

## Why GAO Did This Study

With a budget of \$43 billion in fiscal year 2021, NIH funds multiple R&D activities that contribute to drug development. NIH-funded biomedical R&D generates basic scientific knowledge on biological mechanisms of various diseases, supports clinical trials investigating if drugs are safe and effective, and trains biomedical scientists who go on to work at universities, in government, and industry. Although not all NIH-funded R&D is directly related to drug development, developing drugs and treatments is one of the agency's strategic goals.

GAO was asked to review how NIH-funded biomedical R&D contributes to drug development. This report examines, among other things, (1) NIH funding for basic research, clinical trials, and biomedical workforce training; (2) reporting of information about NIH-funded clinical trials in the public registry ClinicalTrials.gov; and (3) the extent to which NIH support is disclosed in patents arising from research funded by the agency. GAO reviewed relevant laws and agency documents, analyzed clinical trial and patent data, and interviewed NIH officials, grantees, and academic experts.

## What GAO Recommends

GAO is making two recommendations to NIH, including that its guidance clarify that awardees should name NIH and include the NIH award number when disclosing the agency's support in patent applications. HHS concurred with the recommendations.

View [GAO-23-105656](#). For more information, contact Candice N. Wright at (202) 512-6888 or [WrightC@gao.gov](mailto:WrightC@gao.gov).

# NATIONAL INSTITUTES OF HEALTH

## Better Data Will Improve Understanding of Federal Contributions to Drug Development

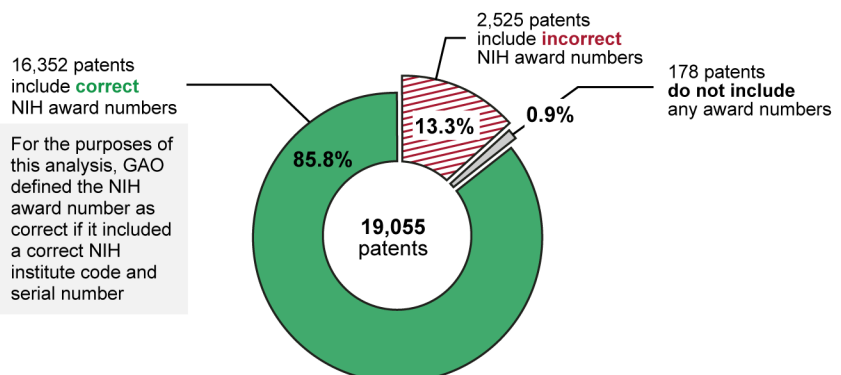
### What GAO Found

National Institutes of Health (NIH), an agency in the Department of Health and Human Services (HHS), is the largest public funder of biomedical research and development (R&D). In fiscal years 2017 through 2021, NIH obligated \$97 billion for basic research, \$28 billion for clinical trials and related activities, and \$9 billion for biomedical workforce training, as part of its investments in biomedical R&D.

GAO found that, in fiscal years 2019 through 2022, up to 16 to 18 percent of NIH-funded clinical trials were registered late in the public database ClinicalTrials.gov. The HHS Office of Inspector General reported in August 2022 that only about half of NIH-funded clinical trials submitted results on time to the database in calendar years 2019 and 2020 due to insufficient monitoring and enforcement by NIH. NIH generally requires an NIH-funded clinical trial to be registered within 21 days of enrolling the first participant and results to be reported within 1 year of the trial's completion. NIH officials stated the agency has been taking additional actions since October 2021 to address noncompliance with these requirements, including automated checks for noncompliance and the monitoring of noncompliance rates by analyzing ClinicalTrials.gov data. Timely reporting of information about NIH-funded clinical trials provides transparency of NIH's research to advance drug development.

NIH awardees did not consistently disclose NIH support in patents arising from research funded by the agency. GAO found that about 2,700 of 19,055 patents with application dates in calendar years 2012 through 2021 did not fully or correctly disclose NIH support (see figure), as required. NIH does not provide clear guidance that its awardees should name NIH as the funding agency and correctly identify the award number when disclosing NIH support in patents. The disclosure of federal support informs the public and other interested parties of the federal government's involvement. When awardees do not disclose the agency's support correctly, or do not name NIH as the funding agency, these parties cannot link patents to NIH funding and determine the extent of the agency's involvement in developing the patented technologies, including drugs.

**Figure: Patents Disclosing Support from the National Institutes of Health (NIH) with Application Dates in Calendar Years 2012 through 2021**



Source: GAO analysis of U.S. Patent and Trademark Office data. | [GAO-23-105656](#)