

Report on Research Compliance Volume 20, Number 7. June 22, 2023 NIH Pledges 'Enforcement' of ClinicalTrials.gov Reporting

By Theresa Defino

Accurate and complete reporting to ClinicalTrials.gov is not only vital for patients seeking appropriate studies in which to enroll, the data shows the world where NIH and other funders are spending their dollars and—hopefully—the outcomes and findings of that research.

Reporting to ClinicalTrials.gov has been required since 2007 and was greatly expanded in 2016 with a compliance date of November 2018. NIH and the Food and Drug Administration (FDA) announced in 2016 that they would be jointly enforcing the reporting requirements.^[1]

FDA subsequently said in final guidance issued August 2020 that it would warn organizations of noncompliance and offer 30 days' notice to come into compliance before issuing a fine.^[2]

Based on adjustments for inflation, FDA could fine an organization up to \$13,237 per day for noncompliance—but it has not. Nor has it issued any warning letters since April of last year. As of mid-June, FDA had issued a total of only four such letters: three in 2021 and one in 2022. All of the organizations have come into compliance, according to resolution letters FDA posted.

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