

Report in Brief

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Why OIG Did This Audit

The National Institutes of Health (NIH) provides funding for clinical trials carried out by NIH scientists in NIH laboratories on its campuses (Intramural) and through awards to the community of scientists at universities, medical centers, hospitals, and research institutions throughout the United States and abroad (Extramural). NIH is responsible for ensuring that NIH-funded Intramural and Extramural clinical trials are reported on ClinicalTrials.gov. Our 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.

Our objective was to determine whether NIH ensured that NIH-funded Intramural and Extramural clinical trials complied with Federal reporting requirements.

How OIG Did This Audit

We reviewed all 72 NIH-funded Intramural and Extramural clinical trials for which Federal law and NIH policy required the results to be reported in calendar year 2019 or 2020. To determine whether responsible parties complied with reporting requirements, we compared the date the results should have been submitted with the date they were submitted. We also determined whether NIH posted the clinical trial results submitted by the responsible parties to ClinicalTrials.gov within 30 days of the submission date.

The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance With Federal Requirements

What OIG Found

NIH did not ensure that all NIH-funded Intramural and Extramural clinical trials complied with Federal reporting requirements for responsible parties to submit the results of clinical trials to ClinicalTrials.gov. The Table summarizes the number of clinical trials requiring results to be submitted in 2019 or 2020 that were submitted on time, late, or not submitted at all.

Table: Summary of Clinical Trials Requiring Results To Be Submitted in 2019 or 2020

	Intramural	Extramural	Total
Submitted on Time	20	15	35
Submitted Late	11	1	12
Results Not Submitted	5	20	25
Subtotal of Noncompliance	16	21	37
Total	36	36	72

The noncompliance with Federal reporting requirements occurred because NIH did not have adequate procedures for ensuring that responsible parties submitted the results of clinical trials, took limited enforcement action when there was noncompliance, and continued to fund new research of responsible parties that had not submitted the results of their completed clinical trials. For the 47 NIH-funded clinical trials in which the responsible party submitted their results (35 submitted on time and 12 submitted late) NIH complied with the Federal reporting requirements to post the results to ClinicalTrials.gov.

What OIG Recommends

We recommend that NIH (1) improve its procedures to ensure that responsible parties of NIH-funded clinical trials comply with requirements to submit results to ClinicalTrials.gov in a timely manner, (2) take enforcement actions against responsible parties that are late in submitting trial results or do not submit results, and (3) work with the responsible parties to understand their challenges related to ClinicalTrials.gov and implement procedures to address the challenges.

In written comments on our draft report, NIH concurred with our recommendations and described the actions it has taken or plans to take to address them. For example, NIH stated it has begun to implement improvements to its internal procedures and activities to enhance its ability to take compliance action against responsible parties out of compliance.