Medicines Partnership (AMP), a public-private consortium involving the National Institutes of Health (NIH), 10 pharmaceutical companies, the Foundation for the NIH, the Food and Drug Administration (FDA), several patient organizations and other partners from the nonprofit world. The goal of AMP is to transform the current model for drug development by jointly identifying and validating promising biomarkers and drug targets, with the ultimate aim being to provide patients with an increased number of diagnostics and therapeutics in a swifter, more cost-effective manner.

Since its launch in 2014, the AMP consortium has undertaken collaborative projects in three disease areas: Alzheimer's, type 2 diabetes and the autoimmune disorders of lupus and rheumatoid arthritis. Through this cross-sector endeavor, NIH and its partners are sharing expertise and resources in an integrated governance structure

that enables the best informed contributions to science from all participants. A critical component of AMP is that all partners have agreed to make the data and analyses publicly accessible.

As another example of a new model for doing research, consider the NIH-led Precision Medicine Initiative® (PMI). PMI seeks to create a new paradigm in which participants are regarded as true partners in research, not merely subjects. More than 1 million volunteers will be invited to sign up to join PMI's All of Us℠ Research Program by 2020. Not only will these volunteers agree to share their electronic health records and other data with researchers, but they will also have access to their own data plus a wide range of study results.

PMI's All of Us℠ Research Program will intersect in a synergistic way with other fundamental changes in medicine and research to empower Americans to lead healthier lives. Among those changes are new federal regulations and policies aimed at ensuring information about clinical trials is shared widely and rapidly. Clinical trials are crucial for the translation of research advances into new approaches for prevention and treatment of disease.

Volunteers who take part in clinical trials often do so with no assurance of personal benefit, but with the expectation that their involvement will add to a growing body of biomedical knowledge that may help others someday. To uphold this trust, all trial results need to be reported publicly in a timely fashion — and yet we know that has not always happened in the past.

A regulation issued Sept. 16, 2016, by the Department of Health and Human Services, details requirements for registering certain clinical trials and submitting their summary results within one year of completion of data collection to ClinicalTrials.gov, a database managed by NIH's National Library of Medicine (NLM). The regulation applies to most interventional studies of drug, biological and device products regulated by the FDA. Also, because of our commitment to data sharing, NIH has issued a complementary policy that applies to all NIH-funded trials, including those of behavioral interventions.

ClinicalTrials.gov already contains a vast trove of information, and its value will only continue to grow as more studies and results are added. So, I am delighted that NLM plans to work with leading information technology experts to make ClincalTrials.gov more user-friendly. This partnership will build on lessons learned from the National Cancer Institute's recent collaboration, facilitated by the Vice President's Cancer Moonshot initiative, in which technical experts and Presidential Innovation Fellows are enhancing access to oncology trial information at Cancer.gov.

Rapid, broad sharing of research information is a core value of NIH, as well as an issue that has long been close to my heart. Two decades ago, under the leadership of myself and others, the international Human Genome Project established data-sharing policies for depositing genetic data into public databases within 24 hours. This year, we are setting forth bold initiatives for sharing summary-level results of clinical trials. But we still have work to do. Sharing individual patient-level data from trials with qualified researchers is still a desirable framework for even more expanded data access, and NIH is evaluating various models for making such sharing possible.

The bottom line is that NIH remains firmly committed to engaging patients, empowering researchers and encouraging public-private partnerships. I hope each of you will join us in this effort!