

Dr. Margaret Hamburg
Commissioner
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Dear Dr. Hamburg,

This is a letter from clinical trial participants and their loved ones all across the United States, who have a very important request: Please, do more to make sure that study volunteers receive the results of their clinical trials directly, in lay language.

Obtaining results of trials, in language the general public can understand, has been an unmet need for decades and we are asking for your help. Right now, you are discussing whether researchers should be required to prepare easy-to-understand summaries of clinical trial results, under Department of Health and Human Services Docket Number NIH-2011-0003, RIN 0925-AA52, section III.C.6. We implore you to use this opportunity to help ensure trial participants get the information we are requesting.

Doctors ask patients to join clinical trials because it may help others suffering from disease in the future, but when the trial is over, no one tells study volunteers what was learned or that their participation mattered. With thousands of new drugs in development, representing improved treatment options for millions of patients, keeping trial participants apprised of trial results will go a long way in ensuring a continued, engaged, and willing pool of participants.

It is important to remember that without clinical trial participants, there can be no treatment advancement. Therefore, it is imperative that those who are willing to participate are treated as research partners and are respectfully appreciated for their contribution to research. The highly-technical summaries that are currently put on ClinicalTrials.gov do not meet the needs of patients, or even most scientists. Plain, non-technical language is badly needed. Please, tell researchers that the United States *will* make easy-to-understand lay summaries available to participants. And while that is in progress, please let researchers know – as clearly as you can – that the U.S. Food and Drug Administration supports fulfilling the obligation to honor clinical research volunteers through giving them the results of their clinical trials in a format that is clear and understandable.

Sincerely,

[signatures from patients...]