FDAAA: Push to open data in clinical medicine

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In 2005 registration of clinical trials in publicly available databases before the first patient was entered became mandatory for papers submitted to the most important medical journals. In September of last year, U.S. President Bush signed the Federal Drug Administration Amendment Act (FDAAA) into law. Starting September 2008, all clinical trials registered in the clinicaltrials.gov database (with the exception of phase I trials) have to report key results of the main outcomes no later than 12 months after data for the last subject were received.

This required reporting of results has so far largely gone unnoticed in the medical community, but will dramatically change the way research involving patients is conducted and reported. The 12 month deadline will probably lead to earlier reporting of many trial results, and not publishing negative results will be much more difficult. The required reporting in a standardized format will also facilitate the meta-analysis of several similar trials.

Reporting of trial results in this format will not be considered previous publication by member journals of The Internal Committee of Medical Journal Editors (ICMJE).