United States Government Accountability Office

Report to Congressional Requesters

April 2023

NATIONAL INSTITUTES OF HEALTH

Better Data Will Improve Understanding of Federal Contributions to Drug Development

Accessible Version

GAO-23-105656

GAO Highlights

Highlights of GAO-23-105656, a report to congressional requesters

April 2023

NATIONAL INSTITUTES OF HEALTH

Better Data Will Improve Understanding of Federal Contributions to Drug Development

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.

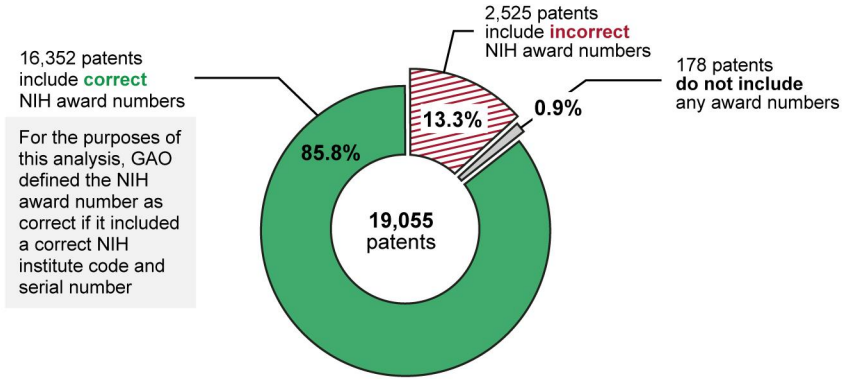
What GAO Found

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

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

Patents disclosing NIH support	Number of patents	Percentage
Patents include correct NIH award number	16,352	85.8
Patents include incorrect NIH award number	2,525	13.3
Patents do not include any award numbers	178	0.9
Total	19,055	100.0

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Abbreviations

FDA	Food and Drug Administration
HHS	Department of Health and Human Services
HHS OIG	Department of Health and Human Services Office of Inspector General
NIH	National Institutes of Health
NIH RePORT	National Institutes of Health Research Portfolio Online Reporting Tools
NSF	National Science Foundation
R&D	research and development
UMETRICS	Universities: Measuring the Impacts of Research on Innovation, Competitiveness, and Science
USPTO	United States Patent and Trademark Office

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April 4, 2023

The Honorable Jamie Raskin
Ranking Member
Committee on Oversight and Accountability
House of Representatives

The Honorable Debbie Stabenow
United States Senate

With a budget of $43 billion in fiscal year 2021, National Institutes of Health (NIH) funds multiple research and development (R&D) activities that can lead to the development of new drugs or new uses for existing drugs.[1] A federal agency in the Department of Health and Human Services (HHS), NIH is the largest public funder of biomedical R&D in the United States. Although not all NIH-funded R&D is directly related to drug development, "developing and optimizing treatments, interventions, and cures" is one of NIH's strategic goals.[2]

While the pharmaceutical industry's role in bringing drugs to market is easier to grasp, the extent of NIH contributions to drug development, which typically take place years before a drug is marketed, is not well understood or recognized. Access to data and data-driven analysis about NIH contributions can help the public understand how NIH investments in science and innovation translate into drugs that benefit Americans' health. It can also provide policymakers with new evidence to make decisions related to biomedical innovation and future R&D investments. Further, this information could be relevant to future drug pricing negotiations

[1]The term "drug" in this report generally includes small molecule drugs, biologics, in vivo diagnostic agents, and drug-device combination products approved by the Food and Drug Administration (FDA). While we refer to these products collectively as FDA-approved drugs, they are generally reviewed and approved under different statutory and regulatory procedures. For example, small molecule drugs are reviewed under different procedures than biologics, which are a diverse category of products typically derived from living material.

[2]National Institutes of Health, *NIH-Wide Strategic Plan for Fiscal Years 2021-2025*.

between HHS and drug manufacturers mandated by the Inflation Reduction Act of 2022.[3]

As discussed in our prior work, scientific discoveries made by NIH scientists contributed directly to the development of drugs, including cancer treatments and vaccines.[4] More broadly, NIH-funded biomedical R&D contributes to basic research investigating biological mechanisms of different diseases, clinical trials that study the safety and effectiveness of drug candidates and other biomedical or behavioral interventions, and training biomedical scientists who go on to work in federal labs, universities, hospitals, and the pharmaceutical industry.

You asked us to review how NIH-funded biomedical R&D contributes to drug development. This report examines (1) NIH funding for basic research, clinical trials, and biomedical workforce training in fiscal years 2017 through 2021 and how that funding is tracked; (2) reporting of information about NIH-funded clinical trials in the public registry ClinicalTrials.gov maintained by NIH; (3) the extent to which NIH support is disclosed in patents arising from NIH-funded research; and (4) the extent to which microdata for NIH grants are accessible to researchers for tracing linkages between NIH contributions and drug development.[5] In addition to this report, we are publishing a patent dataset, which can be accessed on our website at https://www.gao.gov/products/gao-23-105656.

For all four objectives, we reviewed applicable laws and regulations, and NIH policies, procedures, and guidance. We obtained and analyzed data on NIH funding for biomedical R&D, NIH-funded clinical trials, and disclosure of NIH support in patents arising from NIH-funded research. We assessed the reliability of these data by reviewing related documentation and reviewing the data for errors, omissions, and outliers, among other things, and determined the data to be reliable for the purposes of our reporting objectives. We reviewed select academic

[3]As part of the Drug Price Negotiation Program, established under the Inflation Reduction Act of 2022, manufacturers of certain high-priced single source drugs will be required to submit data to HHS regarding R&D costs and prior federal financial support. Pub. L. No. 117-169, § 11001, 136 Stat. 1818, 1833-54. HHS will consider these data in the negotiation process.

[4]GAO, *Biomedical Research: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property*, GAO-21-52 (Washington, D.C.: Oct. 22, 2020).

[5]Microdata are unit-level data obtained from administrative systems, censuses, and other sources. For more information, see a sidebar in the background section of this report.

studies that used NIH and federal R&D microdata to evaluate outcomes of federally funded R&D.

We also interviewed officials and experts, including cognizant officials from the NIH Office of the Director and several NIH institutes and centers, scientists from several drug discovery centers, and researchers from several universities who have received NIH funding or studied NIH programs. We compared the agency's efforts to inform NIH awardees of federal support disclosure requirements when applying for patents against *Standards for Internal Control in the Federal Government* related to communicating quality information.[6] (See app. I for more details about our scope and methodology.)

We conducted this performance audit from January 2022 to April 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Drug Development

The development and approval of a new drug is a complex and costly process that can take 15 or more years and involve multiple public and private entities that fund and conduct R&D.[7] NIH and other federal agencies provide support for most aspects of scientific discovery and basic biomedical research relevant to drug development. The industry then advances those discoveries and early-stage technologies from the

[6]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

[7]The cost of developing a new drug is a subject of debate. A study published in 2016 estimated the cost of developing a new drug at more than $2.5 billion; see J.A. DiMasi, H.G. Grabowski, and R.W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, vol. 47 (2016). A more recent study estimated the cost at $1.3 billion; see O.J. Wouters, M. McKee, and J. Luyten, "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018," *Journal of the American Medical Association*, vol. 323, no. 9 (2020).

laboratory to a marketable drug. Typically, the drug development process consists of the following stages:

- **Basic research.** Scientific investigation of the molecular, cellular, or biological mechanisms of a disease that lays the foundation for the development of new drugs;
- **Drug discovery.** Screening of thousands of compounds in the laboratory to identify promising candidates to treat the disease;
- **Preclinical research.** Laboratory and animal testing to further narrow the list of compounds and answer basic questions about safety and proof of concept;
- **Clinical trials.** Testing of the drug in human volunteers for safety and efficacy that is conducted in phases;[8] and
- **Review and approval.** FDA conducts a regulatory review and approves the drug for marketing and sales in the United States if it is found to be safe and effective for its intended use.

However, in practice, the process is nonlinear, with some activities attributed to different stages of drug development taking place concurrently, and uncertain. Many new drug candidates fail to advance to the next stage or to gain FDA approval. Often, drug candidates and drugs that already have FDA approval are studied for new therapeutic uses.

[8]Clinical trials are usually conducted in phases that build on one another, though the phases may overlap. Phase 1 trials generally test the safety of a drug with a small group of healthy volunteers (usually fewer than 100) to determine the drug's initial safety profile and find the highest dose of the new drug or treatment that can be given safely without causing severe side effects. If the drug does not show unacceptable toxicity in phase 1 clinical trials, phase 2 clinical trials are conducted in a larger group of volunteers (usually dozens to hundreds) to assess the drug's safety and effectiveness for a particular disease or condition and determine common short-term side effects and risks. In phase 2 clinical trials, generally some volunteers receive the drug and others receive a control, such as a placebo. If there is evidence that the drug is effective in phase 2 clinical trials, phase 3 clinical trials are conducted to gather additional information on the drug's safety and effectiveness in several thousand volunteers.

Because such work builds upon previous R&D efforts, new candidate therapies could be ready for clinical trials more quickly.[9]

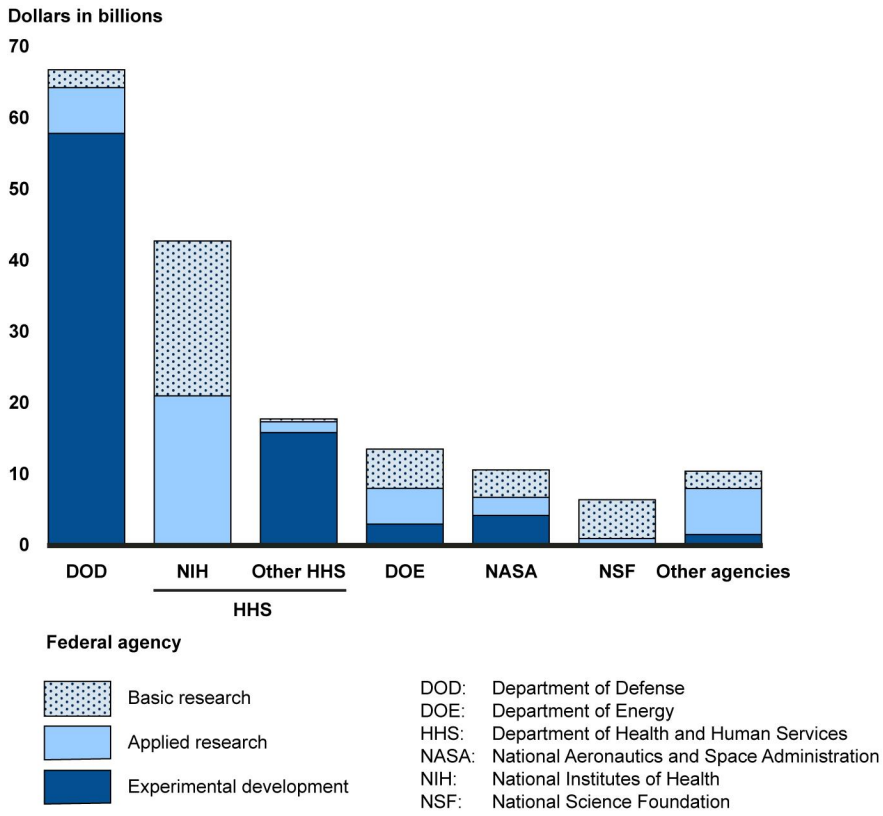
NIH and Federal R&D Funding

As an agency whose mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability, NIH plays an essential role in funding related scientific activity in the United States. In the federal government, NIH is the second largest funder of R&D after the Department of Defense and provides about half of all federal funding for basic research.[10] In fiscal year 2020, NIH obligated $43 billion for R&D, including about $22 billion for basic research and $21 billion for applied research (fig. 1).

[9]As an example, the development of remdesivir—a drug used to treat COVID-19—illustrates how drug development builds on prior biomedical R&D. Before the COVID-19 pandemic, remdesivir was a drug candidate originally invented to treat viral hepatitis and respiratory syncytial virus infection and later studied for its antiviral properties against multiple other viruses, including coronaviruses, in preclinical research and several clinical trials. As a result of those extensive multi-year R&D efforts, which involved federal support, the manufacturer of remdesivir was able to start a phase 3 clinical trial testing the drug's efficacy against COVID-19 in the early months of the pandemic, and remdesivir became the first drug approved by FDA to treat the disease. GAO, *Biomedical Research: Information on Federal Contributions to Remdesivir*, GAO-21-272 (Washington, D.C.: Mar. 31, 2021).

[10]This report focuses on federal R&D funds obligated by federal agencies. The federal government also provides R&D support through the tax credit for increasing research activities and the orphan drug credit for companies to develop medications and treatments for rare diseases that affect small populations. The credits and assessment of their effectiveness are out of the scope of this report.

Figure 1: Federal Obligations for Research and Development in Fiscal Year 2020



Source: National Science Foundation *Survey of Federal Funds for Research and Development: Fiscal Years 2020-2021.* | GAO-23-105656

Accessible Data for Figure 1: Federal Obligations for Research and Development in Fiscal Year 2020

Agency	Total R&D (in billions of dollars)	Basic research (in billions of dollars)	Applied research (in billions of dollars)	Experimental development (in billions of dollars)
DOD	66.70	2.50	6.42	57.78
HHS (total)	60.01	21.81	22.42	15.77
HHS: NIH	42.66	21.74	20.93	0
HHS: Other HHS	17.36	0.07	1.51	15.77
DOE	13.45	5.50	5.02	2.93
NASA	10.54	3.84	2.55	4.14
NSF	6.35	5.46	0.89	0
Other agencies	10.36	2.44	6.45	1.47

Note: Basic research is experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundations of phenomena and observable facts. Applied research is original investigation undertaken in order to acquire new knowledge and directed primarily towards a specific practical aim. Experimental development is creative and systematic work, drawing on knowledge gained from research and practical experience, which is directed at producing new products or processes, or improving existing products or processes.

NIH is the top public funder of biomedical R&D in the United States and the world. About 80 percent of the NIH budget funds its extramural program, which involves R&D performed at universities, medical centers, hospitals, other research institutions, and companies. Although the majority of the extramural funding goes to academic institutions, NIH also directs funding to small businesses conducting biomedical R&D. The agency is the second largest funder of the federal Small Business Innovation Research and Small Business Technology Transfer programs established to strengthen the role of small business concerns in federal R&D.[11] R&D conducted at NIH itself—the agency's intramural program—receives 11 percent of the NIH budget.

Both the extramural and intramural programs at NIH support basic research, clinical trials, and biomedical workforce training, among other activities. Consistent with its mission, NIH is the largest funder of basic biomedical research in the United States. While industry provides the majority of funding for clinical trials of drugs in the United States, NIH funded over 9,000 grants supporting clinical trials that tested drugs and other interventions in fiscal year 2021, according to public NIH data. NIH is also the largest public funder of biomedical workforce training, which enhances the knowledge and research skills of scientists in biomedical disciplines at the undergraduate, graduate, and postdoctoral levels. According to National Science Foundation (NSF) data, 70 percent of federally funded graduate students and postdoctoral researchers in biomedical sciences received NIH funding in fiscal year 2020.

[11]Federal agencies with an extramural budget for research or R&D in excess of $100 million are required to participate in the Small Business Innovation Research program, and those with such obligations of $1 billion or more are required to participate in the Small Business Technology Transfer program. In fiscal year 2021, 11 federal agencies and their components that participated in one or both programs awarded nearly $3 billion, including $1.2 billion from NIH. See GAO, *Small Business Research Programs: Reporting on Award Timeliness Could Be Enhanced*, GAO-23-105591 (Washington, D.C.: Oct. 12, 2022).

NIH provides the vast majority of its extramural funding through multiple grant mechanisms.[12] An NIH grant can support multiple R&D activities, including basic research, clinical trials, and biomedical training. At the same time, NIH also has grants dedicated solely to clinical trials and biomedical training.

Grant applications for NIH funding undergo a two-stage review. During the initial review, each application receives an overall score reflecting multiple review criteria.[13] The second review considers the application in the context of the goals and needs of NIH institutes and centers and makes recommendations concerning funding decisions.[14] The institute or center director makes final funding decisions. In fiscal year 2021, NIH institutes and centers provided 56,957 extramural grants to 2,696 institutions.

Public Data about NIH Biomedical R&D

NIH publicly reports extensive information about NIH-funded biomedical R&D in its web-based database NIH Research Portfolio Online Reporting Tools (NIH RePORT), which consists of several portals.[15] The RePORT Expenditures and Results (RePORTER) portal allows users to search a repository of NIH-funded research projects and access publications and patents resulting from NIH funding. NIH RePORTER draws information on publications from PubMed, a database of scientific publication abstracts, and on patents from interagency Edison (iEdison), a federal database of inventions and patents arising from federally funded

[12]In fiscal year 2021, NIH distributed 90 percent of its extramural funding via grants and 10 percent via contracts. R01 and equivalent grants, which are designed to support discrete, specified, circumscribed research projects and can be 3-5 years in length, accounted for about half of all extramural funding.

[13]The initial review is carried out by Scientific Review Groups, also known as study sections, which are composed primarily of nonfederal scientists who have expertise in relevant scientific disciplines and current research areas. Reviewers develop the overall impact score after assessing each application against multiple review criteria, including significance, investigator(s), innovation, approach, and environment.

[14]The second review is conducted by National Advisory Councils or Boards for NIH institutes or centers with the involvement of NIH program staff. These bodies are composed of both scientific and public representatives chosen for their expertise, interest, or activity in matters related to health and disease.

[15]See https://report.nih.gov/.

research.[16] The Categorical Spending portal provides annual funding information for various research, condition, and disease categories based on NIH grants, contracts, and other funding mechanisms. Another portal, the NIH Data Book, provides basic summary statistics on NIH grants and contracts, recipient organizations, and NIH-funded training, among other things. The data in NIH RePORT are generally a subset of NIH's internal grant management database for the extramural program known as Information for Management, Planning, Analysis, and Coordination II (IMPAC II).

ClinicalTrials.gov is a public, web-based registry and results database of U.S. and international clinical trials, including NIH-funded trials, created in response to a statutory mandate and maintained by NIH's National Library of Medicine.[17] Information on ClinicalTrials.gov is provided and updated by the party responsible for the clinical trial.[18] Generally, the responsible party submits information about the trial to ClinicalTrials.gov (that is, registers the trial) when the trial begins, updates the information throughout the trial, and reports results after the trial ends. Under an NIH policy issued in 2016, the responsible party of a clinical trial funded in full or in part by NIH is generally required to register the trial no later than 21

[16]PubMed is a public database maintained by NIH's National Library of Medicine, which contains more than 34 million citations for biomedical literature from life science journals and other sources. The iEdison database is a web-based nonpublic database designed around the Bayh-Dole Act reporting requirements and used by several federal agencies. Recipients of federal research funding report—and the funding agencies review—inventions and patents arising from the funded research in iEdison. The database was maintained by NIH until August 2022, when the National Institute of Standards and Technology took over the responsibility.

[17]See https://clinicaltrials.gov/. NIH was directed by federal law to create a public data bank and registry of clinical trials, culminating in ClinicalTrials.gov, which opened to the public in 2000. The law stipulates that the data bank would share information on clinical trials for drugs for serious or life-threatening diseases and conditions with members of the public, health care providers, and researchers. Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, § 113, 111 Stat. 2296, 2310-12 (codified as amended at 42 U.S.C. § 282). The law was later amended to broaden the types of trials required to be registered. See the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 801, 121 Stat. 823, 904-22.

[18]The clinical trial's responsible party is its sponsor or the principal investigator, if so designated by a sponsor, grantee, contractor, or awardee. 42 U.S.C. 282(j)(1)(A)(ix); 42 C.F.R. § 11.4.

days after enrolling the trial's first participant and report the trial's results on ClinicalTrials.gov within 1 year of the primary completion date.[19]

Disclosure of Federal Support for R&D in Patents

NIH-funded R&D can generate patentable inventions. A patent is an exclusive right granted for a fixed period to an inventor.[20] An FDA-approved drug is typically associated with patents.[21] The Bayh-Dole Act of 1980 created a legal framework for ownership of patent rights arising from federally funded research and for disclosing federal support.[22] The act enabled universities, nonprofit research institutions, and businesses to own, patent, and commercialize inventions developed with federal funding. Contracts and awards subject to the requirements of the Bayh-Dole Act must contain a provision requiring contractors and awardees, who seek to patent inventions developed with federal funding, to include in the patent application a statement disclosing federal support (known as the government interest statement). The requirement provides transparency by informing interested parties of the federal government's involvement, and that the government has certain rights in the invention.

[19]National Institutes of Health, "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information" (Sept. 21, 2016). The NIH policy, which covers NIH-funded clinical trials, complements the federal regulations implementing the Food and Drug Administration Amendments Act of 2007. 42 C.F.R. § 11.2-11.64. Whereas the federal regulations apply to applicable clinical trials of FDA-regulated drug, biological, and device products in phase 2 and later phases, the NIH policy generally applies to all NIH-funded clinical trials regardless of the phase and the type of intervention tested in the trials. According to the NIH definition, clinical trial interventions include small molecule drugs, biologics, medical devices, procedures, and behavioral treatments that are either investigational or already available.

[20]A patent grants the right to "exclude others from making, using, offering for sale, or selling" the invention throughout the United States or importing into the United States. 35 U.S.C. § 154(a)(1). This right can be assigned to other entities.

[21]If an inventor invents or discovers a new chemical compound, the inventor may seek a patent claiming the invention. An inventor can also patent a group of distinct chemical compounds. Also patentable are drug formulations, methods of using a drug to treat a particular disease, methods and technologies to administer or manufacture a drug, as well as technologies that test for and diagnose diseases, if they meet certain patentability requirements.

[22]Patent and Trademark Law Amendments Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended in 35 U.S.C. §§ 200-212), commonly referred to as the Bayh-Dole Act.

The U.S. Patent and Trademark Office (USPTO), an agency of the Department of Commerce, grants patents in the United States and maintains a public database PatentsView on U.S. patent activity. Researchers have analyzed patent government interest statement data to trace federal contributions to biomedical innovation and drug development.

Studies of Federal Contributions to Drug Development

Academic researchers have analyzed federal contributions to biomedical innovation and drug development.[23] The primary output of NIH-funded R&D is scientific knowledge, whose purpose is to maximize the benefits of that knowledge in multiple research and disease areas in both the public and private sectors.[24] A common method for tracing NIH-funded activities to drug development used in existing studies, typically conducted by social scientists, is to investigate linkages among NIH funding, scientific publications resulting from that funding, and biomedical patents. Publications (and publication citations) are a widely used measure of scientific output and productivity as well as knowledge dissemination, and patents are a common measure of innovation. Similar to patents, publications resulting from federally funded research typically acknowledge federal funding, and thus provide data for studying the linkages.

Tracing Direct and Indirect Effects of National Institutes of Health (NIH) Grants

Effect	Biomedical innovation	Drug development
Direct	<10 percent of NIH grants generate patents	<1 percent of NIH grants acknowledged by drug patents
Indirect	31 percent of NIH grants generate research cited by patents	5 percent of NIH grants result in publications cited by drug patents

Source: D. Li, P. Azoulay, and B.N. Sampat, “The Applied Value of Public Investments in Biomedical Research,” *Science*, vol. 356 (2017). | GAO-23-105656

[23]We reviewed select studies analyzing the effects of NIH funding on biomedical innovation and drug development. See app. I for more details about our methodology.

[24]A distinguishing feature of investments in R&D are knowledge spillovers, which arise when benefits of R&D spill over to others who may use the knowledge, even though they have not paid for the costs of creating that knowledge. Knowledge spillovers are by-products of R&D activities because it is difficult to exclude others from accessing the benefits of such knowledge.

Some studies we reviewed found that NIH generally enables biomedical innovation and drug development through developing scientific knowledge and other indirect support, rather than through direct contributions to specific drugs.[25] The studies also illustrate limitations related to different methodologies used to analyze NIH contributions. One study tracing linkages from NIH funding to patents and publications found that indirect effects of NIH-funded activities on drug development, as measured by publications cited in patents, are likely greater than direct effects, as measured by grants acknowledged by patents (see sidebar).[26] The study's authors acknowledged that their approach likely underestimated linkages between NIH funding and patenting because it did not account for other NIH contributions, such as NIH-funded biomedical training.[27] Another study suggested that NIH funding contributed to published research associated with every one of the 210 new drugs approved by FDA from 2010 through 2016.[28] This study examined a broader set of basic research contributions to drug development through publication citations, but did not identify the extent to which the publications were pivotal in enabling the development of these drugs.

[25]We found in our prior work that discoveries made by scientists in the NIH intramural program directly contributed to 34 drugs approved by FDA between 1980 and 2019, including cancer treatments and several vaccines, and that these drugs were associated with 93 patents owned by NIH; see GAO-21-52.

[26]D. Li, P. Azoulay, and B.N. Sampat, "The Applied Value of Public Investments in Biomedical Research," *Science*, vol. 356 (2017).

[27]Furthermore, this study only examined first-generation publication citations, but some grants may generate articles that are not cited by patents but are cited by other articles that in turn are cited by patents.

[28]E. G. Cleary et al., "Contribution of NIH Funding to New Drug Approvals 2010–2016," *PNAS*, vol. 115, No. 10 (2017).

What Are Microdata?

Microdata are unit-level data obtained from sample surveys, censuses, and administrative systems.

They provide information about characteristics of individual people or entities such as households, business enterprises, facilities, farms or even geographical areas such as villages or towns. They allow in-depth understanding of socio-economic issues by studying relationships and interactions among phenomena.

Microdata are thus key to designing projects and formulating policies, targeting interventions and monitoring and measuring the impact and results of projects, interventions, and policies.

Source: The World Bank. | GAO-23-105656

Several studies we reviewed analyzed NIH contributions to biomedical innovation and drug development using nonpublic data from NIH's internal program management system IMPAC II. NIH, like other federal funders of R&D, possesses extensive microdata about research projects that are reviewed for funding (see sidebar). NIH microdata include complete application data: that is, data on grant applications, with review scores, that NIH approves for funding (funded research) or rejects for funding (unfunded research that could be funded by entities other than NIH). In addition, NIH microdata have information on all scientists, both established and junior, whose research and training are supported by NIH. As we discuss later in this report, studies that obtained NIH and other federal microdata on funded and unfunded research explored causal relations between federal funding and its outcomes.[29]

NIH Tracks and Publicly Reports Funding by Grant or Project

Funding for biomedical R&D activities—including basic research, clinical trials, and biomedical workforce training—is tracked and reported by NIH at the grant or project level. Because a grant funded by the extramural program (or a project funded by the intramural program) usually supports multiple activities that cannot be easily separated, funding amounts for basic research, clinical trials, and biomedical workforce training represent bundles of related activities and partially overlap. For example, an NIH grant whose primary purpose is basic research can involve an early-stage clinical trial and support training of graduate students and postdoctoral researchers who carry out the research and are compensated by the grant funding.

The following explains how NIH publicly reports funding for basic research, clinical trials, and biomedical workforce training, and what that funding represents:

[29]The distinction between causal relations and associations has implications for the kind of conclusions one can draw about the linkage between federal support and drug development. Causal relations mean that drug development resulted from the federally funded research. In contrast, associations mean that federally funded research may have contributed to drug development, but association alone does not establish that the former enabled the latter.

- **Basic research.** NIH reports basic research funding to NSF as part of the annual *Survey of Federal Funds for Research and Development*.[30] This funding represents extramural and intramural support for research projects whose main purpose is basic research but which can involve other activities typically performed in conjunction with basic research, such as preclinical studies and early-stage clinical trials. Because basic research and related activities are conducted by teams of scientists, including students and postdoctoral researchers, many grants supporting basic research provide funding for stipends and salaries and serve as an important source of funding for biomedical workforce training.
- **Clinical trials.** NIH reports extramural and intramural funding for research projects that include clinical trials in NIH RePORT's Categorical Spending portal under "clinical trials and supportive activities." According to NIH officials, while most funding for clinical trials and supportive activities is classified as applied research funding, some clinical trials are conducted as part of basic research and supported by basic research funding. Effective January 25, 2018, NIH requires all grant applications involving one or more clinical trials to be submitted through a funding opportunity announcement specifically designed for clinical trials.[31] (Prior to January 25, 2018, grant applications with and without clinical trials could be submitted in response to the same funding opportunity announcements.)

[30]NSF's *Survey of Federal Funds for Research and Development* is an annual census completed by the federal agencies that conduct R&D programs, including HHS and NIH. The agencies report funding information (obligations and outlays) for different types of R&D, such as basic research, applied research, and experimental development, among other things. NSF requires federal agencies participating in the survey to report R&D funding data that are consistent with the data they submit to the Office of Management and Budget as part of the preparation of the annual President's budget request. For more information about the federal government's reporting of R&D funding data, see GAO, *Federal Research and Development: Funding Has Grown Since 2012 and Is Concentrated within a Few Agencies*, GAO-23-105396 (Washington, D.C.: Dec. 15, 2022).

[31]National Institutes of Health, "Policy on Funding Opportunity Announcements (FOA) for Clinical Trials," NOT-OD-16-147 (Sept. 16, 2016) and "Reminder: Policy on Funding Opportunity Announcements (FOA) for Clinical Trials Takes Effect January 25, 2018," NOT-OD-18-106 (Nov. 30, 2017). NIH adopted funding opportunity announcements specific to clinical trials to improve the agency's ability to identify proposed clinical trials, ensure that key pieces of trial-specific information were submitted with each application, and uniformly apply trial-specific review criteria. NIH officials told us that these changes were responsive to recommendations in a GAO report examining NIH stewardship of clinical trials; see GAO, *National Institutes of Health: Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency*, GAO-16-304 (Washington, D.C.: Mar. 10, 2016).

Announcements stipulate if clinical trials are required, optional, or not allowed. Similar to basic research funding, funding for clinical trials can support multiple related activities. It can also support the stipends and salaries of scientists in training involved in conducting the clinical trials.

- **Biomedical workforce training**. NIH reports extramural funding for biomedical workforce training in the NIH Data Book. The reported funding amount accounts only for grants dedicated to training and career development, and does not account for training (that is, student stipends and postdoctoral researcher salaries) funded by grants for basic research and clinical trials.[32]

For fiscal years 2017 through 2021, NIH reported that it obligated $97 billion for basic research, $28 billion for clinical trials and supportive activities, and $9 billion for biomedical workforce training, according to data from public sources and provided to us by NIH (see table 1).[33] Because the funding amounts capture overlapping activities, we did not provide total funding for all three activities for each fiscal year.[34]

Table 1: National Institutes of Health (NIH) Obligations for Select Biomedical Research and Development Activities, Fiscal Years 2017 through 2021 (in billions)

Activity	2017	2018	2019	2020	2021	Total
Basic research[a]	16.6	18.2	19.0	21.7	21.7	**97.3**
Clinical trials and supportive activities[b]	3.8	5.2	6.1	6.6	6.5	**28.2**
Biomedical workforce training[c]	1.6	1.7	1.8	1.9	2.1	**9.1**

Source: GAO presentation of information from the National Science Foundation (NSF) and NIH. | GAO-23-105656

Notes: The funding amounts represent nominal dollar values that are not adjusted for inflation.

[a]These funding amounts are obligations for extramural grants and intramural projects for basic research that NIH reports to the NSF annual *Survey of Federal Funds for Research and Development*. The fiscal year 2021 basic research funding amount is preliminary, according to NSF.

[32]A working group of the advisory committee to the Director of NIH noted in 2012 that more graduate students and postdoctoral researchers were supported by NIH research grants than by training grants and fellowships; National Institutes of Health, *Biomedical Research Workforce Working Group Report* (June 14, 2012).

[33]We requested and obtained obligations data from NIH for clinical trials and supportive activities and biomedical workforce training to ensure consistency with basic research obligations that NIH reports to NSF. The funding amounts in table 1 reflect extramural and intramural obligations.

[34]Based on the data NIH reported to NSF in the annual *Survey of Federal Funds for Research and Development*, NIH obligated about $189 billion for biomedical R&D—comprising basic research, applied research, and experimental development—in fiscal years 2017 through 2021.

[b]These funding amounts are obligations for extramural grants and intramural projects that include clinical trials and supportive activities and were provided by NIH. NIH publicly reports expenditures for grants and projects that include clinical trials and supportive activities in the Categorical Spending portal of NIH RePORT.

[c]These funding amounts are obligations for extramural grants and intramural projects that include training and were provided by NIH. NIH publicly reports only extramural expenditures for training (reflecting extramural grants for career development, research training, and fellowships) in the NIH Data Book. The funding amounts reported in this table do not account for biomedical research training funded by research grants.

NIH officials said the agency's systems are designed to track funding at the grant level in the extramural program and project level in the intramural program. NIH does not and cannot fully disaggregate funding to the level of various activities funded by those grants and projects. NIH tracks extramural grant funding by requiring grantees to submit budget forms, which provide expenses at the project level. These budgets do not include details about whether expenses are for basic research, clinical trials, or training. In accordance with the NIH Grants Policy Statement, grantees generally have the flexibility to rebudget funds and carry over unobligated balances from one budget period to the next without NIH approval when changes are within the scope of the approved project.[35] According to NIH officials, if NIH were to introduce a requirement to disaggregate funding at the activity level, it would create a considerable administrative burden for grantees and NIH program staff and would be unlikely to produce accurate data with practical value.

NIH Did Not Ensure Timely Registration and Result Reporting on ClinicalTrials.gov but Is Taking Steps to Improve Compliance

NIH did not ensure that all NIH-funded clinical trials subject to the agency's requirements were registered in a timely manner and their results reported on ClinicalTrials.gov in recent years. NIH is taking actions to improve clinical trial registration and result reporting, including by analyzing ClinicalTrials.gov data, according to NIH officials.

[35]The NIH Grants Policy Statement contains the policy requirements that serve as the terms and conditions of NIH grant awards.

NIH Did Not Ensure Compliance with Registration and Result Reporting Requirements for NIH-Funded Clinical Trials

In recent years, NIH did not ensure that all NIH-funded clinical trials subject to the agency's requirements were registered in a timely manner and their results reported in the public database ClinicalTrials.gov. The "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information" issued on September 21, 2016 (henceforth, the NIH 2016 dissemination policy) contains the agency's requirements for the registration of clinical trials funded in full or in part by NIH and reporting of their results on ClinicalTrials.gov.[36] The responsible party for fulfilling these requirements is generally the clinical trial's sponsor or its principal investigator, if so designated by a sponsor or grantee. For intramural clinical trials, the NIH 2016 dissemination policy went into effect on January 18, 2017. For extramural clinical trials, the policy applies to grant applications submitted on or after January 18, 2017, that request funding to conduct a clinical trial that is initiated on or after that date.[37]

Registration of NIH-Funded Trials on ClinicalTrials.gov

We found that some NIH-funded clinical trials, including trials testing drugs, were registered late on ClinicalTrials.gov in fiscal years 2019 through 2022. Under the NIH 2016 dissemination policy, parties responsible for an NIH-funded clinical trial are required to register the trial

[36]The NIH requirement to register the trial on ClinicalTrials.gov no later than 21 days after enrolling the trial's first participant matches the statutory requirement for applicable clinical trials under the Food and Drug Administration Amendments Act of 2007. Codified as amended at 42 U.S.C. § 282(j); see also 42 C.F.R. pt. 11.

[37]This means that the effective date of the policy varies for clinical trials funded by NIH grants in recent years and that it does not apply to clinical trials initiated before Jan. 18, 2017, or to trials initiated after Jan. 18, 2017, if the trials were funded by grants and awards with applications submitted before that date. Because NIH research grants are typically for 3-5 years, this also means that the percentage of NIH-funded extramural clinical trials that are not subject to the policy has decreased in each year since January 2017.

NIH extended reporting flexibilities under this policy for basic experimental studies involving humans until Sept. 24, 2024; see National Institutes of Health, "Continued Extension of Certain Flexibilities for Prospective Basic Experimental Studies with Human Participants," NOT-OD-22-205 (Aug. 30, 2022). In addition, the policy does not apply to clinical trials that use NIH-supported infrastructure but do not receive NIH funds to support their conduct.

on ClinicalTrials.gov no later than 21 days after enrolling the trial's first participant.

We found that the number of NIH-funded clinical trials registered on ClinicalTrials.gov in each fiscal year from 2019 through 2022 ranged from 1,385 to 1,485. In each of those 4 fiscal years, up to 16 to 18 percent of NIH-funded clinical trials were registered late, and they were registered, on average, between several months and more than 1 year late. Although the share of NIH-funded trials subject to the NIH 2016 dissemination policy increased during this period, a similar percentage of NIH-funded clinical trials was registered late in fiscal year 2022 compared to the previous 3 fiscal years.

We also found that some of the NIH-funded trials that were registered late involved testing drugs.[38] The number of NIH-funded drug trials registered on ClinicalTrials.gov in each fiscal year from 2019 through 2022 ranged from 437 to 595, including up to 9 to 10 percent of such trials that were registered late.

Table 2 presents the results of our analysis of registration data for NIH-funded extramural and intramural trials from ClinicalTrials.gov.

Table 2: Clinical Trials Funded by the National Institutes of Health (NIH) on ClinicalTrials.gov, Including Trials Registered Late, in Fiscal Years 2019 through 2022

			Trials registered late			
Category	Fiscal year	Total number of registered trials	Number	Percentage of total number	Mean number of days late	Median number of days late
All NIH-funded clinical trials	2019	1,485	244	16%	492	123
All NIH-funded clinical trials	2020	1,397	220	16%	799	211
All NIH-funded clinical trials	2021	1,385	242	18%	432	97

[38]NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Interventions include small molecule drugs, biologics, medical devices, procedures, and behavioral treatments that are either investigational or already available.

			Trials registered late			
Category	Fiscal year	Total number of registered trials	Number	Percentage of total number	Mean number of days late	Median number of days late
All NIH-funded clinical trials	2022	1,408	233	17%	426	93
NIH-funded clinical trials involving drugs	2019	574	53	9%	443	54
NIH-funded clinical trials involving drugs	2020	595	60	10%	1,214	621
NIH-funded clinical trials involving drugs	2021	486	43	9%	412	87
NIH-funded clinical trials involving drugs	2022	437	37	9%	396	46

Source: GAO analysis of data from ClinicalTrials.gov. | GAO-23-105656

Note: Our analysis includes NIH-funded clinical trials and excludes observational studies registered on ClinicalTrials.gov. Under the "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information" issued on Sept. 21, 2016, parties responsible for an NIH-funded clinical trial are required to register the trial on ClinicalTrials.gov no later than 21 days after enrolling the trial's first participant. However, not all trials included in this table may have been subject to the policy, and ClinicalTrials.gov does not indicate which of the trials are.

The information posted on ClinicalTrials.gov shows that some sponsors repeatedly registered clinical trials late.[39] We found that, among NIH institutes and centers, the National Cancer Institute and the National Heart, Lung, and Blood Institute sponsored the largest number of drug trials that were registered late: 81 and 18, respectively, in fiscal years 2019 through 2022. Among nonfederal entities, two medical centers with the largest number of late-registered NIH-funded clinical trials sponsored 34 of them during those 4 years.

Late registrations prevent members of the public, health care providers, and researchers from having timely and accurate information about active NIH-funded clinical trials, including their purpose, recruitment status, and eligibility criteria. In addition, lengthy registration delays raise concern that some trials may never be registered. Late registrations can limit

[39]NIH defines a sponsor as the organization or individual who initiates a clinical investigation.

understanding of how these trials might contribute to drug development and are inconsistent with the NIH 2016 dissemination policy.

Reporting of Results of NIH-Funded Clinical Trials on ClinicalTrials.gov

In August 2022, HHS Office of Inspector General (OIG) reported that only about half of NIH-funded extramural and intramural clinical trials complied with NIH requirements for reporting clinical trial results on ClinicalTrials.gov in calendar years 2019 and 2020.[40] Under the NIH 2016 dissemination policy, parties responsible for NIH-funded clinical trials are required to report the results of such trials on ClinicalTrials.gov within 1 year of the primary completion date. HHS OIG found that parties responsible for 72 NIH-funded clinical trials were required to submit results in 2019 or 2020, but that they did not submit results or submitted them late for, respectively, 25 and 12 of those trials. HHS OIG determined that NIH did not have sufficient procedures to monitor and enforce result reporting, and recommended that NIH improve its monitoring and enforcement procedures for ClinicalTrials.gov.[41]

As stated in the HHS OIG report, NIH concurred with the recommendations and expressed intent to take several actions in response to them. NIH stated in the report that it had begun to implement additional enhancements in how it verified compliance and notified clinical trial responsible parties of noncompliance.

Trial results must include the number of participants starting and completing the trial, baseline characteristics of the study population, outcome measures and statistical analysis, and adverse events, among other things. As noted in the HHS OIG report, the reporting of clinical trial results on ClinicalTrials.gov helps researchers focus on areas in need of study and avoid unnecessary duplication of studies, improves future research designs, increases public trust in research, enhances patient

[40]Department of Health and Human Services, Office of Inspector General, *The National Institutes of Health Did Not Ensure That All Clinical Trial Results Were Reported in Accordance with Federal Requirements, A-06-21-07000* (Washington, D.C.: August 2022).

[41]Earlier studies had found that the compliance with result reporting requirements was lower among NIH-funded clinical trials than among industry clinical trials. See N.J. DeVito, S. Bacon, and B. Goldacre, "Compliance with Legal Requirement to Report Clinical Trial Results on ClinicalTrials.gov: A Cohort Study," *Lancet*, vol. 395, no. 10221 (2020); C. Piller, "Transparency on Trial," *Science*, vol. 367, no. 6475 (2020).

access to and understanding of the results of clinical trials, and ultimately advances the development of clinical interventions.

NIH Is Taking Actions to Improve Clinical Trial Registration and Result Reporting on ClinicalTrials.gov

According to NIH officials, several actions initiated during the HHS OIG audit are expected to bring both registration and result reporting of NIH-funded clinical trials on ClinicalTrials.gov in compliance with the NIH 2016 dissemination policy going forward. These actions involve expanding monitoring and enforcement protocols for both extramural and intramural clinical trials.

For extramural clinical trials, NIH introduced two measures to improve compliance. First, NIH modified its grant review process to incorporate automatic checks and notifications, according to NIH officials. NIH generally verifies grantees' compliance with the requirements for ClinicalTrials.gov once a year when NIH program officers review grantees' annual progress reports.[42] Beginning in October 2021, an automatic check prevents grant recipients from submitting annual progress reports without proof that they registered and reported the results of clinical trials funded by their grants on ClinicalTrials.gov as required.[43] NIH also began to generate quarterly reports, which include data imported from ClinicalTrials.gov, to determine the number of potentially noncompliant extramural trials and monitor rates of noncompliance.

Second, in July 2022, NIH created a new compliance procedure for extramural clinical trials subject to the NIH 2016 dissemination policy.[44]

[42]Grantees cannot receive funding for subsequent budget years if they do not submit an annual research performance progress report to NIH.

[43]Grantees submit information about clinical trials funded by NIH grants to an NIH system, which prevents submissions for trials that are overdue to register or submit results; see National Institutes of Health, "Guidance electronic Research Administration (eRA) Research Performance Progress Report (RPPR) Submission Validations for Clinical Trial Registration and Results Reporting," NOT-OD-22-008 (Oct. 29, 2021).

[44]According to NIH officials, the compliance procedure, which they referred to as the "Clinical Trials Compliance Workflow," was created in collaboration with the HHS Office of the General Counsel and FDA, in an effort to standardize and centralize how NIH verifies that extramural grant recipients are complying with both the 2016 NIH dissemination policy and the Food and Drug Administration Amendments Act of 2007.

The procedure requires two levels of outreach: first, through the funding institute or center and, second, from the Office of Policy for Extramural Research Administration, to bring the recipient into compliance before NIH takes an enforcement action. According to NIH officials, a grants compliance officer at the Office of Policy for Extramural Research Administration monitors grantees' compliance with the requirements for ClinicalTrials.gov.[45] If the recipients do not address NIH's concerns within 60 days of the initial NIH notification, NIH can suspend grant funding.[46] NIH officials told us that, under the new procedure, NIH had brought 235 delinquent grantees into compliance as of November 2022. Further, officials said they expected improved grantee compliance as a result of notification and outreach actions, without having to enforce compliance by suspending funding.[47]

For intramural clinical trials, NIH began requiring in January 2022 both principal investigators and NIH leadership to be notified of failure to comply with registration and result reporting requirements. It also modified procedures during the HHS audit for taking corrective actions regarding intramural researchers who failed to comply with ClinicalTrials.gov reporting requirements. Effective January 14, 2022, NIH can issue letters of reprimand or remove intramural researchers from federal service if they fail to comply with the NIH and federal requirements for ClinicalTrials.gov, among other things.[48] Before these changes, NIH only notified, but did not penalize, intramural researchers who did not comply with the requirements.

[45]According to NIH officials, this position has existed for over a decade, and is one of 12 compliance officer positions for the extramural program.

[46]The specific enforcement actions for noncompliance with NIH and federal requirements for ClinicalTrials.gov depend on whether an NIH-funded trial meets the definition of the "applicable clinical trial" under the Food and Drug Administration Amendments Act of 2007, as implemented through federal regulation in 42 C.F.R. § 11.22. If the noncompliant trial meets the definition of the applicable clinical trial under the act, NIH can suspend funding to the grant recipient on an institution-wide basis. NIH notifies FDA when an enforcement action is taken against recipients whose NIH-funded applicable clinical trials have failed to comply with requirements. If the noncompliant trial does not meet that definition and is covered only by the NIH 2016 dissemination policy, NIH can suspend funding of the specific award supporting the noncompliant trial.

[47]NIH officials told us that the agency has never suspended grant funding for noncompliance with the requirements for ClinicalTrials.gov.

[48]For the current procedures, see National Institutes of Health, *NIH Policy Manual*, Chapter 3007. Available online at https://policymanual.nih.gov/3007, accessed Aug. 18, 2022.

According to NIH officials, as a result of these actions, all 775 active intramural clinical trials were registered on ClinicalTrials.gov as of November 2022. In addition, principal investigators of all 49 intramural trials subject to the result reporting requirement in 2022 reported their results as of December 2022. These 49 trials included two for which results had not been reported within 1 year of the primary completion date, as required by the NIH 2016 dissemination policy. NIH officials told us the principal investigators of these two trials reported trials results on ClinicalTrials.gov after NIH had withheld approval of new research and initiated other actions consistent with the procedures that took effect in January 2022.

Our analysis shows that similar percentages of NIH-funded clinical trials were registered late in fiscal year 2022 compared to the previous 3 fiscal years. This could be because not enough time has passed for the agency's corrective actions to take effect for all NIH-funded clinical trials. NIH officials told us all information on ClinicalTrials.gov is submitted by the parties responsible for the trials, and that it is incumbent upon those parties to ensure timely registration and result reporting of NIH-funded trials. In addition, officials said, ClinicalTrials.gov is not the only source of public information about NIH-funded clinical trials and the public database NIH RePORT provides information about such trials. However, NIH RePORT generally pulls its clinical trial information from ClinicalTrials.gov, and detailed information for specific trials, such as trial protocols and results, is available on ClinicalTrials.gov and not in NIH RePORT.[49]

Corrective actions, if implemented effectively, will help NIH ensure compliance with the registration and reporting requirements stated in its 2016 dissemination policy. Timely registration of NIH-funded clinical trials and reporting of their results on ClinicalTrials.gov is important for improving transparency of NIH research to advance clinical interventions and drug development. In addition, it will help NIH achieve its strategic goal of fostering a culture of good scientific stewardship, which includes timely and accessible dissemination of information about NIH-funded activities.[50]

[49]National Institutes of Health, "Frequently Asked Questions (FAQs) | RePORT," https://report.nih.gov/faqs, accessed Dec. 13, 2022.

[50]National Institutes of Health, *NIH-Wide Strategic Plan for Fiscal Years 2021-2025*.

NIH Support Is Not Consistently Disclosed in Patents Arising from NIH-Funded Research

NIH awardees do not consistently disclose NIH support in patents arising from research funded by the agency. In our analysis of patents with application dates in calendar years 2012 through 2021, we found that about 2,700 patents did not fully or correctly disclose NIH support. NIH does not provide clear guidance for how awardees applying for patents should disclose the agency's support.

NIH Awardees Do Not Consistently Disclose NIH Support in Patents

NIH support is not consistently disclosed by awardees in patents arising from NIH-funded research. In our analysis of U.S. Patent and Trademark Office (USPTO) data for patents with application dates in calendar years 2012 through 2021, we found inaccurate and incomplete reporting as well as underreporting of NIH support in patent government interest statements. Specifically, 2,703 patents did not disclose NIH support accurately or completely, and another 56 disclosed support from a different entity, but likely arose from NIH-funded research.[51] The implementing regulations for the Bayh-Dole Act require that contractors and awardees use the following wording in their patent applications: "This invention was made with government support under (identify the contract) awarded by (identify the Federal agency). The government has certain rights in the invention."[52] In terms of the federal agency that should be identified in government interest statements, NIH officials told us they preferred awardees to name NIH, but, as discussed below, the agency's existing guidance does not explicitly state that.

We define inaccurate reporting to involve an incorrect NIH award number and incomplete reporting to involve failing to include an award number.[53]

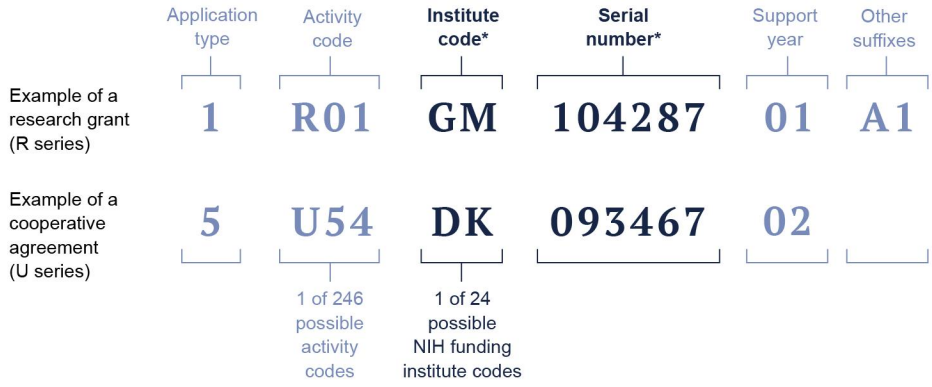
[51]We are publishing a dataset with these 2,759 patents, which can be accessed on our website at https://www.gao.gov/products/gao-23-105656.

[52]37 C.F.R. § 401.14(f)(4). The regulations were developed by the National Institute of Standards and Technology, an agency in the Department of Commerce responsible for the implementation of the Bayh-Dole Act across the federal government.

[53]According to NIH officials, inaccurate reporting can also involve changing the language in the government interest statement to include conditional language regarding the government's rights to the invention.

As shown in figure 2, the NIH award number consists of several elements, including an activity code identifying one of 246 possible award types and an institute code identifying one of 24 NIH institutes that can award funding. According to NIH officials, the correct NIH award number must include, at minimum, the two-digit institute code and six-digit serial number to be traceable to the funding institution and the award dollar amount.

Figure 2: Elements of the National Institutes of Health (NIH) Award Number



*Elements necessary to identify an NIH award.

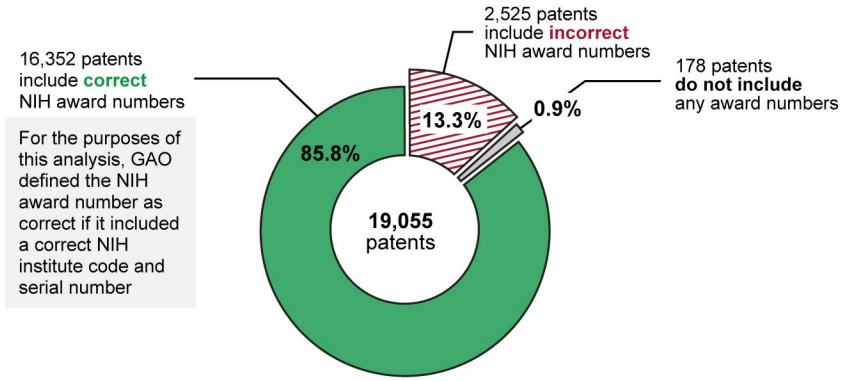
Source: GAO presentation of information from the National Institutes of Health. | GAO-23-105656

Accessible Text for Figure 2: Elements of the National Institutes of Health (NIH) Award Number

A National Institutes of Health (NIH) award number can be composed of up to six elements in the following order: application type, activity code, institute code, serial number, support year, and other suffixes. Two of these elements are required in order for an NIH award to be identifiable: institute code and serial number.

Figure 3 summarizes the results of our analysis regarding inaccurate and incomplete reporting of NIH support in patents. We identified 19,055 patents that disclosed NIH support among all patents with application dates in calendar years 2012 through 2021. Of these, 16,352 (about 86 percent) included correct NIH award numbers and the remaining 2,703 (about 14 percent) did not. Of the latter, 2,525 patents (about 13 percent of the total) included an inaccurate award number that did not have an institute code or a six-digit serial number, and 178 patents (about 1 percent of the total) disclosed NIH support incompletely because they did not include any award number.

Figure 3: Patents Disclosing Support from the National Institutes of Health (NIH) with Application Dates in Calendar Years 2012 through 2021



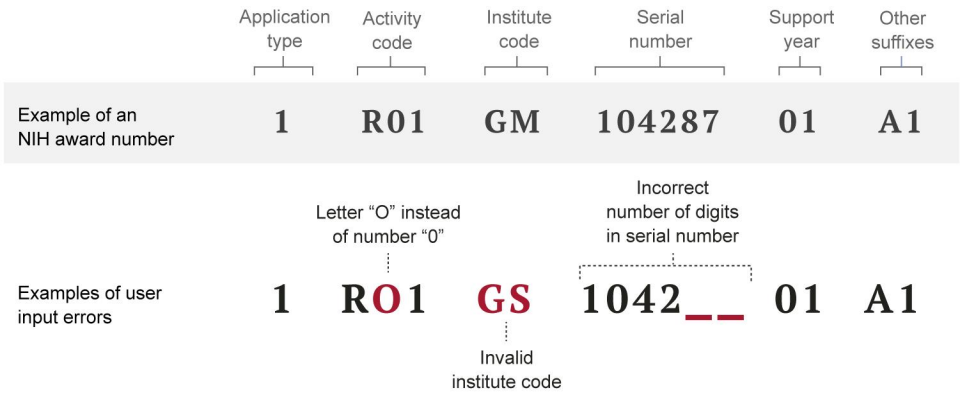
Source: GAO analysis of U.S. Patent and Trademark Office data. | GAO-23-105656

Accessible Data for Figure 3: Patents Disclosing Support from the National Institutes of Health (NIH) with Application Dates in Calendar Years 2012 through 2021

Patents disclosing NIH support	Number of patents	Percentage
Patents include correct NIH award number	16,352	85.8
Patents include incorrect NIH award number	2,525	13.3
Patents do not include any award numbers	178	0.9
Total	19,055	100.0

Moreover, some of the 16,352 patents that we characterize as having correct NIH award numbers in their government interest statements had errors. For example, we found that in about 5 percent of these patents the activity code contained the letter O instead of zero. Figure 4 illustrates some common user input errors related to NIH award numbers we found in the patents that disclosed NIH support.

Figure 4: Examples of User Input Errors for National Institutes of Health (NIH) Award Numbers in Patent Government Interest Statements



Source: GAO analysis of National Institutes of Health and U.S. Patent and Trademark Office data. | GAO-23-105656

Accessible Text for Figure 4: Examples of User Input Errors for National Institutes of Health (NIH) Award Numbers in Patent Government Interest Statements

Examples of common user input errors for National Institutes of Health award numbers include: inputting the letter “O” instead of the number “0”; using an invalid institute code; and inputting the incorrect number of serial number digits.

We found that six patents, which disclosed NIH support and included inaccurate or incomplete award numbers, were associated with three FDA-approved drugs. This means that an interested party cannot identify the relevant NIH awards in the public NIH RePORT database to determine the amount of NIH funding that contributed to the development of these drugs.

We also found evidence of underreporting of NIH support in patents, which we define as naming an entity other than NIH as the funding agency. We analyzed 5,813 patents with application dates in calendar years 2012 through 2021 that disclosed support from the U.S. government, HHS, the Public Health Service, and the Small Business Innovation Research program, and identified 56 patents that likely arose

from NIH-funded research (table 3).[54] We determined that they likely arose from NIH-funded research based on two factors: the patents disclosed award numbers that contained an NIH activity code, institute code, and serial number and had a biomedical field classification.[55]

Table 3: Patents Likely Underreporting Support from the National Institutes of Health (NIH) with Application Dates in Calendar Years 2012 through 2021

Patents that disclosed federal support other than from NIH but likely arose from NIH-funded research	Number of patents
Patents disclosing support from the U.S. government	32
Patents disclosing support from the Department of Health and Human Services	9
Patents disclosing support from the Public Health Service	8
Patents disclosing support from the Small Business Innovation Research program	7
Total	**56**

Source: GAO analysis of U.S. Patent and Trademark Office data. | GAO-23-105656

Note: We determined that a patent likely arose from NIH-funded research if (1) the award number disclosed in the government interest statement contained an NIH activity code, institute code, and serial number; and (2) the patent had a biomedical field classification. To determine the latter, we analyzed the patents' World Intellectual Property Organization (WIPO) field classifications. Each patent we analyzed had one or more WIPO field classifications, with the exception of 355 patents without any WIPO field classifications. After making a list of all WIPO field classifications associated with 19,055 patents that disclosed support from NIH, we designated fields associated with 95 percent of the patents as biomedical. The biomedical field classifications were: analysis of biological materials, biotechnology, chemical engineering, computer technology, macromolecular chemistry, measurement, medical technology, microstructural and nanotechnology, optics, organic fine chemistry, other special machines, and pharmaceuticals.

We provided NIH officials with illustrative examples of six patents from among the 56 patents. These patents are identified in the NIH RePORT

[54]In addition to NIH, the Public Health Service comprises nine other HHS entities—the Administration for Strategic Preparedness and Response, Agency for Healthcare Research and Quality, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, Office of Global Affairs, and Substance Abuse and Mental Health Services Administration—and the Commissioned Corps, a uniformed public health service headed by the U.S. Surgeon General.

[55]By biomedical field classification, we mean World Intellectual Property Organization (WIPO) field classifications common for 19,055 patents with application dates in calendar years 2012 through 2021 that disclosed support from NIH. Each patent we analyzed has one or more WIPO field classifications, with the exception of 355 patents without any WIPO field classifications. After making a list of all WIPO field classifications associated with these patents, we designated fields associated with 95 percent of the patents as biomedical. The biomedical field classifications were: analysis of biological materials, biotechnology, chemical engineering, computer technology, macromolecular chemistry, measurement, medical technology, microstructural and nanotechnology, optics, organic fine chemistry, other special machines, and pharmaceuticals. For more information about our methodology, see app. I.

database, which draws patent data from iEdison, indicating that these patents arose from NIH-funded research.[56] According to agency officials, an NIH awardee submitted a certificate of correction to USPTO and evidence of the correction to iEdison for one of the six patents.[57] NIH awardees had not provided a government interest statement in another patent and had not submitted evidence of correction for the four remaining patents, as of December 2022. NIH officials stated they would follow up with these awardees for updates.

Our findings are consistent with earlier studies that found evidence of underreporting of federal funding in patent government interest statements. For example, one academic study found that government interest statements were missing in 20-40 percent of biomedical patents issued between 1980 and 2007 arising from federally funded research, including patents associated with FDA-approved drugs.[58] USPTO also found evidence of underreporting of federal support in government interest statements. According to its analysis of government interest statements in patents granted between 1976 and 2019, 19 percent of those statements disclosed support from the "U.S. government" generically instead of naming a specific agency.[59] This means that about one-fifth of patents with government interest statements did not disclose support from the agencies that provided it. When NIH awardees do not disclose the agency's support accurately and completely, or do not name NIH as the funding agency, the public and other interested parties cannot

[56]The iEdison database is used by recipients of federal funding to report their government interest statements and by the funding agencies to review them. According to NIH officials, when NIH rejects government interest statements that disclose NIH support inaccurately or incompletely, NIH awardees who submitted them receive automated iEdison notifications to correct the statements by filing a certificate of correction with USPTO and submitting evidence of doing so to iEdison.

[57]Patent applicants can correct a mistake in an issued U.S. patent by filing a certificate of correction with USPTO. A recent study found that 12 of 16 patents associated with FDA-approved drugs disclosed federal funding by adding a government interest statement through a certificate of correction 6 years, on average, after patent issuance. See M. Durvasula, L.L. Ouellette, and H. Williams, "Private and Public Investments in Biomedical Research," *AEA Papers and Proceedings*, vol. 111 (2021).

[58]A.K. Rai and B.N. Sampat, "Accountability in Patenting of Federally Funded Research," *Nature Biotechnology*, vol. 30 (2012).

[59]USPTO's analysis shows that 145,177 patents granted in 1976-2019 had government interest statements. Of them, 27,006 patents (19 percent) acknowledged support from the "U.S. government." See table 2 at https://patentsview.org/government-interest/results-analysis, accessed Sept. 22, 2022.

link patents to NIH funding and determine the extent of the agency's involvement in developing the patented technologies, including drugs.

NIH Lacks Clear Guidance for How Awardees Should Disclose NIH Support

NIH does not have clear guidance for how NIH awardees should disclose its support. NIH officials told us they preferred awardees applying for patents to disclose the agency's support by naming NIH or the Public Health Service and including the NIH award number that contained, at minimum, the institute code and serial number.[60] However, the NIH Grants Policy Statement, which lays out the terms and conditions of grant awards, only includes the wording required by the Bayh-Dole Act's implementing regulations. It does not specify that awardees applying for patents should name NIH as the federal agency that provided funding and include an NIH award number containing an institute code and serial number as the two core elements. In addition, disclosing support from the Public Health Service, which consists of several agencies besides NIH, on patents arising from NIH-funded research complicates a clear identification of patents linked to NIH funding. In response to our questions, NIH officials told us in November 2022 that they planned to update the Grants Policy Statement during the annual review process by October 2023.

In addition, NIH's training materials did not provide clear direction about the agency's preferred way for disclosing NIH support in patent government interest statements. For example, training materials from NIH's 2021 Virtual Grants Conference only summarized the Bayh-Dole Act requirement. By contrast, an NIH training video from 2014, which NIH officials said was outdated, instructed awardees to name NIH as the federal agency providing support and include an award number that followed the award number format in the funding opportunity announcement. NIH officials told us they planned to update the training materials to make awardees aware of NIH's preferred way for disclosing NIH support in patent government interest statements.

[60]Under 37 C.F.R. § 401.5, agencies are permitted to make certain modifications to the required language in the government interest statement, such as, for example, replacing the agency with a particular office within the agency.

Federal standards for internal control call for management to communicate quality information to achieve the entity's objective—in this case, ensuring that awardees disclose NIH support in patents arising from NIH-funded research.[61] By providing clear guidance in its Grants Policy Statement and related training, NIH could reduce the number of incorrect government interest statements and improve its awardees' compliance with the federal support disclosure requirement under the Bayh-Dole Act of 1980. Accurate disclosure of NIH support in patents is important because patent and award data are used to inform the public of the federal government's involvement. Such data are also used by researchers to investigate linkages between NIH funding and patented biomedical technologies, including drugs.[62] Patent government interest statements that do not identify NIH as the funding agency or do not include a correct NIH award number make it difficult or impossible to establish such linkages.

Microdata Allow Researchers to Better Understand the Impact of NIH Funding, but NIH Does Not Have a Procedure for Them to Access These Data

Existing studies using microdata advance analyses of impacts of federal R&D funding on innovation. NIH provided nonpublic microdata to some researchers in the past, but does not have a procedure for interested parties to access the microdata for research and evaluation purposes.

Studies Using Microdata Can Advance Analyses of Impacts of Federal R&D Funding on Innovation

Analyses using microdata can investigate causal relations between federally funded R&D and innovation, including NIH contributions to

[61]GAO-14-704G.

[62]For example, see M. Durvasula, L.L. Ouellette, and H. Williams, "Private and Public Investments in Biomedical Research," *AEA Papers and Proceedings*, vol. 111 (2021); G. Long, "Federal Government-Interest Patent Disclosures," *Journal of Medical Economics*, vol. 22, no. 12 (2019); R.K. Nayak, J. Avorn, and A. S. Kesselheim, "Public Sector Financial Support for Late-Stage Discovery of New Drugs in the United States," *BMJ*, vol. 367 (2019); and D. Li, P. Azoulay, and B.N. Sampat, "The Applied Value of Public Investments in Biomedical Research," *Science*, vol. 356 (2017).

biomedical innovation and drug development. We identified two types of grant microdata that can be analyzed to improve the public's, policymakers', and NIH's own understanding of how NIH-funded R&D contributes to drug development. The first type is complete grant application data, which are application data on both the research that NIH funded and did not fund (funded and unfunded research) that include review scores with thresholds separating winning applications from rejected applications. Complete grant application data enable researchers to explore causal relations between federal funding and its outcomes by enabling comparisons between the outcomes of research funded by NIH and the outcomes of research that NIH did not fund (and which may have been funded elsewhere). The second type is comprehensive data on NIH-funded research staff and trainees. Comprehensive data on research staff and trainees can enable tracing of linkages between NIH investments in biomedical workforce training and biomedical innovation.

Complete Grant Application Data

Access to complete grant application data can help to identify organizations and scientists that are more likely to receive an NIH award, how the award affects the R&D they conduct, and whether they are more likely than unfunded organizations and scientists to generate more innovative technology that leads to drug development, among other things.

Researchers studying federal R&D programs, who were given access to complete grant application data, were able to examine causal relations, rather than associations, between agency R&D support and commercial innovation, including drug development. Authors of several studies we reviewed obtained such data from NIH and were able to generate insights that would not have been possible without data on unfunded applications:[63]

- One study comparing research funded by NIH with research that was not shows that NIH funding spurs private sector biomedical innovation.[64] According to the study, a $10 million boost in funding

[63]Additional studies using internal NIH data may exist. For example, we identified another study that used internal NIH microdata that we do not describe here: D.K. Ginther and M.L. Heggeness, "Administrative Discretion in Scientific Funding: Evidence from a Prestigious Postdoctoral Training Program," *Research Policy*, vol. 49, no. 4 (2020).

[64]P. Azoulay et al., "Public R&D Investments and Public Sector Patenting: Evidence from NIH Funding Rules," *Review of Economic Studies*, vol. 86 (2019).

leads to 2.7 additional private-sector patents and approximately $20 million in drug sales for patents that lead to drugs. To preclude other drivers of innovation that could affect their findings, the authors developed a quasi-experiment using funded and unfunded grants for a narrow band of applications around NIH funding thresholds in a given disease area. The quasi-experiment assumed that half of applications right below and right above the funding score threshold were expected to receive funding, but if more grants were funded than expected, then a particular research area received more funding. This narrow comparison of funded and unfunded applications allowed the authors to causally link NIH funding to drug innovation, providing evidence of the return on public investment in science R&D.

- Another study investigated if NIH policy can direct scientific pursuits toward new knowledge areas and technological breakthroughs.[65] The study found that government policy could induce scientists to shift their research focus from one area of science to another, but that doing so required substantial additional funding to attract new applications. Access to data on unfunded applications allowed the author to characterize whether NIH policy can chart new pathways of scientific innovation in science, because funded applications alone do not capture all applications willing to pursue new areas of science. NIH funds only a limited number of applications each year (NIH success rates for R01 grants in the study were 23 percent), and many meritorious applications do not receive funding. In terms of scientific productivity, awards for new scientific opportunities were more productive on a per-dollar basis, but this effect was driven by new opportunities attracting more productive scientists, and for scientists the shift in new research areas was temporary.
- According to a study that used historical NIH data, exposing medical school graduates to intensive research programs early in their careers could have a large impact on their long-term professional development and productivity of academic research careers.[66] The study compared physicians selected for NIH's Associate Training Program with applicants who passed a first admission screening but were ultimately not selected. The authors found that the selected program participants were twice as likely to choose a research-focused position after training. Program participants also garnered

[65]K. Myers, "The Elasticity of Science," *American Economic Journal: Applied Economics*, vol. 12, no. 4 (2020).

[66]P. Azoulay, W.H. Greenblatt, and M. L. Heggeness, "Long-Term Effects from Early Exposure to Research: Evidence from the NIH 'Yellow Berets'," *Research Policy*, vol. 50, no. 9 (2021).

publications, citations, and grant funding at a much higher rate than unfunded applicants, and went on to mentor more trainees who themselves became successful scientists. Program participants acquired a more "translational" style of research, allowing them to seamlessly transition their research to clinical practice. This analysis would not have been possible without data on all applicants whether funded or unfunded by NIH.

In addition to being the largest federal funder of biomedical R&D, NIH is the second largest funder of the Small Business Innovation Research and Small Business Technology Transfer programs. A study using complete application data from the Department of Energy's Small Business Innovation Research program compared outcomes for companies that received and did not receive funding. The study offers an example of analyses researchers could conduct using NIH's microdata for these programs:[67]

- The study found that Small Business Innovation Research grants have statistically significant and economically notable effects on receiving companies' measures of innovative, financial, and commercial success compared to similar companies that did not receive such grants. Receiving a grant from the program increases the probability that a firm would patent a technology and obtain venture capital investment, among other things.
- The study also examined outcomes of early-stage versus later-stage R&D, and concluded that the Small Business Innovation Research program could achieve better outcomes by reallocating money from larger, later-stage grants to more numerous smaller, early-stage grants, and from older firms and repeat recipients to younger firms and first-time applicants.

Comprehensive Research Staff and Trainee Data

NIH distributes most of its funding via research grants that support principal investigator-led teams of research staff and trainees. The public database NIH RePORT provides information about principal investigators but not about other members of research teams supported by grants. In addition, although NIH is the largest public funder of biomedical workforce training in the United States, data about biomedical scientists whose training is and was previously supported by NIH are limited. In 2012, a

[67]S.T. Howell, "Financing Innovation: Evidence from R&D Grants," *American Economic Review*, vol. 107, no. 4 (2017).

working group of the advisory committee to the Director of NIH noted the lack of comprehensive data about biomedical researchers and recommended that NIH take steps to collect information on the biomedical and scientific workforce on an ongoing basis.[68] NIH officials told us the agency has improved its internal microdata about the NIH-funded workforce since then. However, NIH's publicly available data do not capture the extent of NIH investment in biomedical workforce. As a result, the contribution of that workforce to biomedical innovation and drug development is not well understood by NIH or the broader research community.

NIH investment in biomedical research training largely determines the size of biomedical workforce in the United States, as discussed in the 2012 working group report. While NIH has some information about NIH-trained scientists who stay in the NIH funding stream and conduct NIH-funded research, NIH officials told us little is known about NIH-trained scientists who pursue careers outside of the NIH funding stream.[69] For example, little is known about how many NIH-trained scientists go on to work in the pharmaceutical industry, their research output and career progression, and contributions to drug development in that setting.

The vast majority of scientists conducting NIH-funded research are not principal investigators. According to NIH, of the approximately 300,000 scientists supported by the extramural program, about 43,000 (14 percent) are principal investigators and about 257,000 (86 percent) are research staff and trainees. In the intramural program, which supports about 8,000 scientists, 1,200 (15 percent) are principal investigators,

[68]National Institutes of Health, *Biomedical Research Workforce Working Group Report* (June 14, 2012).

[69]The agency has the NIH Alumni Database for scientists who were trained in the intramural program: https://www.training.nih.gov/alumni/register. NIH officials estimated that about 15 percent of former trainees submitted their information to it.

1,800 (22.5 percent) are staff clinicians and scientists, and 5,000 (62.5 percent) are trainees.[70]

Individual-level data from NIH can be matched with individual-level data from other sources to investigate more fully the research output and career progression of NIH-funded workforce. The Universities: Measuring the Impacts of Research on Innovation, Competitiveness, and Science (UMETRICS) project offers a model of matching such data from different sources to study the relationship between funding, on the one hand, and scientific productivity and career progression, on the other.[71] The UMETRICS project enables researchers to match administrative records for graduate students and research staff at universities where federally funded research takes place with data from the U.S. Census Bureau and other sources.[72] For example, studies using UMETRICS data found the following:

- NIH funding stimulates research by supporting teams of scientists that conduct it, and the research output of all team members, including research staff and trainees, who are supported by NIH research

[70]A study published in 2016 used IMPAC II data for grants funded in fiscal year 2009 to conduct the first-ever census of NIH-funded extramural research workforce. According to the study, 50,885 research project grants funded by NIH in fiscal year 2009 created 313,049 full- and part-time positions spanning all job functions involved in biomedical research. These positions were staffed by 247,457 people at 2,604 institutions. Each research project grant supported 6 full- or part-time positions, on average. See L.R. Pool et al., "Size and Characteristics of the Biomedical Research Workforce Associated with U.S. National Institutes of Health Extramural Grants," *The FASEB Journal*, vol. 30 (2016).

[71]The UMETRICS project and its data repository are managed by the Institute for Research on Innovation and Science at the University of Michigan. The institute is a consortium of research universities, and it collects record-level administrative data from its members to produce a de-identified dataset that researchers use to explain and improve the public value of research.

[72]At present, UMETRICS data account for about 40 percent of extramural federal funding. According to the U.S. Census Bureau, the UMETRICS data are useful for analyzing the social and economic effects of research investments; the scientific production function; the career outcomes and earnings of graduate students and trainees; questions pertaining to science and engineering workforce and the STEM pipeline; and many other possible topics.

grants, is several times larger than the research output linked to principal investigators.[73]

- Almost 40 percent of federally and nonfederally funded doctorate recipients entered industry, and disproportionately got jobs at large and high-wage establishments in high-tech and professional service industries. Although Ph.D. recipients spread nationally, the employment patterns also reflected geographic clustering near the universities that trained and employed the researchers.[74]

In addition to providing insights into employment patterns of scientists whose training was funded by NIH, these findings illustrate that analyses using publicly available NIH data that only identify principal investigators understate the effect of public funding on scientific productivity and innovation. Use of individual-level data for all members of research teams would enable a fuller understanding of the scientific workforce involved in conducting NIH-funded R&D. This can in turn enable analyses of the contribution NIH's support for biomedical workforce training makes to biomedical innovation and drug development more broadly.

NIH Does Not Have a Procedure for Researchers to Access NIH Microdata

NIH provided microdata data to researchers in the past on an ad hoc basis, but does not have a procedure describing how researchers who are interested in these data for studying and evaluating NIH activities can access them. IMPAC II, NIH's internal program management system for extramural research, holds microdata on funded and unfunded grant applications, with application review scores. The microdata include information about principal investigators, research staff, and trainees supported by the extramural program as well as about principal investigators in the intramural program. Data that NIH reports publicly in the NIH RePORT database are generally a subset of the IMPAC II microdata.

[73]R. Sattari et al., "The Ripple Effects of Funding on Researchers and Output," *Science Advances*, vol. 8 (2022). The study was able to compare the number of publications authored by all team members, because UMETRICS data provided information for all team members, including trainees, supported by NIH research funding.

[74]N. Zolas et al.,"Wrapping It Up in a Person: Examining Employment and Earnings Outcomes for Ph.D. Recipients," *Science*, vol. 350, no. 6266 (2015).

Because microdata include confidential and proprietary information, they cannot be reported publicly. Access to such data is governed by federal laws and regulations and is restricted to organizations and entities cleared for access based on their research needs and qualifications. In addition, personally identifiable information is generally required to be removed before microdata are made available for restricted access.

In recent years, an advisory committee to the Director of NIH recommended expanding access to NIH microdata and the Office of Management and Budget (OMB) created a unified process for users to access federal microdata:

- In December 2018, an advisory committee to the Director of NIH recommended that NIH increase accessibility of NIH administrative [microdata] for both members of the biomedical research community and researchers investigating biomedical science.[75] In response to this recommendation, the agency explored making microdata available for research purposes in 2019. NIH considered resources needed to establish, maintain, and oversee access to confidential microdata in a secure physical or virtual environment, as allowable under applicable federal laws. Options for a secure environment that NIH considered involved depositing NIH microdata at the National Center for Health Statistics (NCHS) and the U.S. Census Bureau.[76] NIH estimated that the annual costs needed to establish and oversee the data sharing would range from about $116,000 for depositing NIH's microdata at NCHS to $352,000 for depositing the microdata at the U.S. Census Bureau.[77] According to NIH officials, NIH determined in 2019 that these microdata sharing options were too labor-intensive for its extramural program.[78]

[75]National Institutes of Health, *NIH Advisory Committee to the Director (ACD) Next Generation Researchers Initiative Working Group Report* (December 2018).

[76]NCHS is part of the Centers for Disease Control and Prevention. The U.S. Census Bureau operates more than 30 federal statistical research data centers (FSRDCs), which are partnerships between federal statistical agencies and leading research institutions. FSRDCs provide secure environments supporting qualified researchers using restricted-access data while protecting respondent confidentiality. The UMETRICS project discussed above maintains its own data repository and deposits its microdata in an FSRDC.

[77]By comparison, the average research grant awarded by NIH in fiscal year 2021 was about $594,000.

[78]NIH officials told us in December 2022 that the costs of microdata sharing would be borne by the extramural program's budget.

- In December 2022, the federal government, in collaboration with nonfederal entities, launched a new web-based portal ResearchDataGov for discovery of restricted data in the federal statistical system.[79] The portal was established to advance the evidence-building capabilities of the federal government, a key goal of the Foundations for Evidence-Based Policymaking Act of 2018.[80] The portal allows users to request confidential data from 16 federal statistical agencies, which provided detailed descriptions of each data asset that can be requested.[81] Users can search for data by topic, agency, and keywords. OMB released a memorandum describing a standard application process for requesting federal microdata.[82] The memorandum also established a standard set of review criteria that the statistical agencies should use in determining whether to authorize access to their confidential microdata.[83] Although the process for the ResearchDataGov portal currently applies only to confidential microdata kept by 16 specific statistical agencies as defined under federal law, the memorandum permits other executive branch agencies to use the system to allow researchers to work with their confidential microdata.

The Open, Public, Electronic, and Necessary Government Data Act (Title II of the Foundations for Evidence-Based Policy Making Act of 2018) requires agencies of the federal government to engage the public in using

[79]See https://www.researchdatagov.org.

[80]Enacted in 2019, the act created a framework for federal agencies to take a more comprehensive and integrated approach to evidence building. It requires federal evidence-building activities, open government data, and confidential information protection and statistical efficiency. Pub. L. No. 115-435, 132 Stat. 5529 (2019).

[81]The ResearchDataGov portal is built and hosted by the University of Michigan's Inter-university Consortium for Political and Social Research under contract and guidance from NSF's National Center for Science and Engineering Statistics. The data described in the ResearchDataGov portal are owned by and accessed through the agencies.

[82]Office of Management and Budget, *Memorandum for Heads of Executive Departments and Agencies: Establishment of Standard Application Process Requirements on Recognized Statistical Agencies and Units, M-23-04* (Washington, D.C.: Dec. 8, 2022).

[83]Federal law requires standardized criteria across statistical agencies and units for determining whether to grant an applicant the requested access. 44 U.S.C. § 3583(a). Recognizing that the appropriate criteria necessary to place an applicant in a trusted category would vary across data assets and modes of data access, OMB memorandum M-23-04 established several authorization levels.

public data and encourage collaboration.[84] The federal government recently created a unified process—and launched the ResearchDataGov portal—to facilitate the use of federal microdata for research purposes. NIH officials stated improving the understanding of the linkages between NIH-funded basic research, clinical trials, and biomedical training, on the one hand, and drug development, on the other, is worthwhile but challenging. Collaboration with qualified researchers, including those with specialized social science expertise, could help NIH address those challenges. Establishing a procedure for researchers to expand access to NIH's microdata would be a step toward advancing the agency's evidence-building capabilities in order to improve the public's and NIH's own understanding of its contributions to biomedical innovation and drug development.

Conclusions

NIH dedicated about $189 billion to biomedical R&D in fiscal years 2017 through 2021 to fulfill its mission of seeking fundamental knowledge about the nature and behavior of living systems and applying that knowledge to enhance health, lengthen life, and reduce illness and disability. However, the extent to which NIH contributes to drug development is difficult to measure and not well understood.

Better data, which involve improvements to existing data and expanding access to microdata, can improve our collective understanding of NIH's contributions to drug development. By providing clear guidance in its Grants Policy Statement and related training, NIH can better ensure that its awardees correctly disclose NIH support when applying for patents that arise from NIH-funded biomedical R&D. By developing a procedure to expand qualified researchers' access to the agency's microdata, NIH can advance its capabilities to improve understanding of how biomedical R&D it funds, including biomedical workforce training, contributes to drug development. These steps would be consistent with policymakers' recent efforts to increase the transparency of federally funded R&D, its results, and effectiveness for the benefit of the American public.

[84]Pub. L. No. 115-435, § 201, 132 Stat. 5529, 5534-44 (2019). The act includes requirements for federal agencies to (i) provide opportunities for the public to request specific data assets to be prioritized for disclosure and make suggestions for the development of agency criteria on prioritizing data assets for disclosure; and (ii) assist the public in expanding the use of public data assets, among other public engagement requirements.

Recommendations for Executive Action

We are making the following two recommendations to NIH:

- The Director of NIH should update the Grants Policy Statement and NIH training materials to provide clear guidance that the government interest statement in a patent arising from NIH-funded research should name National Institutes of Health as the federal agency and correctly identify NIH awards using, at the minimum, the institute code and serial number. (Recommendation 1)
- The Director of NIH should develop a procedure describing how researchers can access NIH microdata for the purposes of studying and evaluating NIH's contributions to developing new drugs and treatments. (Recommendation 2)

Agency Comments

We provided a draft of this report to HHS for review and comment. In its comments, reproduced in appendix II, HHS concurred with the recommendations. HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff have questions about this report, please contact me at (202) 512-6888 or WrightC@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report are listed in appendix III.

Candice N. Wright
Director
Science, Technology Assessment, and Analytics

Appendix I: Objectives, Scope, and Methodology

This report examines (1) National Institutes of Health (NIH) funding for basic research, clinical trials, and biomedical workforce training in fiscal years 2017 through 2021 and how that funding is tracked; (2) reporting of information about NIH-funded clinical trials in the public registry ClinicalTrials.gov maintained by NIH; (3) the extent to which NIH support is disclosed in patents arising from NIH-funded research; and (4) the extent to which microdata for NIH grants are accessible to researchers for tracing linkages between NIH contributions and drug development. In addition to this report, we are publishing a patent dataset, which can be accessed on our website at https://www.gao.gov/products/gao-23-105656.

For all four objectives, we interviewed cognizant officials at the NIH Office of the Director, several NIH institutes and centers, Office of Inspector General at the Department of Health and Human Services (HHS), Office of the Chief Economist at the U.S. Patent and Trademark Office (USPTO) as well as former NIH officials knowledgeable about NIH data and evaluation issues. We also interviewed scientists from several drug discovery centers, researchers from several universities who have received NIH funding or studied NIH and other federal R&D programs, and representatives of the pharmaceutical industry.

In the course of our review, we worked with a GAO research librarian to conduct a literature search of studies analyzing the relationship between research and development (R&D) funded by NIH and drug development. The librarian searched several research databases, including ProQuest and Scopus, using search terms that included “National Institutes of Health,” “drug discovery,” and “drug approvals,” to identify papers published from 2011 through 2021. From these searches, we identified and selected relevant studies to include in our review and to identify social science researchers to interview. We also reviewed additional select articles that we identified as part of our work or that were recommended to us by the researchers we interviewed, such as a study published in 2022 and illustrative studies that used NIH and federal microdata to evaluate outcomes of federally funded R&D.

To examine NIH funding for biomedical R&D, we used several sources of publicly available funding data as well as data obtained directly from NIH for fiscal years 2017 through 2021. For basic research, we analyzed obligations data reported by NIH to the National Science Foundation for the annual *Survey of Federal Funds for Research and Development*. For clinical trials and biomedical workforce training, we first considered funding data reported by NIH in the database NIH Research Portfolio Online Reporting Tools (NIH RePORT). NIH reports funding information for the former in the database's Categorical Spending portal under "clinical trials and supportive activities" and for the latter in the NIH Data Book. Because funding data reported in NIH RePORT may not represent obligations, we obtained from NIH obligations data for clinical trials and supportive activities and for biomedical workforce training to make them comparable to obligations data for basic research. To assess the reliability of these data, we conducted extensive interviews with knowledgeable agency officials about how the data were generated. We determined the data to be reliable for the purposes of presenting the funding amounts for basic research, clinical trials and supportive activities, and biomedical workforce training for fiscal years 2017 through 2021 in our report.

To examine the timeliness of registrations of NIH-funded clinical trials in the public database ClinicalTrials.gov, we reviewed NIH registration requirements. According to the "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information" issued on September 21, 2016, clinical trials funded in full or in part by NIH must be registered on ClinicalTrials.gov within 21 days of enrolling the first participant.[1] For intramural clinical trials, the policy went into effect on January 18, 2017. For extramural clinical trials, the policy applies to grant applications submitted on or after January 18, 2017, that request funding to conduct a clinical trial that is initiated on or after that date. This means that the effective date of the policy varies for clinical trials funded by NIH grants in recent years and that it does not apply to clinical trials initiated before January 18, 2017, or to trials initiated after that date, if the trials were funded by grants and awards with applications submitted before that date. Because NIH research grants are typically for 3-5 years, this also means that the percentage of NIH-funded extramural clinical trials that are not subject to the policy has decreased in each year since January 2017. We

[1]The NIH policy's requirement to register the trial on ClinicalTrials.gov no later than 21 days after enrolling the trial's first participant matches the statutory requirement for applicable drug trials under the Food and Drug Administration Amendments Act of 2007. Codified as amended at 42 U.S.C. § 282(j); see also 42 C.F.R. pt. 11.

could not exclude clinical trials that were not subject to the NIH policy because the existing public data did not allow for a separation of grants for which applications were submitted to NIH before and after January 18, 2017.

We obtained and analyzed data for all NIH-funded clinical trials that were registered in fiscal years 2019 through 2022. ClinicalTrials.gov has information on interventional clinical trials and observational studies. We excluded the latter from our analysis because they do not meet the NIH definition of a clinical trial.[2] We analyzed the data to determine the number of all NIH-funded clinical trials registered in each of those 4 fiscal years, including clinical trials that tested a drug; the number of such trials that were registered more than 21 days after enrolling the first participant; and what institutions registered clinical trials late in those 4 fiscal years, and how often.

Using these data, we found that in fiscal years 2019 through 2022 the number of all NIH-funded clinical trials registered on ClinicalTrials.gov ranged from 1,385 to 1,485, and the number of such trials involving drugs ranged from 437 to 595. We also determined that during that period the percentage of NIH-funded trials that were registered late ranged from 16 to 18 percent, and the percentage of NIH-funded trials involving drugs ranged from 9 to 10 percent. These numbers and percentages could overestimate late-registered clinical trials because not all NIH-funded trials registered on ClinicalTrials.gov during this period may have been subject to NIH's 2016 policy; or they could underestimate late-registered trials if not all NIH-funded trials were registered. To assess the reliability of ClinicalTrials.gov data, we reviewed documentation from NIH, interviewed knowledgeable current and former NIH officials, and reviewed the data for potential errors. Based on our review, we determined that these data were sufficiently reliable for the purposes of reporting the timeliness of the registration of NIH-funded clinical trials on ClinicalTrials.gov, with the limitation as noted.

To examine the disclosure of NIH support in patent government interest statements, we reviewed applicable statutes, regulations, NIH guidance,

[2]NIH defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available.

and the federal internal control standards. We determined that the standard stating that management should communicate quality information to achieve the entity's objective was significant to this objective.[3] We analyzed data for patents with application dates in calendar years 2012 through 2021 from the public PatentsView database maintained by USPTO. We identified 54,523 patents with government interest statements. For these patents, we examined whether the government interest statements disclosed support from NIH and included an award identification number. We did not review certificates of correction for possible corrections to the government interest statements after the patents were granted.

We downloaded the following variables from PatentsView: patent ID, patent application and grant dates, government interest statement text, World Intellectual Property Organization (WIPO) field classification, award numbers, and government organization names and related agency hierarchy (level one, level two, and level three, where the levels specify position of the agency in a hierarchical set of relationships). The award numbers, government organization names and related agency hierarchy were identified from the government interest statements by PatentsView.[4] We searched through all unique values of the government organization names and agency hierarchy variables for NIH or any of the 27 NIH institutes or centers. In addition, we searched the government interest statement text for various spellings of NIH and its 27 institutes and centers.

For the purposes of our analysis, a patent disclosed support from NIH if PatentsView's government organization variables for that patent included NIH or one of the 27 institutes or centers, or if our search of the government interest statement text detected various spellings of NIH or its 27 institutes and centers. A patent disclosed support from the U.S. government, HHS, the Public Health Service, or the Small Business Innovation Research program if PatentsView's government organization variables for that patent included these organizations. We also developed an algorithm to detect NIH award numbers. Specifically, we determined the award number to have originated from NIH if one of NIH's 246 activity codes appeared in the first six characters of the award number and if the

[3]GAO-14-704G.

[4]See C. Jones and S. Madhaven, *PatentsView Government Interest Extraction and Processing—Version 2.0.* American Institutes for Research (May 2020).

award number contained an NIH institute code and six-digit serial number.[5] Using this methodology, we identified 19,055 patents with application dates in calendar years 2012 through 2021 that disclosed NIH support. These patents comprised 16,352 with a correct NIH award number, 2,525 patents with an inaccurate award number that did not have an institute code or a six-digit serial number, and 178 patents without an award number.[6]

Because, as we found, patent applicants entered the letter O instead of zero in the activity code in about 5 percent of the 16,352 patents we characterize as having a correct NIH award number, we incorporated both in our searches of activity codes. We checked the accuracy of our data by manually tracing a sample of award numbers to award information published in the NIH RePORT database and confirming activity codes and our methods with agency officials.

We determined that a patent that did not disclose support from NIH likely arose from NIH-supported research if the award number contained an NIH activity code, institute code, and six-digit serial number, and had a WIPO field classification common to the patents that disclosed NIH support. To obtain WIPO field classifications common to such patents, we reviewed the WIPO field classifications of the 19,055 patents that disclosed NIH support. We then identified the WIPO field classifications that were associated with 95 percent of these patents. These field classifications were: analysis of biological materials, biotechnology, chemical engineering, computer technology, macromolecular chemistry, measurement, medical technology, microstructural and nanotechnology, optics, organic fine chemistry, other special machines, and pharmaceuticals. Using this methodology, we identified 5,813 patents with application dates in calendar years 2012 through 2021 that disclosed support from the U.S. government, HHS, the Public Health Service, and the Small Business Innovation Research program, and determined that 56 of these patents likely arose from NIH-funded research.

To assess the reliability of PatentsView data, we reviewed documentation from USPTO, interviewed knowledgeable officials, and reviewed the data

[5]We also found several activity codes, such as “BC” and “RR,” that were not on NIH’s official list of 246 activity codes posted on the agency’s website. For these activity codes, we confirmed with NIH officials that they belonged to NIH and included them in our list.

[6]In addition, our search of the government interest statement text found that 783 of the 19,055 patents disclosed support from an institute or center, but not NIH.

for potential errors. Based on our review, we determined that these data were sufficiently reliable for the purposes of reporting the extent to which NIH awardees did not fully or correctly disclose NIH support in patent government interest statements.

To determine whether the patents that did not fully or correctly disclose NIH support were associated with drugs approved by the Food and Drug Administration (FDA), we merged our patent dataset by patent ID with product data from the FDA Orange Book products and patent files as of December 2022.[7] We reviewed Orange Book documentation, reviewed our prior work using these data, and validated the results by manually searching the Orange Book. Based on our review, we determined that these data were sufficiently reliable for the purposes of reporting the number of FDA-approved drugs associated with the patents in our analysis.

To examine the accessibility of NIH internal microdata for research and evaluation purposes, we reviewed applicable statutes, federal policy guidance, and relevant reports by advisory groups convened by the Director of NIH. We interviewed current and former NIH officials about access to microdata held in NIH's internal Management, Planning, Analysis, and Coordination II (IMPAC II) database.

We interviewed academic social science researchers who were knowledgeable about studies using federal microdata or used such data, including NIH IMPAC II data, in their own published research. We interviewed academic researchers who participated in the Biomedical Research Workforce Working Group convened by the Director of NIH.[8] We also interviewed a representative of the Institute for Research on Innovation and Science at the University of Michigan that manages The Universities: Measuring the Impacts of Research on Innovation, Competitiveness, and Science (UMETRICS) project, which collects microdata from participating universities, and researchers who used the UMETRICS data in their research.

[7]FDA's Orange Book identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act. As we reported in prior work (GAO-21-52), the Orange Book lists only currently active patents and only those reported to FDA by the company applying for FDA approval, according to FDA officials.

[8]National Institutes of Health, *Biomedical Research Workforce Working Group Report* (June 14, 2012).

We conducted this performance audit from January 2022 to April 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

March 10, 2023

Candice N. Wright
Director, Science, Technology Assessment, and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Wright:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"*NATIONAL INSTITUTES OF HEALTH: Better Data Will Improve Understanding of Federal Contributions to Drug Development*" (GAO-23-105656).**

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT – NATIONAL INSTITUTES OF HEALTH: BETTER DATA WILL IMPROVE UNDERSTANDING OF FEDERAL CONTRIBUTIONS TO DRUG DEVELOPMENT (GAO-23-105656)

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

GAO Recommendation 1:
The Director of NIH should update the Grants Policy Statement and NIH training materials to provide clear guidance that the government interest statement in a patent arising from NIH-funded research should name National Institutes of Health as the federal agency and correctly identify NIH awards using, at the minimum, the institute code and serial number.

HHS Response:
HHS Concurs with GAO's recommendation.

NIH will make appropriate edits to the NIH Grants Policy Statement, Section 8.2.4 Inventions and Patents (Exhibit 8), to provide clear guidance to NIH federal funding recipients that they should name in the government interest statements "National Institutes of Health" as the federal agency and correctly identify NIH awards using, at the minimum, the institute code and serial number. NIH expects updates to be included in the next scheduled revision of the NIH Grants Policy Statement in October 2023.

Additionally, NIH will update training materials to provide similar guidance. These Invention Reporting training materials were not presented at the recently held 2023 Virtual NIH Grants Conference but will be updated at the next available opportunity for such presentations in the future, along with including this clarification in the next "NIH Update" presentation on changes and new policy requirements that NIH presents to associations of recipients of federal research funds throughout the year. See the attached associated slide NIH will present at the NIH Update presentation at a Scientific Research Administrators International (SRAI) chapter meeting on March 31, 2023.

GAO Recommendation 2:
The Director of NIH should develop a procedure describing how researchers can access NIH microdata for the purposes of studying and evaluating NIH's contributions to developing new drugs and treatments.

HHS Response:
HHS Concurs with GAO's recommendation.

NIH will develop a procedure describing how researchers can access NIH microdata for analytical purposes.

NIH will provide an action plan to address the recommendation in our 180-day letter response to Congress.

Reminder – Required Language for Government Support Clauses on Patented Intellectual Property

- Per the Bayh-Dole Act, The Government Support Clause is a statement acknowledging federal support of a subject invention that MUST be included in the specification of a U.S. patent application or a U.S. issued patent (35 USC 202(c)(6))
  - See: NIH Grants Policy Statement, Section 8.2.4 "Inventions and Patents"
- Government Support Clauses must specifically identify "the National Institutes of Health" as the funding agency
- Sample: *This invention was made with government support under (grant number, including the two-letter institute code and six-digit serial number, e.g., CA012345) awarded by the National Institutes of Health. The government has certain rights in the invention.*

Accessible Text for Appendix II: Comments from the Department of Health and Human Services

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Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Candice N. Wright, (202) 512-6888 or WrightC@gao.gov.

Staff Acknowledgments

In addition to the contact named above, the following individuals made contributions to this report: Robert J. Marek (Assistant Director), Sada Aksartova (Analyst-in-Charge), Edith Yuh, Lauren Gomez, Cindy Korir-Morrison, Eric Charles, Silda Nikaj, Alec McQuilkin, Virginia A. Chanley, Patrick Harner, Donna Morgan, and Ryan Han.

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