Most Data On Drugs Trials Going Unreported

By ACSH Staff — December 22, 2015

Back in 2008, Congress passed a law requiring all those administering clinical trials governmental agencies, nonprofits and academic institutions and private companies to submit complete data from each trial to the clinicaltrials.gov [3]. A main impetus for codifying submission to the website was to add extra levels of transparency for drug and device trials that many worried were being distorted by pharmaceutical companies.

Now that it's been nearly eight years since the law [4]'s passing, how are these groups doing with compliance? In short, poor would be a compliment, particularly for academic institutions.

STAT news, a new project of Boston Globe owner John Henry (yes that John Henry [5]), launched an investigation [6] focusing on compliance regarding Congress's mandate. It analyzed 9,000 trials from 2008 until September of this year from the website which were subject to the law's reporting mandate. These trials came from 98 labs from universities, nonprofits and corporations. They also analyzed reporting data from the National Institutes of Health (NIH) staff scientists.

The data show that 90 percent of the academic institutions report data late or not at all. Private companies, which were cited as the reason for passing the law requiring reporting, were late or absent 74 percent of the time. The NIH didn't do much better, as it was late, or failed to report data, 75 percent of the time.

Of note from the report, four universities Stanford, the University of Pennsylvania, the University of Pittsburgh and the University of California which are all in the top 10 for receiving federal grant money for clinical trials, failed to report data on time or at all over 95 percent of the time.

Meanwhile six institutions Memorial Sloan Kettering, the University of Kansas, JDRF (formerly the Juvenile Diabetes Research Foundation), the University of Pittsburgh, the University of Cincinnati and New York University were not compliant 100 percent of the time.

The Federal Drug Administration and NIH have the authority to fine each institution $10,000 for every day for each trial that data is absent for. However, they have yet to levy a single fine against any institution. STAT news reports during the period they investigated that they should have
collected $25 billion just from the drug companies.

STAT news reached out to some of the non-compliant researchers and found the most common reason for failure to report data on time (or at all) was that it was too much work. This answer is truly unacceptable, as this missing information is vital to patients looking for information on which if any clinical trial to join. Missing data that shows the dangers or ineffectiveness of a drug is dangerous to patients and "too much effort to comply" is not an acceptable reason for breaking the law.

Furthermore, it is unacceptable that the FDA and NIH are not enforcing this law. The $25 billion they could have collected would have funded them for the next five years. These agencies did tell STAT news that after some fine tuning to procedures they will start penalizing researchers, including their own, for failing to disclose.

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