WilmerHale

International Society for Medical Publication Professionals: New Federal Legislation for Clinical Trial Registration and Results Disclosure: Implications for Publication Planning Professionals & Biomedical Publications

2008-01-17

On September 27, 2007, President Bush signed into law the Food and Drug Amendments Act (FDAAA) – also known as FDARA (Food and Drug Revitalization Act). The bill includes, among many important sections, the 4th renewal of PDUFA (Prescription Drug User Fee Act). New is the section of the bill known as Title VIII—Clinical Trials Databases—which includes regulations that directly affect medical publication professionals, specifically regarding clinical trial registration and public disclosure of clinical trial results.

Passage of this bill brings many significant changes. Until now, pharmaceutical companies registered information on “clinically directive” controlled trials at www.ClinicalTrials.gov, largely in response to major medical journal editors’ policy (ICMJE). Federal legislation only required registering trials that assessed efficacy of an intervention in serious or life-threatening diseases. Now, not only must (nearly all) trials be registered, but their results must be disclosed publicly—within a timeframe that is dictated by the new legislation. In addition, noncompliance may result in significant penalties.

WilmerHale Partner Scott Lassman will speak about this new legislation at this event, hosted by ISMPP.

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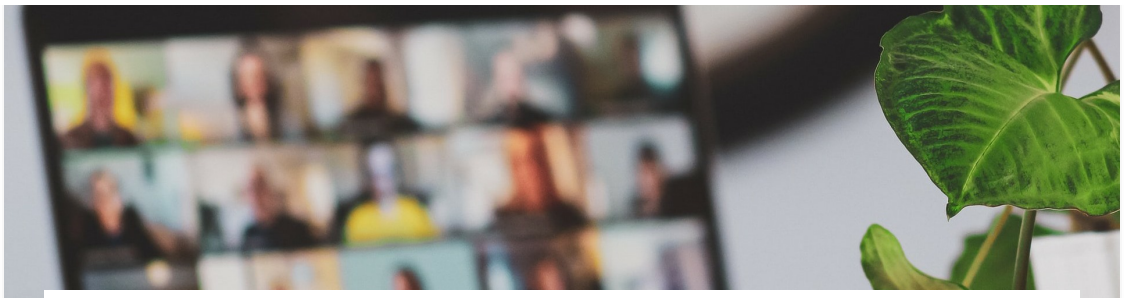
You May Be Interested In



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