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Recent FDA Guidance, OIG Audit Plan Demand Focus on ClinicalTrials.gov

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Prior to considering the imposition of fines for failures to comply with ClinicalTrials.gov reporting, the Food and Drug Administration will give "responsible parties" 30 days to come into compliance, according to new FDA guidance that finalized a 2018 document.[1] This notice of noncompliance will be posted on the agency's website and sent to NIH, which will then post the notification on ClinicalTrials.gov itself.

But before things proceed to that point, the FDA will already have warned the organization, drug company, university or other entity required to report to the database that it "may have committed a prohibited act" by failing to submit information or submitting false information.

This "Preliminary Notice of Noncompliance Letter," also referred to as a "pre-notice" letter, "describes the potential violation and requests that the responsible party take any necessary actions to address the potential violation within 30 calendar days after receiving the letter."

Overall, however, based on how the FDA has structured the notice system, a significant amount of time may elapse before any fine is imposed. The guidance document doesn't specify, for example, how much time the FDA will spend building a case, or how long it will take once it receives responses before moving to another step. Additional procedures for actually assessing a fine also must be followed.

FDA's explanation of how fines could occur marks the latest step in the long evolution of ClinicalTrials.gov, and the guidance came at a time of heightened attention to failures to report all aspects of trials as required.

The HHS Office of Inspector General (OIG) announced Sept. 15 that it would conduct an audit of how well NIH has ensured ClinicalTrials.gov compliance among its awardees (including its role in posting submitted data). Both developments put renewed pressure on organizations to ensure their reporting is up to date.[2]