Data sharing in pharmaceutical industry shows progress

October 16 2014, by Jeff Tolvin

To enhance the transparency of clinical trials for new drugs, a number of pharmaceutical firms have begun sharing data with investigators outside their own companies. Brian L. Strom, chancellor of Rutgers Biomedical and Health Sciences, chairs the independent advisory committee which allows access to the data through a pioneering system that launched in 2013. In a paper published Oct. 15, 2014, in the *New England Journal of Medicine*, Strom and the three other committee members outlined the experience with the system during its first year.

Rutgers Today recently spoke with Strom about the potential impact of data sharing.

What is data sharing in the pharmaceutical industry and what will it accomplish?

Strom: Data sharing is the process of making available the raw data from a company's clinical trials for drugs in development to researchers outside that company, who will then conduct their own analyses and publish their results. Theoretically, it allows researchers to maximize their knowledge and understanding of particular drugs, compare similar drugs for effectiveness and side effects, and develop and test new methodologies for drug development. Data collection is the most expensive element in the development of new drugs, and the most risky to subjects. Data sharing allows this valuable resource to be used maximally.

What was the impetus behind the decisions by pharmaceutical companies to share such valuable information?

Strom: Basically, data sharing is a result of a combination of factors. Patients participating in clinical trials are putting themselves at risk, and so it behooves us to maximize the use of the data. The industry has been criticized for keeping certain information secret, particularly information relating to unsuccessful trials. Ethically, it is appropriate to make data available in a scientifically responsible manner to enhance the utility and transparency of clinical trials.

Data sharing is seen as a monumental change in culture for the pharmaceutical industry. While GlaxoSmithKline took the lead in data sharing, a number of other major firms are also now participating as well. Just on the system my co-authors and I are serving as the independent panel, reviewing all sharing requests, 10 companies have now made more than 1,200 clinical studies available for sharing and additional analyses.

Why would pharmaceutical companies agree to this? Aren't they putting themselves at risk by allowing competitors to study their data?

Strom: While the process is not risk-free – in particular the possibility exists that analyses by other investigators could demonstrate flaws in the analyses in the original studies – pharmaceutical firms sharing their data recognize that this is their public responsibility. Further, they are hoping that additional analyses through data sharing will strengthen the credibility of their analyses and products. The originating firms may also benefit by finding additional uses for their products.

Have we been able to see how data sharing directly benefits consumers?

Strom: Currently, the additional analyses we've authorized through data sharing are still in progress. But one of the stipulations of these data-sharing agreements is that the findings of the additional analyses must be published. Once the findings are published, we anticipate consumers will benefit significantly. Data sharing allows researchers the opportunity to analyze data from multiple trials. Investigators might compare the data on side effects of various medications, or to determine which patients are most likely to benefit from a given drug. Based on a review of the literature, physicians may be moved to place a patient on a different medication. Data sharing hopefully will allow us to begin to answer questions of this nature.

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