Clinical Trials Registration and Results Information Submission (Final Rule)

Details the NIH requirements for submitting registration and summary results information.

Updated last September 16, 2016

WHAT IT DOES

This final rule details the requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drug products (including biological products) and device products and for pediatric postmarket surveillances of a device product to ClinicalTrials.gov, the clinical trial registry and results data bank operated by the National Library of Medicine (NLM) of the National Institutes of Health (NIH). This rule provides for the expanded registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) to help patients find trials for which they might be eligible, enhance the design of clinical trials and prevent duplication of unsuccessful or unsafe trials, improve the evidence base that informs clinical care, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research. The requirements apply to the responsible party (meaning the sponsor or designated principal investigator) for certain clinical trials of drug products (including biological products) and device products that are regulated by the Food and Drug Administration (FDA) and for pediatric postmarket surveillances of a device product that are ordered by FDA.

The final rule is available here.

The HHS Press Release is available here.