In the News

In a First, FDA Warns Company to Remedy Failure to Post Clinical Trial Results

Joan Stephenson, PhD

For the first time, the US Food and Drug Administration (FDA) has issued a “notice of noncompliance” and warning about potential penalties to a drug company for violating a law that requires clinical trial sponsors to report study findings to the federal repository ClinicalTrials.gov. Until now, the FDA has never issued a noncompliance notice nor imposed fines or other penalties for such violations and instead encouraged voluntary compliance.

The FDA said that it was issuing its first noncompliance notice to a Massachusetts-based drug company, Acceleron Pharma, Inc, for failing to submit the required summary of results of a clinical trial evaluating the safety and effectiveness of dalantercept in combination with axitinib in patients with advanced kidney cancer. Although Acceleron had published findings from the study in a journal in 2019, it failed to submit trial results to ClinicalTrials.gov, which is managed by the National Library of Medicine at the National Institutes of Health.

“Being transparent about the results of completed clinical trials enables important advances in the development of medical products and helps ensure a safe, effective and efficient clinical research enterprise,” said FDA’s acting commissioner, Janet Woodcock, MD, in a statement.

Before the current notification, sent on April 27, the FDA sent a letter to Acceleron in July 2020, reminding the company of its failure to report and directing it to “submit all required results information for review promptly.” The noncompliance letter sent last week said that the agency intended to begin a review of the information within 30 days.

Initial efforts to improve reporting of clinical trial information led to the passage in 1997 of a law requiring investigators or sponsors to formally register trials studying the effectiveness of an investigational drug for patients with serious or life-threatening conditions, which led to the launch of ClinicalTrials.gov in February 2000. In 2007, Congress acted again, passing the Food and Drug Administration Amendments Act (FDAAA) of 2007, which expanded reporting requirements so that clinical trial sponsors were instructed to report all trial findings—positive, negative, or inconclusive—to the repository.

It took nearly another decade for the FDA and the National Institutes of Health (which is charged with overseeing the law for investigators that it funds) to issue a final rule to clarify the law’s requirements and penalties for failing to report trial results. The final rule took full effect in January 2018, but despite assurances that the FDA “will help ensure compliance with these new requirements,” the agency has not penalized trial sponsors that have violated the law.

Although compliance with reporting requirements has improved, there have been numerous reports that many sponsors have continued to violate the law. A 2020 report in Science that involved scrutiny of more than 4700 clinical trials found that although most large drug companies and some universities had markedly improved compliance, less than 45% had their results reported early or on time to ClinicalTrials.gov. Of 184 sponsor organizations with reporting for at least 5 trials due as of September 2019, 30 companies, universities, or medical centers never met a single deadline.

Another analysis of more than 4200 trials published by The Lancet last year described overall compliance with the law as poor and showed no improvement since 2018. Noting that findings “raise important questions around lack of enforcement and the need for public accountability,” the authors said that they would maintain updated compliance data for trials and sponsors at FDAAA.

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FDAAA TrialsTracker currently says that about 28% of 9937 clinical trials have not reported their findings to ClinicalTrials.gov, and that at this level of noncompliance, the FDA could have imposed penalties exceeding $19 billion.

In its April 27 noncompliance notice to Acceleron, the FDA told the company that if it fails to respond within 30 days, the agency can collect financial penalties—more than $10,000 per day until the violation is corrected—and impose other actions, “such as injunction and/or criminal prosecution.”