OPINIONS

Registering results: A public database of clinical-trial information

Consumer groups, professional medical associations, and medical journals are calling for public disclosure of all medical studies and for drug manufacturers to register their clinical trials in a public database once the trials begin. PharmaVOICE asked: should companies have to register their clinical trials as they are initiated in a public database?

Great concept

I think this is great concept. Not only will patients be able to know what is available to them aside from the regular treatments for common diseases, but more importantly these data will be available to those who don't have any other recourse but to try drugs that show promise in clinical trials but are not yet on the market.

Carlos Chua
Senior Clinical Research Associate
Organon Pharmaceuticals USA Inc.

Collective best interest

It is in our collective best interest for the results of well-designed, carefully conducted clinical trials to be widely available during the development of new pharmaceutical products and after approval. It allows those who will use the product to understand more about it, both positive and negative. We often learn more from our failures than we do from our successes. But simply registering a study does not mean that it was well-designed at the outset nor that it will ever be completed, perhaps due to problems unrelated to the scientific merit of the product, i.e., poor enrollment, uncertain methodology, or endpoints of disease that are not universally accepted. Perhaps the assumptions about variability and the difference between treatments used for calculating sample size were not met, resulting in a nonsignificant difference. It is called "research" for a reason. If we knew the answers at the start, we wouldn't have to conduct the study.

The industry is highly regulated, and sponsors are required to report the results of all studies to the FDA and other involved regulatory bodies around the world. The proprietary information submitted by the sponsor is rigorously reviewed by the agency, and appropriate action by the agency can be expected. The FDA, and presumably other regulatory agencies, is populated by very capable scientific personnel who rigorously protect the public. If regulatory action is indicated, we can expect the FDA to take appropriate action with or without the publication of results of failed studies.

The impact of calling for wide dissemination of all information about a drug during development or after approval is not limited to the pharmaceutical industry and regulatory bodies. Perhaps prestigious journals should be "required" to publish reports of "failed" or confirmatory studies as well as those that provide positive data. As a scientific community, we should recognize that negative observations require careful consideration so we neither hide a drug-related problem nor saddle a product with an undeserved black eye.

Establishing a registry, whether voluntary or mandatory, does not address the key issues of scientific integrity or comprehensive reporting. The FDA is in place to evaluate medical products and is informed of all regulated studies and results. The agency provides much better oversight than does a registry.

George D'Addamio, Ph.D.
President
PharmConsult Inc.

A valuable resource

Companies conducting clinical trials are paying for the effort and are responsible for the results, therefore they own the information. But given the fact that companies will be held liable for information they possess, it is in their best interest to make public the fact that they have conducted trials and, at least, any adverse events that are linked causally to the trials. By doing this, they can avoid (to the extent possible) liability for any other reactions that might happen in the future. The cost to companies of any reaction (or even death) that occurred from a reaction they "knew" about would be much worse than any value of keeping that information secret. A database documenting the clinical trial itself, along with any adverse reactions, would be both a prudent and valuable resource. Further information, such as participants, timing, and efficacy might more properly be kept as proprietary information by the company paying for and conducting the trials.

Stephen Ruger
Project Manager
21 CFR Part 11 Validation

An idea with merit

The idea of a public trials registry has merit for the following reasons: it puts all sponsors on equal footing regarding accountability for study results; it can speed time to knowledge of favorable (or unfavorable) study results; it can increase public awareness of the success (or failures) associated with conducting trials; it can raise patient awareness of the risks and benefits of participating in clinical trials; and it can help avoid duplicate studies.This registry is consistent with faster and fuller information access and sharing for a common goal.

Philip Lavin, Ph.D.
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Full disclosure

We are in the age of full disclosure and transparency. Everything must be available to all of us whether it is about mutual funds, criminal records, our time in Vietnam, clinical trials, or company finances. Google went public at an appropriate time. I believe all this is good now that we have digital capacity for storing and retrieving lots of information. The downside of this is that we only have 24 hours in a day and all this information becomes "noise" for most of us who have no time to look at all those envelopes we get in the mail from investment firms. At one level, full disclosure becomes no disclosure at all. The intent of any given trial and the results of any given trial are