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HHS OIG Gives NIH Poor Grade for Reporting Results to ClinicalTrials.gov

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Results from fewer than half of NIH-funded or conducted studies were reported to ClinicalTrials.gov as required during two recent years reviewed by the HHS Office of Inspector General (OIG). Data shows intramural studies fared better at being posted to the website: The rate for this group was 55.5%, contrasted with 41.7% of the extramural studies, according to OIG's recent audit.^[1]

The total number of studies in OIG's audit wasn't huge—just 72. But that was the universe of trials whose results were supposed to be reported during calendar years 2019 and 2020. OIG undertook the audit as part of a national effort to foster better compliance with reporting requirements, and because a “preliminary review of data from ClinicalTrials.gov showed that most NIH-funded clinical trials that were completed in calendar year 2018 did not have their results posted,” the agency said.

Reporting to ClinicalTrials.gov has been required since 2007 and was expanded in 2016 under a rule issued by the Food and Drug Administration (FDA) and NIH. Generally, summary trial results are required to be posted 12 months after the study's expected completion date. Compliance with the reporting mandates was required by November 2018, although more time was allowed for certain types of trials.

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