United States Government Accountability Office

Report to Congressional Requesters

September 2024

BIOMEDICAL RESEARCH

Improvements Needed to the Quality of Information about DOD and VA Contributions to Drug Development

GAO-24-107061

GAO Highlights

Highlights of GAO-24-107061, a report to congressional requesters

September 2024

BIOMEDICAL RESEARCH

Improvements Needed to the Quality of Information about DOD and VA Contributions to Drug Development

Why GAO Did This Study

DOD and VA prioritize developing biomedical technologies to treat diseases and conditions that affect military personnel and veterans, including brain and spinal cord injuries, infectious diseases, and post-traumatic stress disorder.

GAO was asked to review DOD and VA research contributions to drug development. This report examines (1) DOD and VA funding for biomedical R&D in fiscal years 2019 through 2023; (2) DOD and VA ownership of biomedical patents and the extent to which agency support is disclosed in other biomedical patents arising from research they fund; and (3) the extent to which information about DOD- and VA-funded clinical trials is publicly reported.

GAO reviewed relevant laws and agency documents; analyzed funding, patent, and clinical trial data; visited five DOD facilities and one VA medical center; and interviewed agency officials and 12 researchers who conducted agency-funded research. This report is a companion to GAO-23-105656, which examined National Institutes of Health research contributions to drug development.

What GAO Recommends

GAO is making two recommendations to DOD and one to VA, including that DOD improve agency-wide training of personnel to better ensure accurate disclosure of DOD support in patents by awardees, and that DOD and VA both take steps to improve the completeness and timeliness of reporting on ClinicalTrials.gov for the trials they fund. DOD and VA agreed with the recommendations.

View GAO-24-107061. For more information, contact Candice N. Wright at (202) 512-6888 or WrightC@gao.gov.

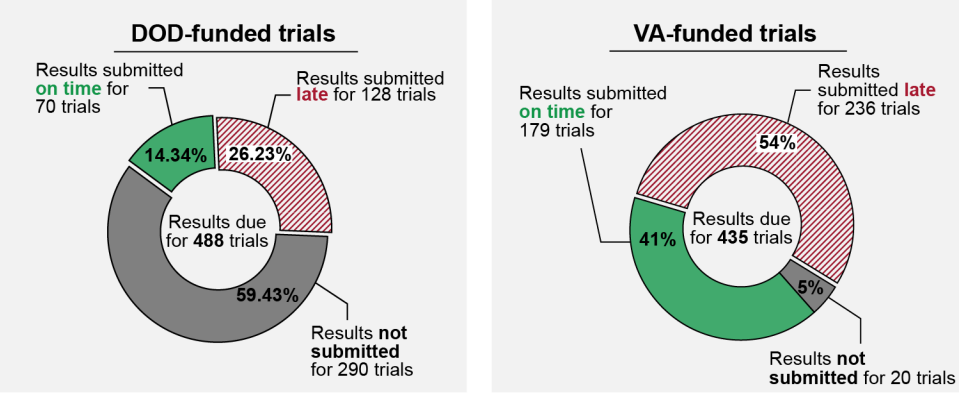
What GAO Found

The Departments of Defense (DOD) and Veterans Affairs (VA) fund biomedical research and development (R&D) that can lead to new drugs and medical devices. DOD and VA dedicated about $20 billion and $10 billion respectively to such R&D in fiscal years 2019 through 2023. Multiple DOD components fund biomedical R&D. The majority of it is performed by external entities, such as universities. VA's R&D is conducted by VA researchers at more than 100 VA medical centers.

DOD- and VA-funded research can lead to the patenting of new inventions. Among biomedical patents with application dates in fiscal years 2014 through 2023, GAO identified 1,146 patents owned by DOD and VA, as well as 3,078 biomedical patents owned by other entities disclosing DOD support. Only federal employees conduct VA-funded research, and VA generally owns the resulting patents. GAO found that 559 of the 3,078 patents did not disclose a correct DOD award number as required. DOD does not provide department-wide training on disclosure of agency support in patents to its personnel responsible for reviewing awardee disclosures. Without DOD personnel ensuring consistent and accurate awardee disclosure of DOD support in patents, the public and policymakers cannot measure the full extent of DOD's contributions to biomedical technologies, including drugs.

GAO found that, according to ClinicalTrials.gov data, among trials registered in fiscal years 2014 through 2023, results were submitted late or not at all for the majority of DOD- and VA-funded trials (see figure). DOD does not provide clear guidance for public reporting of clinical trial information. VA officials stated they saw a benefit to updating information resources for VA investigators and enhancing how investigators are notified of result submission deadlines, which could improve result reporting. Delays in result reporting hinder the transparency of federally funded clinical trials. Without complete and timely reporting, users of ClinicalTrials.gov—including patients, physicians, researchers, and the public—cannot access important scientific information about health outcomes and adverse events associated with those trials.

Figure: Result Reporting for Trials Funded by the Departments of Defense (DOD) and Veterans Affairs (VA) Registered on ClinicalTrials.gov in Fiscal Years 2014–2023



Source: GAO analysis of ClinicalTrials.gov and DOD data. | GAO-24-107061

Contents

Tables

Figures

Abbreviations

CDMRP	Congressionally Directed Medical Research Programs
DOD	Department of Defense
FAR	Federal Acquisition Regulation
FDA	Food and Drug Administration
NIH	National Institutes of Health
ORD	Office of Research and Development
R&D	research and development
USPTO	U.S. Patent and Trademark Office
USAMRDC	U.S. Army Medical Research and Development Command
VA	Department of Veterans Affairs

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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September 26, 2024

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

The Honorable Debbie Stabenow
United States Senate

Several federal agencies—including the Departments of Defense (DOD) and Veterans Affairs (VA)—fund biomedical research and development (R&D) that can lead to new drugs and medical devices.[1] According to National Science Foundation data, DOD and VA obligated $1.1 billion and $1.8 billion respectively for life science research in fiscal year 2023.[2]

However, life science research funding data may not fully reflect budgetary resources DOD and VA dedicate to biomedical R&D, because the definition of life sciences may cover only a portion of that R&D.[3] The extent of these agencies' research contributions to the development of drugs and other medical products is not well understood by policymakers and the public. In addition, as discussed in our prior work, tracing linkages between federal funding and drugs is a complex effort made more difficult by weaknesses in public patent and clinical trial data.[4] Access to data and data-driven analysis about DOD and VA contributions can help the public understand how federal investments in science and innovation translate

[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. Medical devices include instruments that are intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease.

[2]National Science Foundation, *Survey of Federal Funds for Research and Development 2022–2023*. The survey was released in April 2024 and the data for fiscal year 2023 are preliminary, according to the National Science Foundation.

[3]For the purposes of this report, we define biomedical R&D broadly as all DOD and VA activities, including basic research, that support the development of biomedical and medical technologies to address health needs.

[4]GAO, *National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development*, GAO-23-105656 (Washington, D.C.: Apr. 4, 2023).

into products that benefit Americans' health. It can also provide policymakers with new evidence to make decisions related to biomedical innovation and future R&D investments.

You asked us to review DOD and VA research contributions to drug development. This report examines: (1) DOD and VA funding for biomedical R&D in fiscal years 2019 through 2023; (2) DOD and VA ownership of biomedical patents and the extent to which these agencies' support is disclosed in other biomedical patents arising from research they funded; and (3) the extent to which information about DOD- and VA-funded clinical trials is publicly reported. This report is a companion to our April 2023 report that examined National Institutes of Health (NIH) research contributions to drug development.[5] We are publishing a patent dataset, which can be accessed on our website at: https://www.gao.gov/products/gao-24-107061.

For all three objectives, we reviewed applicable laws and regulations as well as DOD and VA policies and guidance. We analyzed data on DOD and VA funding for biomedical R&D, on patents these agencies own and patents owned by other entities that disclosed support from the agencies, and on DOD- and VA-funded clinical trials. We assessed the reliability of these data by reviewing related documentation and reviewing the data for errors and omissions, among other things. We determined the data to be reliable for the purposes of our reporting objectives.

We conducted site visits to five DOD facilities and a VA medical center in January and February 2024. We used agency data and interviews with agency officials and other experts to inform our selection of these sites. We interviewed cognizant officials from DOD and VA. We compared agency efforts to help ensure awardees correctly disclose federal support in patents and to inform responsible parties about publicly reporting clinical trial information 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 September 2023 to September 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the

[5]GAO-23-105656.

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

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. The federal government provides 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 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 a new drug to treat the disease;
- **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.** Studies testing the drug in human volunteers for safety and efficacy that are conducted in phases (see sidebar); and
- **Review and approval.** Regulatory review and approval of the drug by the Food and Drug Administration (FDA) 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 in different stages of drug development taking place concurrently. Outcomes of the process are uncertain because many new drug candidates fail to advance to the next stage or gain FDA approval. Often drug candidates and drugs that already have FDA approval are studied for new

Clinical Trial Phases

Clinical trials are typically conducted in phases that build on one another.

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.

Phase 2. If the drug does not show unacceptable toxicity in phase 1 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.

Phase 3. 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.

Source: GAO. | GAO-24-107061

therapeutic uses. Because such work builds upon previous R&D efforts, new candidate therapies could be ready for clinical trials more quickly.[7]

DOD- and VA-Funded Biomedical R&D

DOD- and VA-funded biomedical R&D prioritizes addressing the health needs of military and veteran populations.[8] Diseases and conditions that affect service members, veterans, and their families include traumatic brain injury, spinal cord injury, extremity trauma and amputation, post-traumatic stress disorder, and effects of long-term toxic exposure. DOD supports research on chemical, biological, and nuclear threats, and the development of medical technologies to counteract them. Both agencies invest significant resources in R&D related to medical devices, including prosthetics.[9] Both DOD and VA provide healthcare to their respective populations, and manage their own networks of hospitals and clinics.

In addition, DOD has a medical school—the Uniformed Services University of the Health Sciences located in Bethesda, MD—which educates physicians and nurses for the military health system and whose faculty and students conduct biomedical research. DOD also works with industry to advance early stage medical technologies from the laboratory to a marketable product. Under a special authority granted by Congress, DOD and FDA collaborate to expedite the approval of drugs and devices to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel.[10]

About two-thirds of DOD's R&D is performed by external entities, such as universities and commercial firms. VA's R&D must be performed by VA researchers, often in partnership with affiliated universities and nonprofit research and education corporations.[11] While biomedical R&D represents

[7]Generally, the process of developing a medical device is similar. FDA has a separate pathway for reviewing and approving devices.

[8]In this respect, DOD's and VA's approach is different from NIH's. NIH funds most aspects of basic biomedical research and scientific discovery for the benefit of general health, as discussed in GAO-23-105656.

[9]The term "prosthetics" refers to any device that supports or replaces a body part or function, such as a hearing implant or prosthetic limb.

[10]Pub. L. No. 115-92, enacted in December 2017, expanded the emergency use authority for DOD under section 564 of the Federal Food, Drug, and Cosmetic Act.

[11]VA's research program is authorized in statute specifically for the purpose of more effectively carrying out "the primary function of the Administration and in order to contribute to the Nation's knowledge about disease and disability." The research is to be done in connection with the provision of medical care and treatment to veterans. 38 U.S.C. § 7303.

a part of DOD's research, development, test, and evaluation budget, all of VA's R&D is veteran health related.

Patent Ownership and Disclosure of Federal Support in Patents

Federally funded R&D can lead to patentable inventions. A patent is an exclusive right granted for a fixed period to an inventor.[12] An FDA-approved drug is typically associated with one or more patents.[13] Inventions can be developed by scientists employed by federal agencies, and patents for those inventions are typically owned by those agencies.

Patentable inventions can also arise from research conducted by scientists employed by universities, commercial firms, and other entities that receive awards from the federal government.[14] 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.[15] The act enabled universities, nonprofit research institutions, and businesses to own, patent, and commercialize inventions developed with federal funding. Awards subject to the Bayh-Dole Act must contain a provision that requires awardees seeking 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. The act's requirements are less relevant to VA because, unlike DOD, it does not give awards to external entities.

The U.S. Patent and Trademark Office (USPTO), an agency of the Department of Commerce, grants patents in the United States and

[12]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.

[13]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.

[14]In this report, we use the term "award" to include contracts, grants, cooperative agreements, and other funding agreements, and "awardee" to denote the nonfederal parties to those agreements.

[15]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.

maintains a public database called PatentsView on U.S. patent activity. Patents are a common measure of innovation, and researchers have analyzed patent government interest statement data to trace federal contributions to biomedical innovation and drug development.[16]

Reporting Clinical Trial Information on ClinicalTrials.gov

There are federal requirements for reporting clinical trial information on a publicly accessible platform that apply to trials funded by federal agencies, including DOD and VA. ClinicalTrials.gov is a public, web-based registry and results database of U.S. and international clinical trials, including federally funded trials. It was created in response to a statutory mandate and is maintained by NIH's National Library of Medicine.[17] Information on ClinicalTrials.gov is to be reported and updated by the principal investigator or another party responsible for a trial.[18] Generally, the responsible party is to submit information about the trial to ClinicalTrials.gov (that is, register the trial) when the trial begins, update the information throughout the trial, and report results after the trial ends.

The responsible party of a trial that meets the definition of an applicable clinical trial is generally required to submit registration information to ClinicalTrials.gov no later than 21 days after enrolling the trial's first participant and submit the trial's results within 1 year of the primary

[16]We discussed that research in GAO-23-105656. For example, see D. Li, P. Azoulay, and B.N. Sampat, "The Applied Value of Public Investments in Biomedical Research," *Science*, vol. 356 (2017).

[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 became available 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.

completion date. For drugs, an applicable clinical trial is a study of an FDA-regulated drug or biologic in phase 2 or later.[19]

Some federal agencies require responsible parties of all trials—that is, not only of applicable clinical trials—to report information on ClinicalTrials.gov in accordance with the federal regulations' registration and result submission timelines for applicable clinical trials.[20] VA's Office of Research and Development (ORD), which funds the majority of VA trials, requires all ORD-funded trials to be registered and report results on ClinicalTrials.gov in accordance with those timelines.[21] DOD-wide guidance requires public reporting of some clinical trial information to comply with certain federal regulations.[22]

DOD and VA Dedicated about $30 Billion to Biomedical R&D in Fiscal Years 2019 through 2023

DOD and VA dedicated about $20 billion and $10 billion respectively to biomedical R&D in fiscal years 2019 through 2023. Multiple DOD agencies, offices, and programs (components)—including the Defense Health Agency, the Army, and the Chemical and Biological Defense Program—support biomedical R&D, the majority of which is performed by external entities under contracts and other awards. VA's biomedical R&D is conducted at more than 100 VA medical centers by VA researchers.

[19]Applicable clinical trials subject to the ClinicalTrials.gov reporting requirements of the Food and Drug Administration Amendments Act of 2007 generally include: (1) trials of drugs: controlled clinical investigations—other than phase I investigations—of a drug subject to FDA regulation authorized by section 505 of the Federal Food Drug, and Cosmetic Act or section 351 of the Public Health Service Act, and (2) trials of devices subject to sections 510(k), 515, and 520(m) of the Federal Food, Drug, and Cosmetic Act: controlled trials with health outcomes, other than small feasibility studies, and pediatric postmarket surveillance. Pub. L. No. 110-85, § 801, 121 Stat. 823, 904-22 (Sept. 27, 2007) (codified as amended at 42 U.S.C. § 282(j)).

[20]NIH generally requires responsible parties of all its funded trials, irrespective of whether they meet the definition of an applicable clinical trial, to register the trials and report results on ClinicalTrials.gov in accordance with those timelines. NIH, "NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information" (Sept. 21, 2016). We discussed the extent of compliance with the policy in GAO-23-105656.

[21]ORD uses the World Health Organization (WHO) definition of a clinical trial, which does not differentiate between applicable and non-applicable clinical trials. WHO defines a clinical trial as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. See G.D Huang, J.K. Altemose, and T.J. O'Leary, "Public Access to Clinical Trials: Lessons from an Organizational Implementation of Policy," *Contemporary Clinical Trials*, vol. 57 (2017).

[22]DOD Instruction 6200.02, *Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs* (Feb. 27, 2008).

DOD and VA Dedicated about $20 Billion and $10 Billion Respectively to Biomedical R&D in Fiscal Years 2019 through 2023

In fiscal years 2019 through 2023, DOD and VA dedicated a total of about $30 billion to biomedical R&D, according to our analysis of these agencies' annual budget submissions (table 1).[23] DOD dedicated about $20 billion, which accounted for 3.4 percent of DOD's overall research, development, test, and evaluation budget of $588 billion during the 5-year period. VA dedicated about $10 billion, and all VA-supported R&D is health-related.[24]

Table 1: Department of Defense and Department of Veterans Affairs Funding for Biomedical Research and Development, Fiscal Years 2019–2023 (in Billions)

Agency	2019	2020	2021	2022	2023	Total
Department of Defense (DOD)	3.19	4.90	3.53	4.04	4.36	**20.02**
Department of Veterans Affairs (VA)	1.93	1.92	1.99	2.16	2.23	**10.23**
Total	**5.12**	**6.83**	**5.53**	**6.20**	**6.59**	**30.25**

Source: GAO analysis of funding information in DOD and VA annual budget submissions and provided by DOD. | GAO-24-107061

Note: Funding may not sum to total due to rounding. We used funding amounts associated with past year obligational authority in DOD and VA annual budget submissions. We calculated total DOD funding by summing amounts associated with biomedical budget activity program elements in research, development, test, and evaluation budget submissions and by obtaining funding data from DOD. We treated all VA research funding as biomedical.

Multiple DOD Agencies and Programs Fund Biomedical R&D

Several appropriation accounts for DOD research, development, test, and evaluation fund biomedical R&D (table 2).

[23]Funding amounts discussed in this section of the report represent obligational authority unless noted otherwise.

[24]To generate an estimate of DOD and VA funding for biomedical R&D, we used funding amounts associated with past year obligational authority in DOD and VA annual budget submissions. We calculated total DOD funding by summing the amounts associated with biomedical budget activity program elements in research, development, test, and evaluation budget submissions and by obtaining funding data from DOD. We treated all VA research funding as biomedical. For more details about our methodology, see app. I.

Table 2: Department of Defense (DOD) Appropriation Accounts Funding Biomedical R&D, Fiscal Years 2019–2023 (in Billions)

DOD component	2019	2020	2021	2022	2023	Total
Defense Health Program	2.18	3.66	2.40	2.64	3.04	**13.91**
Chemical and Biological Defense Program	0.37	0.47	0.37	0.44	0.59	**2.24**
Defense Advanced Research Projects Agency	0.34	0.45	0.39	0.48	0.49	**2.16**
Army	0.27	0.30	0.34	0.45	0.22	**1.57**
Navy	0.04	0.03	0.04	0.03	0.02	**0.15**
Total	**3.19**	**4.90**	**3.53**	**4.04**	**4.36**	**20.02**

Source: GAO analysis of funding information in DOD annual budget submissions and provided by DOD. | GAO-24-107061

Note: Funding may not sum to total due to rounding. We used funding amounts associated with past year obligational authority for biomedical budget activity program elements in DOD annual budget submissions for research, development, test, and evaluation for the Defense Health Program, Defense Advanced Research Projects Agency, Army, and Navy. We obtained comparable obligational authority data for the Chemical and Biological Defense Program from DOD.

Defense Health Program Funding for Biomedical Research and Development

- Core funding is requested by DOD through the annual budget preparation process and supports biomedical research and advanced product development to meet DOD military health priorities, such as battlefield medicine, medical countermeasures for biological defense, traumatic brain injury, and vaccines and treatments for rare viruses.
- The Congressionally Directed Medical Research Programs support research in the areas of general and military health, including cancer, traumatic brain injury and psychological health, and autism.

Source: GAO. | GAO-24-107061

The largest source of funding for DOD's biomedical R&D is the Defense Health Program account, overseen by the Office of the Assistant Secretary of Defense for Health Affairs and managed by the Defense Health Agency:

- This account consists of core funding requested by DOD for military needs and funding for programs directed by Congress (see sidebar).
- DOD is in the process of transferring health R&D functions from the Army—which historically had the largest biomedical R&D program at DOD—and other military departments to the Defense Health Agency, as directed by Congress.[25]

DOD-funded biomedical R&D is driven by the department's requirements to meet the needs of the military health system, not researcher interests, according to DOD.

The majority of DOD biomedical R&D funding supports more advanced phases. For example, in fiscal years 2019 through 2023, the Defense Health Program dedicated about $121 million (less than 1 percent) to basic research, $779 million (6 percent) to applied research, and $13 billion (94 percent) to experimental development and advanced technology and product development. According to DOD officials, the Defense Health Program funds most of DOD-supported clinical trials. They stated that while the Defense Health Agency does not currently

[25]GAO, *Defense Health Care: Improved Monitoring Could Help Ensure Completion of Mandated Reforms*, GAO-23-105710 (Washington, D.C.: June 22, 2023).

track program-wide clinical trial funding, they would like the agency to develop that capability in the future.

Most of DOD-supported biomedical R&D is conducted by external entities, and DOD uses multiple types of awards to fund it. In addition to contracts subject to the Federal Acquisition Regulation (FAR), DOD uses non-FAR agreements such as grants, cooperative agreements, and other transaction agreements.[26] The Congressionally Directed Medical Research Programs (CDMRP) generally award funding in the form of grants and cooperative agreements. DOD's funding for advanced product development—which includes acquisition of drugs and medical products for DOD personnel—is generally provided in the form of contracts and other transaction agreements for prototypes.[27] Officials stated that the Defense Health Program does not have a readily available enterprise-wide breakdown of biomedical R&D funding by agreement type.

VA Supports an Extensive Network of Biomedical Research Partnerships at More Than 100 Medical Centers

VA, through the Veterans Health Administration led by the Under Secretary for Health, operates the nation's largest integrated health care system and funds research. VA's research program seeks to improve veterans' health by studying health conditions affecting veterans, developing treatments for veterans, and recruiting and retaining VA researchers. VA funding can only support research conducted by VA researchers, who can be full-time VA employees or hold dual appointments at VA and an affiliated university or research institution. As of March 2024, 3,777 researchers were engaged in VA-funded research at 105 VA medical centers, including 83 centers that conducted clinical trials, according to VA.[28] The vast majority of the researchers—3,519 (93 percent)—held dual appointments with affiliated institutions. Because the majority of VA-appointed researchers have dual appointments, VA-funded

[26]Other transaction agreements are agreements other than contracts, grants, and cooperative agreements. We examined DOD's use of other transaction agreements in prior work. See GAO, *Defense Acquisitions: DOD's Use of Other Transactions for Prototype Projects Has Increased*, GAO-20-84 (Washington, D.C.: Nov. 22, 2019) and *Other Transaction Agreements: DOD Can Improve Planning for Consortia Awards*, GAO-22-105357 (Washington, D.C.: Sept. 20, 2022).

[27]Federal statutes authorize DOD's use of other transaction agreements for research and prototype projects, among others. 10 U.S.C. §§ 4021-22. Prototype projects help evaluate the feasibility or utility of a technology. We examined DOD's use of other transaction agreements for prototype R&D in GAO-20-84 and for research, prototype, and production in DOD's COVID-19 pandemic response in GAO-22-105357.

[28]In total, the Veterans Health Administration has 172 medical centers at the local level (including 105 that conduct research) and they are organized into the 18 Veterans Integrated Service Networks.

research in effect supports an extensive network of partnerships with universities and other research institutions.

VA's biomedical R&D is funded by congressional appropriations and from external sources, including other federal agencies (table 3):

- The Medical and Prosthetic Research appropriation account provides the largest source of research funding. ORD at the Veterans Health Administration manages the research program funded by this appropriation.[29] Within ORD, there are four services, each responsible for administering and supporting research with a specific focus, as well as a Cooperative Studies Program responsible for large-scale clinical trials and epidemiological studies within VA.[30] VA researchers obtain awards from the five ORD components through a competitive process.[31]
- The Veterans Health Administration allocates additional funding for research support from funding appropriated for VA medical care. Research support involves resources that are not directly related to the specific aims of a particular research project, but rather enable a VA medical facility to support the conduct of research.[32] The Veterans Health Administration allocates those funds to 18 Veterans Integrated Service Networks—regional systems of medical care—which then distribute them among individual medical centers conducting research.[33]

[29]VA refers to the program funded by this appropriation account as the intramural research program.

[30]The four services are (1) Biomedical Laboratory Research and Development Service, (2) Clinical Science Research and Development Service, (3) Health Services Research and Development Service, and (4) Rehabilitation Research and Development Service. Each research service is led by a director and has scientific program managers who are responsible for specific research portfolios (or topic areas) within their service.

[31]For more information about different types of awards available to VA researchers from ORD's components, see GAO, *VA Health Care: Efforts to Prioritize and Translate Research into Clinical Practice*, GAO-20-211 (Washington, D.C.: Jan. 23, 2020).

[32]Examples of research support include salary support for clinicians conducting research, research equipment maintenance costs, and expenses for research oversight and compliance activities.

[33]The Veterans Health Administration distributes VA medical care funding to its health care service networks using the Veterans Equitable Resource Allocation model. We reported on VA's use of this model in GAO, *Veterans Health Care: VA Needs to Improve Its Allocation and Monitoring of Funding*, GAO-19-670 (Washington, D.C.: Sept. 23, 2019).

- Research conducted at VA can be supported by funding from external sources, such as other federal agencies and nonfederal entities.[34] Federal agencies provide the majority of this funding. Nonprofit organizations—known as nonprofit research and education corporations—assist VA researchers with obtaining funding from external sources for specific research projects.[35] In 2022, 78 corporations supported research activities at VA medical centers.

Table 3: Sources of Funding for Department of Veterans Affairs (VA) Biomedical R&D, Fiscal Years 2019–2023 (in Millions)

Funding source	2019	2020	2021	2022	2023	Total
Medical and Prosthetic Research appropriation	779	750	796	882	916	**4,122**
Research support (Veterans Equitable Resource Allocation from a medical care appropriation)[a]	618	648	668	750	778	**3,462**
Other federal agencies and nonfederal organizations	528	523	532	528	540	**2,651**
Total	**1,926**	**1,921**	**1,995**	**2,159**	**2,234**	**10,235**

Source: GAO analysis of funding information in VA annual budget submissions. | GAO-24-107061

Notes: We used funding amounts associated with past year obligational authority in VA annual budget submissions. The table does not include $287 million in other VA budgetary resources for R&D in fiscal years 2019–2023, with reimbursement activity representing the majority of that amount.

[a]The Veterans Equitable Resource Allocation is the model used by the Veterans Health Administration to distribute health care funding, which includes funding for research support, to 18 Veterans Integrated Service Networks.

According to VA data, in fiscal years 2019 through 2023, ORD obligated $668 million for clinical trials, with 96 percent of that amount funding interventional trials.[36]

[34]VA refers to research supported by funding from non-VA sources as extramural. For more detail about this research, see GAO, *VA Research: Opportunities Exist to Strengthen Partnerships and Guide Decision-Making with Nonprofits and Academic Affiliates*, GAO-20-570 (Washington, D.C.: July 29, 2020).

[35]The Veterans Benefits and Services Act of 1988 (Pub. L. No. 100-322) allowed the establishment of private, state-chartered, nonprofit entities to provide flexible funding mechanisms for the administration of funds, other than those appropriated to VA, for the conduct of VA-approved research.

[36]An interventional clinical trial is a study in which participants are assigned to groups that receive one or more interventions (or no intervention), so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available.

DOD and VA Own More Than 1,000 Biomedical Patents, and DOD Support Is Not Disclosed Consistently in Patents Owned by Other Entities

Among biomedical patents with application dates in fiscal years 2014 through 2023, we identified 1,146 patents owned by DOD and VA, as well as 3,078 patents owned by other entities that disclose support from DOD. We found that 559 of the 3,078 patents did not fully or correctly disclose DOD support, as required by law. DOD does not provide department-wide training to its workforce regarding how awardees should disclose DOD support in patents arising from DOD-funded research, including biomedical patents. Patents typically do not disclose VA support as VA only funds research conducted by federal employees.

DOD and VA Own More Than 1,000 Biomedical Patents with Application Dates in Fiscal Years 2014 through 2023

Federal employees can develop and patent biomedical inventions while performing research funded by the federal government. Such patents are typically owned by the agencies that employ them, including DOD and VA. Among biomedical patents with application dates in fiscal years 2014 through 2023, we identified 716 patents owned by DOD and 430 patents owned by VA (table 4).[37] We found that three patents owned by the Army were associated with an FDA-approved drug (tafenoquine succinate) and one patent owned by VA was associated with an FDA-approved drug (baricitinib).

Table 4: Biomedical Patents Owned by the Departments of Defense and Veterans Affairs with Application Dates in Fiscal Years 2014–2023

Agency	Number of patents
Department of Defense (DOD)	716
Department of Veterans Affairs (VA)	430
Total	**1,146**

Source: GAO analysis of U.S. Patent and Trademark Office data. | GAO-24-107061

Note: Our analysis covers patents assigned to DOD, VA, and their components. To identify DOD biomedical patents, we restricted our analysis to patents with the following World Intellectual Property Organization field classifications: analysis of biological materials; biotechnology; macromolecular chemistry, polymers; medical technology; organic fine chemistry; pharmaceuticals. We treated all patents assigned to VA as biomedical.

[37]Our analysis covers patents assigned to DOD, VA, and their components. To identify DOD biomedical patents, we restricted our analysis to patents with the following World Intellectual Property Organization field classifications: analysis of biological materials; biotechnology; macromolecular chemistry, polymers; medical technology; organic fine chemistry; pharmaceuticals. We treated all patents assigned to VA as biomedical. For more details about our methodology, see app. I.

Patents developed by DOD employees can be owned or co-owned by DOD, including the military departments or other components. Of the 716 DOD-owned biomedical patents, 368 (51 percent) are owned or co-owned by the Navy, 220 (31 percent) by the Army, and 127 (18 percent) by the Air Force.[38]

VA-owned patents can arise from research conducted by VA employees, including those with dual appointments at VA and an affiliated university. When VA-funded research conducted by a dually appointed scientist leads to a patentable invention, VA and the affiliated university consider it a joint invention and determine which of them would assume the responsibility for prosecuting and licensing a jointly owned patent. VA or the university may also elect not to assert ownership.[39] General terms for reporting joint inventions and determining which entity would take on primary responsibility for managing patenting and licensing activities are stated in invention management agreements between VA ORD's Technology Transfer Program and an affiliated university.[40]

DOD Support Is Not Disclosed Consistently in Patents

We found that awardees do not always disclose a correct DOD award number in patents arising from DOD-funded research. DOD does not provide department-wide employee training on awardee disclosure of agency support in patents.

[38]Because a patent can be owned by (assigned to) multiple entities, these numbers are not mutually exclusive.

[39]There are occasions when VA asserts ownership after a patent was granted to an inventor or an affiliated university through the determination of rights process. According to VA Technology Transfer Program officials, VA is asserting ownership rights for 45 patents and the right to retain a government use license for 3 patents currently not assigned to VA. In addition, among patents with application dates in fiscal years 2014 through 2023, there are 32 patents that were not disclosed to VA. These patents are assigned to other entities but include a government interest statement disclosing VA support. VA officials told us they are in the process of determining why these patents were not disclosed to VA and whether VA would be interested in asserting government rights for them.

[40]Generally, an invention management agreement (IMA) also describes how VA should be named as the owner or co-owner on patent applications and requires affiliated universities to submit annual reports with information about joint inventions and commercialization activities. As of April 2024, VA had signed IMAs with 72 universities. According to VA officials, in cases of joint inventions developed by a scientist with a dual appointment at a university with which VA does not have an IMA, VA and the university would negotiate their respective roles regarding the inventions on a case-by-case basis.

Awardees Do Not Always Disclose a Correct DOD Award Number

In our analysis of USPTO data for patents with application dates in fiscal years 2014 through 2023, we identified 3,078 biomedical patents that disclosed support from DOD or its components.[41] 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."[42] In addition, two DOD-wide regulations require that patents arising from research funded by DOD contracts and grants include a disclosure of DOD support under the Bayh-Dole Act but do not specify how awardees should disclose DOD support.[43]

We found that in the 3,078 patents awardees identified at least 29 different DOD entities, as illustrated in figure 1.[44]

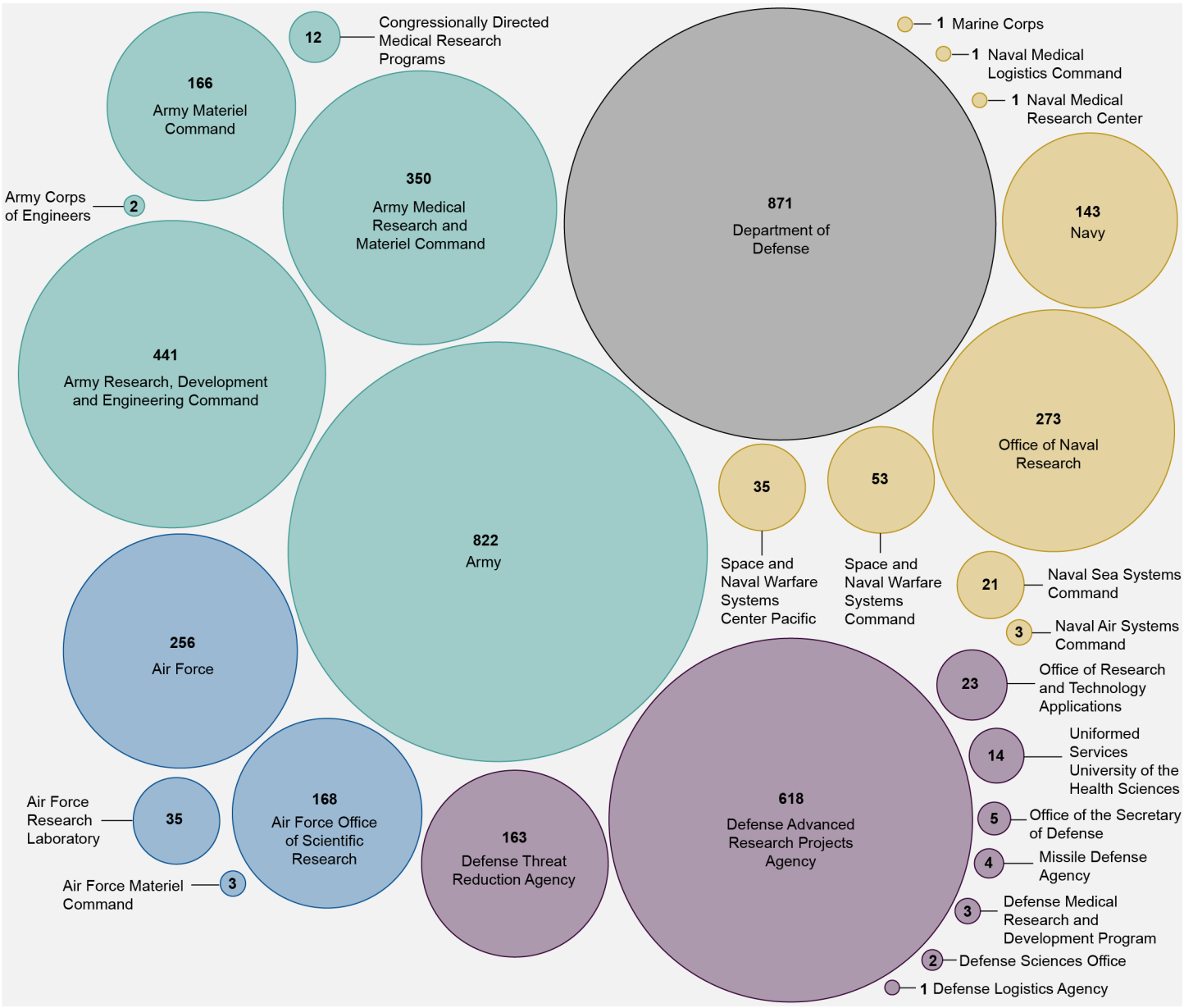
[41]To identify them, we analyzed PatentsView data for the patents with government interest statements disclosing DOD support and World Intellectual Property Organization biomedical field classifications. For more details about our methodology, see app. I.

[42]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.

[43]The Defense Federal Regulation Supplement (DFARS)—overseen by the Office of the Under Secretary of Defense for Acquisition and Sustainment—states requirements for DOD contracts, and the DOD Grant and Agreement Regulations (DODGARS)—overseen by the Office of the Under Secretary of Defense for Research and Engineering—state requirements for DOD grants and cooperative agreements. See DFARS 252.227-7038 (Patent Rights Ownership by the Contractor (Large Business)) and 32 C.F.R. § 34.25 (DODGARs).

[44]We searched through all unique values of the government interest statement, government organization names, and agency hierarchy variables for DOD or a DOD component in the PatentsView data. For more details about our methodology and a description of how we generated a list of possible variations for DOD and its components, see app. I.

Figure 1: Department of Defense (DOD) Entities Identified in Biomedical Patents Disclosing DOD Support with Application Dates in Fiscal Years 2014–2023

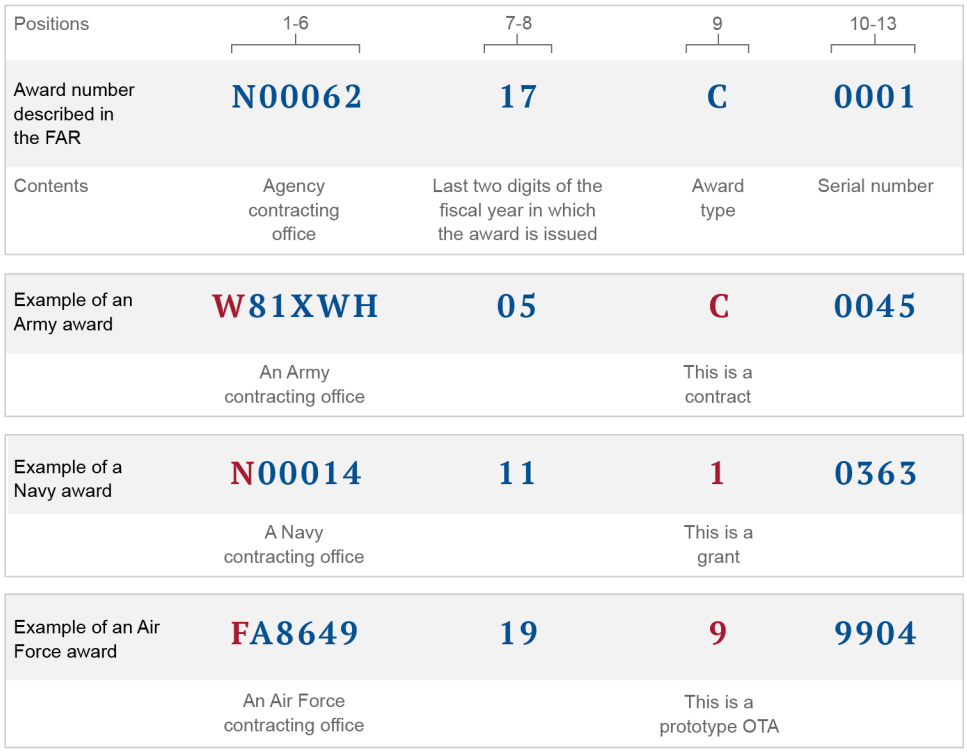


Source: GAO analysis of U.S. Patent and Trademark Office data. | GAO-24-107061

Because a single patent can disclose support from multiple DOD agencies, offices, or programs, the numbers presented in this figure are not mutually exclusive.

A correct DOD award number follows the format specified in the FAR and contains several elements identifying the DOD contracting office issuing the award, fiscal year of its execution, award type, and serial number (fig. 2).[45]

Figure 2: Elements of the Department of Defense (DOD) Award Number



Source: GAO presentation of information from the Federal Acquisition Regulation (FAR) 4.16, DOD guidance, and analysis of U.S. Patent and Trademark Office data. | GAO-24-107061

Other transaction agreements (OTAs) allow federal agencies to enter into agreements other than standard government contracts. Such agreements are generally not subject to federal laws and regulations applicable to federal contracts, including the Bayh-Dole Act of 1980. 10 U.S.C. §§ 4021-22.

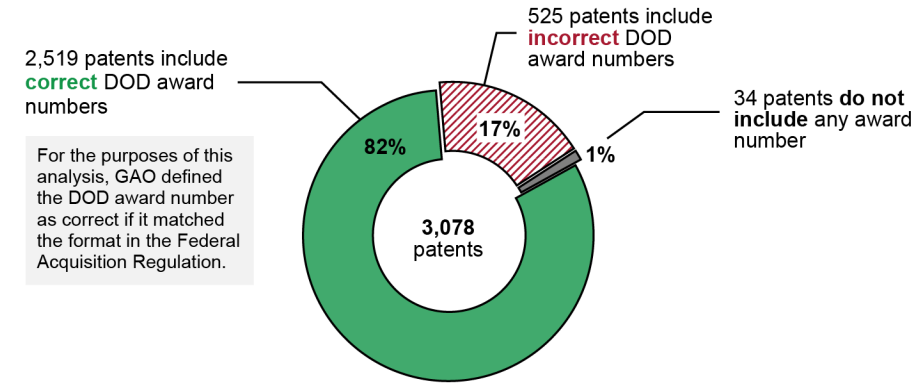
Among the 3,078 biomedical patents with application dates in fiscal years 2014 through 2023 that disclosed support from DOD by identifying DOD or its component, 2,519 (about 82 percent) included correct DOD award numbers. Based on our analysis of the correct award numbers disclosed in the 2,519 patents:

[45]FAR 4.16 (Uniform Procurement Instrument Identifiers) describes elements of the federal award number.

- **Military department.** More patents (1,441 patents, or 57 percent) disclosed awards issued by an Army contracting office than a Navy contracting office (454 patents, or 18 percent) or an Air Force contracting office (297 patents, or 12 percent).
- **Award type.** More patents disclosed grants (1,307 patents, or 52 percent) than cooperative agreements (432 patents, 17 percent), contracts (657 patents, 26 percent), and other transaction agreements for research (33 patents, 1 percent) and for prototype (30 patents, 1 percent).[46]

The remaining 559 patents (18 percent) did not disclose correct DOD award numbers (see fig. 3). These include 525 patents that disclosed incorrect DOD award numbers and 34 that did not disclose any award numbers.

Figure 3: Biomedical Patents Disclosing Support from the Department of Defense (DOD) with Application Dates in Fiscal Year 2014–2023



Source: GAO analysis of U.S. Patent and Trademark Office data. | GAO-24-107061

[46]Because other transaction agreements (OTAs) are not subject to the Bayh-Dole Act, they may not be disclosed in patents. DOD has at least two OTAs funding the development of prototype biomedical technologies whose base terms and conditions include the disclosure of federal support in patents arising from the funded R&D. The OTAs are multi-year agreements. One is with the Medical Technology Enterprise Consortium, and the other with the Medical CBRN Defense Consortium. However, officials told us that when consortium members receive sub-awards under each OTA, some of the base OTA terms and conditions (including the disclosure of federal support in patents) may be negotiated away. In our analysis of patents with application dates in fiscal years 2014 through 2023, we found two patents that disclosed support from the Defense Threat Reduction Agency and included award number W15QKN-16-9-1002. This award number is for the OTA with the Medical CBRN Defense Consortium. We examined the use of OTAs in DOD's COVID-19 pandemic response in GAO-22-105357.

To identify these patents, we analyzed U.S. Patent and Trademark Office data for the patents with government interest statements disclosing DOD support and World Intellectual Property Organization (WIPO) biomedical field classifications. We restricted our analysis to patents with the following WIPO field classifications: analysis of biological materials; biotechnology; macromolecular chemistry, polymers; medical technology; organic fine chemistry; pharmaceuticals.

We provided DOD officials with examples from the 559 patents that did not disclose correct DOD award numbers (see table 5 for a subset of those examples). DOD officials acknowledged that these examples deviated from the requirements and should be addressed in training for DOD personnel who review awardee disclosures going forward.

Table 5: Examples of Government Interest Statements Not Disclosing a Correct Department of Defense (DOD) Award Number in Patents with Application Dates in Fiscal Years 2014–2023

Type of incorrect disclosure	Government interest statement example
Award number does not conform to the format specified in the Federal Acquisition Regulation	This invention was made with government support under UES S-977-02A-001 UIUC subaward awarded by the U.S. Air Force. The government has certain rights in the invention.
	This invention was made with government support under contract number 123723-5043735 awarded by the Defense Advanced Research Projects Agency (DARPA). The government has certain rights in the invention.
	This invention was made with government support under Contract Agreement No. DAMD17-W81XWH-04-2-0022 awarded by the U.S. Army Medical Research and Material Command. The Government has certain rights in this invention.[a]
Award number is not disclosed	This invention was made with government support awarded by the Department of Defense and the National Institutes of Health. The government has certain rights in the invention.
	This invention was made with government support under USU Dean's Research and Education Endowment awarded by the Uniformed Services University. The government has certain rights in this invention.

Source: GAO analysis of the Federal Acquisition Regulation 4.16 and U.S. Patent and Trademark Office data. | GAO-24-107061

Notes: USU = Uniformed Services University of the Health Sciences.

[a]Some patents included award numbers that contained obsolete contracting office identifiers. The disclosed award number reflects an obsolete award identification format, which has not been used, according to DOD officials, since 2003.

Seven patents disclosing DOD support are associated with four FDA-approved drugs.[47] Four patents disclosed support from the Army and included correct award numbers identifying them as Army awards. Two patents disclosed support from DOD and the Army, respectively, and

[47]The four FDA-approved drugs are palovarotene, dihydroergotamine mesylate, vamorolone, and ulipristal acetate.

included incorrect award numbers. One patent disclosed support from the Army and did not include an award number.

We also found evidence of underreporting of DOD support in patents, which we define as not naming DOD or its component as funding agency in the government interest statement. Sixty-five biomedical patents disclosed a DOD award number but did not name DOD. For example, 38 patents disclosed support from the U.S. government, and 2 disclosed support from the Small Business Innovation Research program. We determined that these patents likely arose from DOD-funded biomedical research based on two factors: the patents disclosed a DOD award number and had a biomedical patent classification.

DOD Does Not Provide Department-Wide Employee Training on Awardee Disclosure of Agency Support in Patents

DOD does not provide department-wide training that explicitly addresses the disclosure of DOD support in patents arising from DOD-funded research to the agency's personnel who review awardee disclosures. According to DOD, agency personnel, including contracting officials and attorneys, review awardee disclosures during and at the end of the award period. An awardee is required to report a subject invention arising from the research funded by the award and notify DOD of plans to submit a patent application for the invention.[48]

Existing DOD-wide training for cognizant employees does not cover the Bayh-Dole Act's requirement regarding the disclosure of federal support in patents or how these disclosures should be reviewed for completeness and accuracy. According to DOD officials, the Technology Transfer and Commercial Partnerships program in the Office of the Under Secretary of Defense for Research and Engineering offers annual employee training on intellectual property, invention disclosures, and patenting, but the training does not cover the Bayh-Dole Act's requirement regarding the disclosure of federal support in patents. The military departments developed their own training for cognizant personnel; however, as of June 2024 only the training provided by the U.S. Army Medical Research and Development Command (USAMRDC) explicitly covered Bayh-Dole Act disclosure requirements.[49]

[48]DFARS 252.227-7038 and 32 C.F.R. § 34.25 (DODGARs). Under the Bayh-Dole Act, the term "subject invention" means any invention of a contractor conceived or first actually used in the performance of work under a funding agreement with the federal government. Awardees report subject inventions to DOD using DOD-wide form DD-882.

[49]In addition, in recent years USAMRDC developed a user guide to Bayh-Dole requirements for awardees.

The Bayh-Dole Act requires that awardees disclose federal support when patenting inventions developed with federal funding. Such disclosures inform interested parties of the federal government's involvement and that the government has certain rights in those inventions. Federal agencies have discretion in how they can ensure that awardees disclose agency support accurately. According to DOD officials, improvements in training for DOD personnel responsible for reviewing awardee disclosures of DOD support in patents arising from DOD-funded research can improve compliance with the Bayh-Dole Act. Federal standards for internal control call for management to communicate quality information to achieve the entity's objective—in this case, improving training to convey information to cognizant employees to ensure that awardees correctly disclose DOD support in patents.[50]

Enhancing existing training so that awardees fully and correctly disclose DOD support in patents increases the potential for better quality information, which would align with the Bayh-Dole Act requirement. Further, developing such training in the near future would be timely as DOD prepares to standardize how it tracks and reviews subject inventions and patents arising from research funded by DOD awards.[51] When awardees do not disclose DOD support fully or accurately, the public and interested parties cannot link patents to DOD funding and determine the extent of the agency's involvement in developing the patented technologies, including drugs.

[50]GAO-14-704G.

[51]An executive order directs the Secretary of Commerce to develop an action plan to consolidate the reporting by nine departments and agencies, including DOD, of inventions and patents in the federal database iEdison by 2025. Exec. Order No. 14104, *Federal Research and Development in Support of Domestic Manufacturing and United States Jobs*, 88 Fed. Reg. 51,203 (Aug. 2, 2023). The order's goal is to make the reporting of inventions under the Bayh-Dole Act easier and to provide more consistent data, among other things. The iEdison database is a web-based nonpublic database designed around the Bayh-Dole Act reporting requirements and used by several federal agencies. Not all DOD components used iEdison as of June 2024. Among components that fund biomedical R&D, USAMRDC and the Defense Advanced Research Projects Agency use iEdison.

Results of DOD- and VA ORD-Funded Clinical Trials Are Often Not Reported On Time

Although the majority of trials funded by DOD and VA ORD over the past decade were registered on ClinicalTrials.gov in a timely manner, DOD and VA did not ensure timely reporting of results for most of those trials. We found that among interventional trials registered in fiscal years 2014 through 2023 results were submitted late or not at all for 86 percent of DOD-funded trials and for 59 percent of VA ORD-funded trials. In addition, DOD was not reported as a funder for more than 150 trials. DOD does not provide clear guidance to responsible parties regarding the reporting of clinical trial information on ClinicalTrials.gov. VA ORD officials stated they saw a benefit to taking steps to improve result reporting.

DOD Is Not Reported as Funder of Some Trials and Results of Many Trials Are Not Reported in a Timely Manner

We identified 966 DOD-funded interventional clinical trials registered on ClinicalTrials.gov in fiscal years 2014 through 2023. At least one DOD component—the Office of Regulated Activities at USAMRDC—requires information for all DOD-funded trials under its purview to be reported on ClinicalTrials.gov in accordance with the timelines for applicable clinical trials specified in the federal regulations.[52] Other DOD entities require responsible parties to meet these timelines for their funded applicable clinical trials, but not for other trials. To obtain a consistent measure, we analyzed the timeliness of registration and result reporting of all DOD-funded trials based on the timelines specified in the federal regulations, irrespective of whether the trials met the definition of an applicable clinical trial. We found several gaps in information reported for DOD-funded trials (see fig. 4):

- **DOD is not reported as a funder of some trials.** By comparing data from ClinicalTrials.gov and data provided by several DOD components, we found that parties responsible for 808 trials (84 percent) reported DOD or its component as a funder.[53] We also found

[52]The Office of Regulated Activities supports USAMRDC's mission of developing FDA-regulated medical products for military personnel. Its responsibilities include oversight of clinical trials sponsored by the Surgeon General of the Department of the Army.

[53]Based on our analysis of ClinicalTrials.gov data, among the 808 trials, parties reported DOD as a funder as follows: DOD (without specifying a component) for 351 trials, the Army for 239 trials, the Navy for 94 trials, the Uniformed Services University of the Health Sciences for 59 trials, the Air Force for 32 trials, more than one DOD component for 20 trials, and the Defense Advanced Research Projects Agency for 13 trials. In our analysis, the Army includes USAMRDC, the Walter Reed Army Institute of Research, the CDMRP, and the Office of Regulated Activities.

that parties responsible for 158 trials (16 percent) did not do so on ClinicalTrials.gov.[54] This means that the parties submitting information to ClinicalTrials.gov for those trials did not identify DOD (or a component name) as a sponsor or collaborator and did not enter the DOD award number in an "other study IDs" data field (see sidebar).

- **Some trials were registered late.** Parties responsible for 772 (80 percent) of the 966 DOD-funded trials submitted registration information to ClinicalTrials.gov within 21 days of enrolling the first participant, and parties responsible for 194 trials (20 percent) submitted registration information late.[55]
- **Results were reported late for most trials.** Of the 966 trials, 488 were due for result reporting. Responsible parties submitted results within 1 year of the primary completion date for 70 (14 percent) of the 488 trials, late for 128 trials (26 percent), and did not submit them for 290 trials (59 percent). This means that results were not submitted in a timely manner for 418 trials (86 percent).[56]

ClinicalTrials.gov Data Fields That Can Identify a Trial Funder

There are ClinicalTrials.gov data fields that responsible parties can use to report the funder(s) of a trial.

Sponsor. The organization or person who initiates the study and who has authority and control over the study.

Collaborator. An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

Other Study IDs. Identifiers or ID numbers (other than the unique trial identifier assigned by ClinicalTrials.gov at registration) that are assigned to a clinical study by the study's sponsor, funders, or others. These numbers may include unique identifiers from other trial registries and federal agency award numbers.

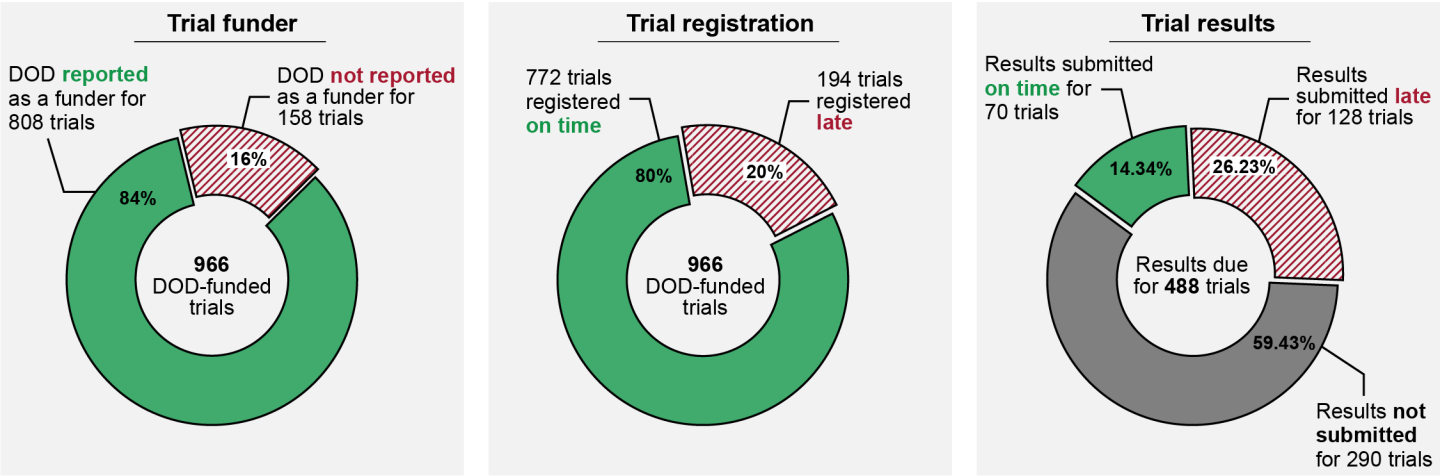
Source: GAO presentation of information from ClinicalTrials.gov. | GAO-24-107061

[54]To conduct our analysis, we downloaded data from ClinicalTrials.gov and obtained data from DOD components involved in biomedical R&D. Comparing the two sets of data allowed us to identify DOD-funded trials registered on ClinicalTrials.gov for which DOD was not reported as a funder. Of the 158 trials for which DOD was not reported as a funder, 154 were funded by the CDMRP, 5 by the Chemical and Biological Defense Program, 3 by the Uniformed Services University of the Health Sciences, and 1 by the Air Force. For more details about our methodology, see app. I.

[55]Based on our analysis of ClinicalTrials.gov and DOD data, among the 194 trials, 71 were funded by DOD, 61 by the Army, and the remaining 62 by other DOD components.

[56]Based on our analysis of ClinicalTrials.gov and DOD data, among the 418 trials, 153 were funded by the Army, 151 by the DOD, and the remaining 114 by other DOD components.

Figure 4: Interventional Clinical Trials Funded by the Department of Defense (DOD) Registered on ClinicalTrials.gov in Fiscal Years 2014–2023



Source: GAO analysis of ClinicalTrials.gov and DOD data. | GAO-24-107061

Factors that explain these gaps include variation among DOD components in guidance, requirements, and practices for reporting trial information:

- **Variation in guidance among DOD components.** DOD-wide guidance does not explicitly address the reporting of information to ClinicalTrials.gov.[57] According to DOD officials, the majority of DOD-supported clinical trials are funded by the Defense Health Program.[58] The Office of the Assistant Secretary of Defense for Health Affairs, which oversees the program, has not issued clear guidance specifically addressing how responsible parties should report DOD as a funder and the registration and result reporting timelines. After reviewing the results of our analysis, DOD officials acknowledged that although federal regulations do not require responsible parties to report the funder(s) of a clinical trial, including that information in the trial's public records would be beneficial to accurately reflect the

[57]DOD Instruction 6200.02 states that components should follow relevant FDA regulations when conducting investigational clinical research subject to FDA regulations.

[58]Based on our analysis of the data provided by DOD, 385 of the 966 trials were funded by the CDMRP, which is part of the Defense Health Program (DHP). The DHP provides funds to other DOD components involved in biomedical R&D, and those components can award that funding to external entities to conduct clinical trials. It is likely that other trials in our analysis, in addition to the 385 trials mentioned above, were funded by the DHP. The share of the DHP-funded trials is likely to increase when the transfer of DOD's biomedical R&D to the Defense Health Agency from other components is completed.

agency's role in supporting clinical trials.[59] In the absence of such guidance, some DOD components provide their own guidance regarding the reporting of information to ClinicalTrials.gov, and some provide no guidance:

- The terms and conditions of CDMRP awards require responsible parties to enter the award number in the "other study IDs" data field, but do not require them to report DOD or the CDMRP in the sponsor or collaborator data fields.
- Officials from the Chemical and Biological Defense Program and Defense Advanced Research Projects Agency told us that they do not provide direction to awardees regarding the reporting of trial information to ClinicalTrials.gov. In response to our questions, Chemical and Biological Defense Program officials told us that the party responsible for one of five trials for which DOD was not reported as a funder updated the record on ClinicalTrials.gov in March 2024 to reflect that DOD funded the trial by adding the "United States Department of Defense" to the collaborator data field. The records for the other four trials funded by the program had not been updated as of July 2024.

- **Varying requirements and practices for reporting trial information.** One DOD component requires the reporting of information for all relevant trials on ClinicalTrials.gov, while other components do not:
  - The Office of Regulated Activities requires the reporting of information on ClinicalTrials.gov for all trials under its purview, irrespective of whether they meet the definition of an applicable clinical trial. Officials told us that the office introduced this requirement more than 15 years ago to increase the transparency of information about the trials it oversees. In addition, according to officials, since that time the staff has taken over the responsibility of submitting the information to ClinicalTrials.gov from responsible parties to ensure better information quality.

[59]Our analysis of ClinicalTrials.gov data may not have captured all DOD-funded trials due to a wide variation in how responsible parties named DOD or its components when submitting this information to ClinicalTrials.gov. We found more than 20 names and spellings of DOD and its components, such as "US Department of Defense," "United States Department of Defense," "U.S. Army," and "US Air Force." The user submitting information to ClinicalTrials.gov enters the name of an entity as free text into unstructured data fields asking for the sponsor or collaborator of the clinical trial. We observed wide variability, and the same agency name can be entered in more than one way due to the use of abbreviations and symbols, or typographical errors.

- The CDMRP has different requirements for applicable clinical trials and other trials. Although responsible parties of all CDMRP-funded trials are required to register them on ClinicalTrials.gov, they are required to report results only for applicable clinical trials. CDMRP officials acknowledged that awardees are often confused by the distinctions between applicable and other clinical trials. Officials also acknowledged that CDMRP funding opportunity announcements, in which the CDMRP communicates its clinical trial reporting requirements to awardees, do not make clear distinctions between applicable and other clinical trials and do not clearly state the differences in reporting requirements for them. CDMRP officials told us in March 2024 they were modifying fiscal year 2025 funding opportunity announcements to clarify clinical trial definitions and reporting requirements.
- According to the principal investigators of several DOD-funded trials we contacted, DOD did not provide direction regarding the registration and result reporting requirements for ClinicalTrials.gov.

Federal standards for internal control call for management to communicate quality information to achieve the entity's objective—in this case, ensuring that information about DOD-funded clinical trials is available to the public, and that parties responsible for those trials identify DOD as a funder and report information about the trials in a timely manner.[60] By providing clear guidance requiring responsible parties of all trials funded by the Defense Health Program to register the trials on ClinicalTrials.gov, report DOD as a funder, and submit registration and result information in a timely manner, DOD can increase the transparency of information about the agency's support for clinical trials. Although federal requirements for reporting information on ClinicalTrials.gov apply to a subset of trials funded by DOD and other federal agencies, ClinicalTrials.gov is the primary public source of information about federally funded clinical trials. Without improvement in the completeness and quality of information about DOD-funded trials, users of ClinicalTrials.gov—including the public, researchers, health care providers, and patients—cannot know the full extent of DOD support for clinical research, learn of any harms or benefits resulting from a treatment tested in a trial, or share evidence for future trials.

[60]GAO-14-704G.

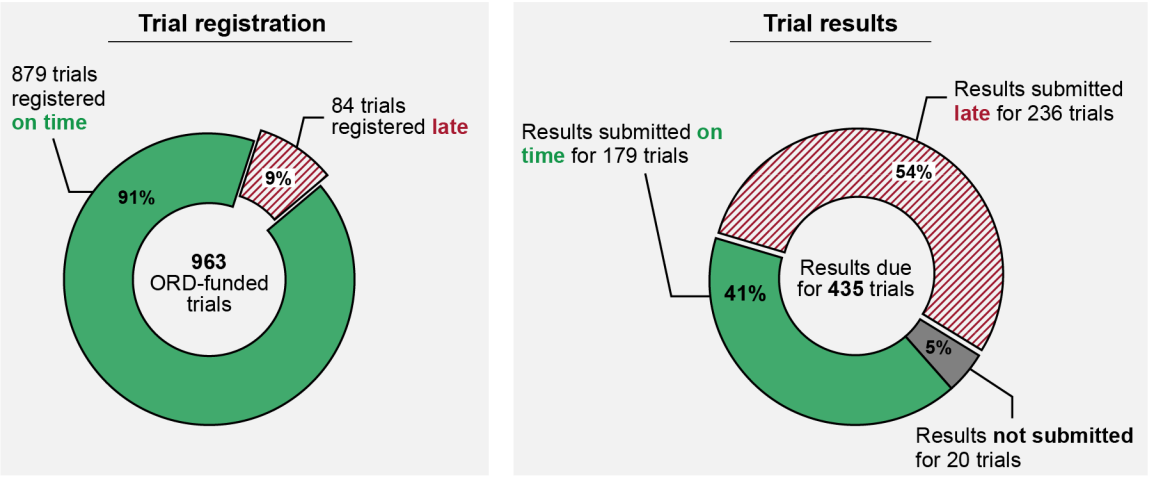
Results for Many VA ORD-Funded Clinical Trials Are Not Reported On Time

We identified 963 VA ORD-funded interventional trials registered on ClinicalTrials.gov in fiscal years 2014 through 2023, which was consistent with the information we received from ORD.[61] ORD requires all ORD-funded trials to be registered and results reported on ClinicalTrials.gov in accordance with the timelines specified in the federal requirements for applicable clinical trials. According to our analysis, parties responsible for VA-funded clinical trials generally submitted registration information, but not trial results, on time (see fig. 5):

- **Most trials were registered on time.** Parties responsible for 879 trials (91 percent) submitted registration information to ClinicalTrials.gov, as required, within 21 days of enrolling the first participant, and parties responsible for 84 trials (9 percent) submitted registration information late.
- **Results were reported late for most trials.** Of the 963 trials, 435 were due for result reporting during that period. Responsible parties submitted results, as required, within 1 year of the primary completion date for 179 (41 percent) of the 435 trials. Results were submitted late for 236 trials (54 percent) and were not submitted at all for 20 trials (5 percent). This means that results were not submitted in a timely manner for 256 trials (59 percent).

[61]In total, we identified 1,206 interventional clinical trials registered on ClinicalTrials.gov in fiscal years 2014 through 2023 that may have been funded by VA. After reviewing their internal records for clinical trials, ORD officials identified 963 of those trials as funded by ORD and 243 trials as not funded by ORD. According to ORD officials, these 243 trials may have been funded by VA entities other than ORD or from non-VA sources. For more information about our analysis, see app. I.

Figure 5: Interventional Clinical Trials Funded by the Department of Veterans Affairs (VA) Registered on ClinicalTrials.gov in Fiscal Years 2014–2023



Source: GAO analysis of ClinicalTrials.gov data. | GAO-24-107061

ORD has established a centralized process for ensuring compliance with ORD's own requirements and ClinicalTrials.gov reporting requirements. This process is managed by staff who work with principal investigators of ORD-funded clinical trials to help them comply with the ClinicalTrials.gov registration and result reporting requirements.[62]

ORD officials, who reviewed the results of our analysis, noted that even though results were submitted late for many trials, the delay did not exceed 4 months for the majority of those trials.[63] They further stated that parties responsible for at least 36 of those trials received extensions from ORD to delay the submission of results, and that this number likely represents an undercount of all trials with ORD-approved extensions.

[62]ORD's Assessment and Research Reporting Tool (ART) Program staff manage the reporting of information to ClinicalTrials.gov. According to the ORD webpage on registration and result submission requirements for ClinicalTrials.gov, ART Program staff notify principal investigators of trials by email about information needed for registering new trials on ClinicalTrials.gov. After investigators provide that information to the ART Program, program staff upload the information to ClinicalTrials.gov. As described on the webpage, clinical trial records are updated and verified at least every 12 months and investigators receive automated email reminders from the ART Program. Office of Research and Development, "ORD Sponsored Clinical Trials: Registration and Submission of Summary Results," accessed July 5, 2024, https://www.research.va.gov/resources/ORD_Admin/clinical_trials/.

[63]Based on our analysis of ORD-funded trials, 155 (66 percent) of the 236 trials that did not submit results within 1 year of the primary completion date submitted them with a delay of no more than 4 months.

According to ORD officials, a VA investigator conducting an ORD-funded trial other than an applicable clinical trial can request an extension from the ORD service that funded the trial to delay the submission of results to ClinicalTrials.gov beyond 1 year after the trial's primary completion date. If an ORD-funded trial meets the definition of an applicable clinical trial, the investigator can request an extension, with approval from ORD, from NIH to delay the result submission.[64] Whereas information about NIH-approved extensions is available on ClinicalTrials.gov, information about ORD-approved extensions is not.[65] ORD officials stated they do not track how many trials due to report results received extensions from ORD services, but they determined that at least 36 trials had received such extensions as of June 2024 by reviewing their emails.

According to ORD officials, common reasons for late result submissions may include challenges with recruiting trial participants, need for additional funding to address ClinicalTrials.gov result reporting requirements, loss of study staff, or the departure of the principal investigator. ORD officials stated they saw opportunities to emphasize the importance of timely submission of trial results by updating information available to investigators, including the ORD webpage for ClinicalTrials.gov reporting requirements, frequently asked questions, and ORD's internal information system containing clinical trial policies and requirements.[66] Although ORD sends email notifications to principal investigators 90 days before the trial result submission deadline, VA officials stated that they would consider improving the timing and clarity of the notifications.

VA states that its requirement for principal investigators of all ORD-funded clinical trials—irrespective of whether they meet the definition of an applicable clinical trial—to submit trial results to ClinicalTrials.gov within 1 year of the primary competition date represents a higher standard that VA has chosen to honor its commitment to veterans. By taking steps to address delays, ORD can improve compliance with its own

[64]Under federal regulations, NIH can grant a good cause extension to delay the result submission deadline for trials meeting the definition of an applicable clinical trial; see 42 C.F.R. 11.44(e). The responsible party requesting such an extension may delay result submission up to 2 years after the request was approved. Information about NIH-approved extensions is available on ClinicalTrials.gov.

[65]Our analysis of result reporting accounts for NIH-approved extensions.

[66]The system is called Focused Inquiry Navigational Database or FIND Pro and maintained by the ORD Enterprise Protections, Regulatory, Outreach and Systems (ePROS) division.

requirements and increase transparency of clinical trial information for veterans, the public, and policymakers. Such steps could include updating ORD information resources for clinical trial investigators, improving the timing and clarity of notifications of the trial result submission deadlines ORD sends to investigators, and systematically tracking ORD-approved extensions to be able to analyze factors causing delays and determine how to address them. Timely result reporting is important to enable patients, researchers, and physicians to learn about the outcomes of the trials. It is also consistent with VA's own stated commitment to inform veterans and the public about its research and to maximize the impact of the studies it supports.

Conclusions

DOD- and VA-funded biomedical R&D can lead to the development of drugs and medical devices, but these contributions are difficult to measure and not well understood by the public. Improving the quality of public data about DOD- and VA-funded R&D can improve our collective understanding of how these agencies contribute to broader biomedical innovation.

Correctly disclosing federal support in patents arising from federally funded research, as required by the Bayh-Dole Act of 1980, is important for transparency and accountability. By enhancing department-wide training for the DOD personnel who review the accuracy of awardees' disclosure of DOD funding in patents, DOD can improve compliance with the Bayh-Dole Act. Although our findings concern inconsistent disclosure of DOD support in biomedical patents, better employee training could also lead to improved disclosure of DOD support in other patents developed with DOD funding.

Registering a federally funded clinical trial that tests a drug, device, or another health intervention on ClinicalTrials.gov informs the public and other interested parties of the trial's existence and, when funding agencies are identified in trial records, of the federal government's involvement. Reporting complete and timely information about the trials, including their results, provides insights about the effectiveness of studied interventions and adverse health events. This information can be helpful to patients as well as researchers designing trials that involve related interventions, health conditions, or patient populations. Investigators conducting the trials have 1 year after completing data collection to report results. While the majority of DOD- and VA ORD-funded trials are registered on ClinicalTrials.gov in a timely manner, the reporting of results for many trials is delayed, which diminishes the trials' impact. By providing evidence to determine if a drug or device can be used safely

and effectively to treat a disease or medical condition, clinical trials are essential in FDA's review before the drug or device can be approved for marketing and sale. Additional steps by DOD and VA to improve the quality of information about the trials they fund would increase the transparency of federally funded R&D, its outcomes, and effectiveness for the benefit of the American public.

Recommendations for Executive Action

We are making a total of three recommendations, including two to DOD and one to VA. Specifically:

The Office of the Under Secretary of Defense for Acquisition and Sustainment, in collaboration with the Office of the Under Secretary of Defense for Research and Engineering, should enhance department-wide training for the DOD personnel who review information submitted by awardees to ensure that awardees disclose DOD support correctly in patents arising from DOD-funded research. (Recommendation 1)

The Office of the Assistant Secretary of Defense for Health Affairs should develop clear guidance requiring responsible parties of all trials funded by the Defense Health Program to report DOD as a funder when registering a trial on ClinicalTrials.gov, register the trial within 21 days of enrolling the first patient, and submit trial results within 1 year of the primary completion date to improve the quality and completeness of public information about DOD-funded clinical trials. (Recommendation 2)

The Under Secretary of Health at VA should direct ORD to take steps to better ensure that VA investigators conducting ORD-funded clinical trials submit results to ClinicalTrials.gov within 1 year of the primary completion date. Such steps could include improving procedures for notifying VA investigators of the trial result submission deadlines and collecting and analyzing data to determine how to address factors causing delays. (Recommendation 3)

Agency Comments

We provided a draft of this report to DOD and VA for review and comment. In their written comments, reproduced in appendixes II and III, respectively, DOD and VA concurred with the recommendations. DOD and VA also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretaries of Defense and Veterans Affairs, 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 IV.

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

Appendix I: Objectives, Scope, and Methodology

This report examines: (1) Departments of Defense (DOD) and Veterans Affairs (VA) funding for biomedical research and development (R&D) in fiscal years 2019 through 2023; (2) DOD and VA ownership of biomedical patents and the extent to which these agencies' support is disclosed in other biomedical patents arising from research they funded; and (3) the extent to which information about DOD- and VA-funded clinical trials is publicly reported. This report is a companion to our April 2023 report that examined National Institutes of Health (NIH) research contributions to drug development.[1] We are also publishing a patent dataset, which can be accessed on our website at https://www.gao.gov/products/gao-24-107061.

For all three objectives, we interviewed cognizant DOD and VA officials. At DOD, we interviewed officials from multiple components and offices, including the Office of the Assistant Secretary of Defense for Health Affairs, Office of the Under Secretary of Defense for Acquisition and Sustainment, Office of the Under Secretary of Defense for Research and Engineering, Defense Health Agency, U.S. Army Medical Research and Development Command, and Defense Advanced Research Projects Agency. We interviewed officials from the two offices that share responsibilities for managing the Chemical and Biological Defense Program: the Joint Science and Technology Office and the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense. We also interviewed DOD officials responsible for implementing the Bayh-Dole Act requirements, including from the Office of General Counsel, Army, Air Force, and Navy. At VA, we interviewed officials from the Office of Budget and the Office of Research and Development (ORD), including the Technology Transfer Program and Nonprofit Program Office.

We interviewed 12 researchers who were principal investigators of DOD- and VA-funded clinical trials; our selection, which was not generalizable, was informed by our analysis of the timeliness of trial result reporting on ClinicalTrials.com and geographical location of the investigators' institutions. We also interviewed representatives of two technology transfer offices from a non-generalizable sample of universities that had invention management agreements with VA, based on the universities' geographic region and the number of joint inventions with VA.

[1]GAO-23-105656.

We conducted site visits to DOD and VA facilities in January and February 2024 as follows: (1) the headquarters of the U.S. Army Medical Research and Development Command and (2) the U.S. Army Medical Research Institute of Infectious Diseases (both in Fort Detrick, MD); (3) the Walter Reed Army Institute of Research, including the Pilot Bioproduction Facility, and (4) the Naval Medical Research Command (both in Silver Spring, MD); (5) the Uniformed Services University of the Health Sciences in Bethesda, MD; and (6) the VA Medical Center in Baltimore, MD. We used agency data and interviews with DOD officials and other experts to inform our selection of DOD sites that represented a range of biomedical R&D from basic research to product development. We selected the VA medical center in Baltimore due to a range of biomedical research activities conducted there, including clinical trials.

To generate our estimate of DOD and VA biomedical R&D funding in fiscal years 2019 through 2023, we used the agencies' annual budget submissions, which are public, as our primary source of information. We used funding amounts associated with past year obligational authority in the DOD and VA budget submissions. For DOD, we used research, development, test, and evaluation (RDTE) budget submissions. Our DOD estimate includes all Defense Health Program RDTE funding. It also includes funding amounts associated with the biomedical budget activity program elements in the Defense Advanced Research Projects Agency, Army, and Navy RDTE budget submissions. In addition, we obtained obligational authority data for activities associated with the development of drugs and medical products for fiscal years 2019 through 2023 from DOD's Chemical and Biological Defense Program.[2]

For VA, we treated all of the agency's research funding as biomedical.[3] To assess the reliability of these data, we conducted interviews with knowledgeable agency officials about how the data were generated. We determined the data to be reliable for the purposes of presenting the

[2]This is because the program's budget submission for RDTE does not use the same program elements as the budget submissions for the other DOD components in scope for our review.

[3]VA's research program is authorized in statute specifically for the purpose of more effectively carrying out "the primary function of the Administration and in order to contribute to the Nation's knowledge about disease and disability." The research is to be done in connection with the provision of medical care and treatment to veterans. 38 U.S.C. § 7303.

funding amounts for biomedical R&D in fiscal years 2019 through 2023 in our report.

To examine DOD and VA patent ownership and the disclosure of DOD support in patent government interest statements, we reviewed applicable statutes, regulations, and DOD guidance, the federal internal control standards.[4] We determined that the standard stating that management should communicate quality information to achieve the entity's objective was significant to this objective.[5] We analyzed patent data with application dates in fiscal years 2014 through 2023 from the public PatentsView database maintained by the U.S. Patent and Trademark Office (USPTO).

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, applicant, assignee, 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.[6] We searched through all unique values of the government interest statement text, government organization names, agency hierarchy, and assignee variables for DOD and VA agencies, offices, programs (components).

Additionally, because DOD-funded R&D is not limited to biomedical R&D, when determining if patents named DOD as an assignee or disclosed DOD support, we restricted our analysis to patents with a biomedical WIPO field classification. These field classifications are: analysis of biological materials; biotechnology; macromolecular chemistry; polymers; medical technology; organic fine chemistry; and pharmaceuticals. We considered all patents assigned to VA as biomedical. We did not review certificates of correction for possible corrections to assignments or government interest statements after the patents were granted.

[4]Patents typically do not disclose VA support as VA only funds research conducted by federal employees.

[5]GAO-14-704G.

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

For the purposes of our analysis of patent ownership, we determined that DOD or VA owned a patent if the assignee variable named DOD, VA, or a component of either, respectively.[7] Using this methodology, we identified 1,146 patents with application dates in fiscal years 2014 through 2023 owned by DOD or VA. The patents comprised 716 owned by DOD and 430 owned by VA.

For the purposes of our analysis of the disclosure of DOD support, a patent disclosed support from DOD if PatentsView's government organization variables or the text of the patent's government interest statement included DOD or its component. Using this methodology, we identified 3,078 biomedical patents with application dates in fiscal years 2014 through 2023 that were owned by entities other than DOD and disclosed DOD support by naming DOD or its component. We found that in the 3,078 patents patent applicants identified at least 29 different DOD entities, as illustrated in figure 1. The patents comprised 2,519 patents with a correct DOD award number, 525 with an incorrect award number, and 34 without an award number. For the purposes of our analysis, a correct DOD award number was consistent with the award number format described in the Federal Acquisition Regulation (FAR) and contained a DOD component code in the first six characters of the award number.[8] Further, we used DOD guidance to identify DOD components that issued the awards and award types in our analysis of the 2,519 biomedical patents that named DOD or its components and disclosed correct DOD award numbers.[9]

In addition to the 3,078 patents, we found 65 patents that disclosed a DOD award number but did not name DOD or a DOD component in the government interest statements. Instead, the PatentsView's government organization variables for some of these patents included the U.S. government or the Small Business Innovation Research program. We determined that these patents likely arose from DOD-funded biomedical

[7]We performed manual checks on the data to ensure identified assignees were DOD, VA, or a component of either.

[8]Our analysis included DOD awards with several obsolete component codes, such as DAAD, DAMD, and DAM. According to officials, DOD has not used them since 2003.

[9]We identified the DOD component that issued the award using Defense Logistics Manual 4000.25, Vol. 6 (Oct. 4, 2023). Using FAR 4.16 and Defense Contract Management Agency Manual 2501-08 § 3.1, we identified whether an award was a grant, cooperative agreement, contract, other transaction agreement for research or for prototype.

research based on two factors: the patents disclosed a DOD award number and had a biomedical patent classification.

We identified 94 patents with application dates in fiscal years 2014 through 2023 that disclosed VA support. According to VA Technology Transfer Program officials, VA is asserting ownership rights to 45 of those patents and the right to retain a government use license for 3 other patents currently not assigned to VA. Another 32 patents were not disclosed to VA, according to VA officials. These patents are assigned to other entities but include a government interest statement disclosing VA support. VA officials told us that they are in the process of determining why these patents were not disclosed to VA and whether VA would be interested in asserting government rights for them. According to VA officials, VA has elected to not establish ownership or a government use license through the agency's determination of rights process for the remaining 14 patents.

To assess the reliability of PatentsView data, we reviewed our prior reliability determination and the data used for this report for potential errors.[10] Based on our review, we determined that these data were sufficiently reliable for the purposes of reporting (1) DOD and VA ownership of biomedical patents, and (2) the extent to which patent applicants did not fully or correctly disclose DOD support in government interest statements of biomedical patents owned by other entities.

To determine whether the patents assigned to DOD or VA and the patents disclosing DOD 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 product and patent files as of March 2024.[11] We reviewed our prior reliability determination and current Orange Book documentation, and validated the results by manually searching the Orange Book.[12] Based on this review, we determined that these data were sufficiently reliable for the purposes

[10]See GAO-23-105656.

[11]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, 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. See 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).

[12]See GAO-21-52 and GAO-23-105656.

of reporting the number of FDA-approved drugs associated with the patents in our analysis.

To examine the extent to which information about DOD- and VA-funded clinical trials is reported in the public registry ClinicalTrials.gov and the timeliness of those trials' registration and result submission, we reviewed applicable federal regulations, DOD and VA guidance on registration and result reporting requirements, 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.[13] According to the federal regulations, parties responsible for an applicable clinical trial must generally submit the trial registration information within 21 days of enrolling the first participant and report the trial results within 1 year of the primary completion date.

Our analysis of ClinicalTrials.gov data covered all DOD- and VA-funded interventional trials we could identify on ClinicalTrials.gov, without differentiating between applicable clinical trials and other interventional trials. This is because (1) at least one DOD component requires all trials under its purview—and not just applicable clinical trials—to report trial information, including results, on ClinicalTrials.gov within the timelines specified in the federal requirements for applicable clinical trials, and (2) at VA, ORD requires all ORD-funded trials to be registered and results reported on ClinicalTrials.gov within those timelines.

We obtained and analyzed data for all interventional clinical trials registered on ClinicalTrials.gov in fiscal years 2014 through 2023 that were funded by DOD and VA:[14]

- To identify DOD-funded clinical trials, we searched for DOD or its components in the sponsor/lead and sponsor/collaborator data fields and observed wide variability, as the same agency name can be entered in more than one way due to the use of abbreviations and symbols, or typographical errors.[15] We also analyzed information in the "other study IDs" data field to determine if responsible parties

[13]GAO-14-704G.

[14]We downloaded the data from ClinicalTrials.gov using Application Programming Interface (API) version 2.0.

[15]We identified more than 20 different names and spellings of DOD and its components.

reported a DOD award number in that field.[16] In addition, we obtained clinical trial data from the Army (including the Congressionally Directed Medical Research Programs housed at the U.S. Army Medical Research and Development Command, and the Office of Regulated Activities, which oversees trials sponsored by the Army's Surgeon General), Air Force, Chemical and Biological Defense Program, and Uniformed Services University of the Health Sciences.[17] By comparing the ClinicalTrials.gov data with the DOD data, we identified 966 DOD-funded interventional clinical trials registered in fiscal years 2014 through 2023, and found that responsible parties for 158 of those trials did not report DOD as a funder. This means that they did not enter DOD or its component in the sponsor/lead and sponsor/collaborator fields and did not enter a DOD award number in the "other study IDs" data field.

- To identify VA-funded clinical trials, we searched for "US Department of Veterans Affairs" and "VA Office of Research and Development" in the sponsor/lead and sponsor/collaborator data fields. We identified 1,206 interventional clinical trials that reported VA in one or both of those data fields. ORD officials reviewed the list of the trials we generated and divided them into two subsets: (1) 963 trials funded and overseen by ORD, and (2) 243 trials supported by funds or resources from other VA entities outside of ORD. According to ORD officials, these trials were not funded or overseen by ORD. We excluded these 243 trials from our analysis.[18]

[16]This is because responsible parties for some trials may not enter DOD or its component in the sponsor/lead and sponsor/collaborator data fields but may enter a DOD award number in the "other study IDs" data field. For example, Congressionally Directed Medical Research Programs (CDMRP) officials told us that they require responsible parties to enter a CDMRP award number in that data field when registering a trial on ClinicalTrials.gov.

[17]The Defense Advanced Projects Research Agency and the Navy did not provide clinical trial data.

[18]A VA researcher with a dual appointment at VA and an affiliated university can conduct a clinical trial at a VA medical center using non-ORD funds. Those funds could be from a VA office or program outside of ORD or from an external entity, such as the National Institutes of Health or a pharmaceutical company. According to ORD officials, ORD's requirement to register all clinical trials and report their results on ClinicalTrials.gov applies only to ORD-funded trials, and VA does not currently have a VA-wide policy that would apply to other trials using VA funding outside of ORD or other VA resources. ORD officials also noted that if a trial was funded by an entity other than VA, parties responsible for that trial would likely have to comply with the funder's requirements for reporting trial information on ClinicalTrials.gov.

To analyze the timeliness of trial registration, we calculated the number of days between the date when the first participant was enrolled and the date when registration information was first submitted to ClinicalTrials.gov.

To analyze the timeliness of result reporting, we identified the number of trials with registration dates in fiscal years 2014 through 2023 that were due to submit results within 1 year of the primary completion date.[19] We identified 488 DOD- funded clinical trials and 435 ORD-funded clinical trials due to submit results. For these trials, we calculated the number of days between the primary completion date and the date when trial results were first submitted to ClinicalTrials.gov. We excluded from our analysis trials that were withdrawn and trials that received NIH approval to delay the submission of results.

To assess the reliability of ClinicalTrials.gov data, we reviewed documentation from ClinicalTrials.gov, interviewed knowledgeable DOD, VA, and 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 and result reporting of DOD- and ORD-funded clinical trials.

We conducted this performance audit from September 2023 to September 2024 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.

[19]Many trials initiated in recent years have not yet reached their primary completion date or are within 1 year of the primary completion date.

Appendix II: Comments from the Department of Defense

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

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

Dear Ms. Wright,

This is the Department of Defense's (DoD) response to the GAO Draft Report, GAO-24-107061, "BIOMEDICAL RESEARCH: Improvements to the Quality of Information about DOD and VA Contributions to Drug Development Needed," dated July 26, 2024 (GAO Code 107061). Attached is DoD's response to the subject report. My point of contact is Dr. Terry Rauch, who can be reached at terry.m.rauch.civ@mail.mil and phone 703-681-8390.

Sincerely,

MULLEN.SEILEEN.MARIE.1519853007 Digitally signed by MULLEN.SEILEEN.MARIE.1519853007 Date: 2024.08.19 12:42:20 -04'00'

Lester Martínez-López, M.D., M.P.H.

Attachments:
As stated.

GAO DRAFT REPORT DATED JULY 26, 2024
GAO-24-107061 (GAO CODE 107061)

"BIOMEDICAL RESEARCH: Improvements to the Quality of Information about DOD and VA Contributions to Drug Development Needed"

DEPARTMENT OF DEFENSE COMMENTS TO THE GAO RECOMMENDATIONS

RECOMMENDATION 1: The GAO recommends that the Office of the Under Secretary of Defense for Acquisition and Sustainment, in collaboration with the Office of the Under Secretary of Defense for Research and Engineering, should enhance department-wide training for the DOD personnel who review information submitted by awardees to ensure awardees disclose DOD support correctly in patents arising from DOD-funded research.

DoD RESPONSE: Concur.

RECOMMENDATION 2: The GAO recommends that the Office of the Assistant Secretary of Defense for Health Affairs should develop clear guidance requiring responsible parties of all trials funded by the Defense Health Program to report DOD as a funder when registering a trial on ClinicalTrials.gov, register the trial with 21 days of enrolling the first patient, and submit trial results within 1 year of the primary completion date to improve the quality and completeness of public information about DOD-funded clinical trials.

DoD RESPONSE: Concur.

Appendix III: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON

September 11, 2024

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

Dear Ms. Wright:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office (GAO) draft report: Biomedical Research: Improvements to the Quality of Information about DOD and VA Contributions to Drug Development Needed (GAO-24-107061).

The enclosure contains technical comments and the action plan to address the draft report recommendation. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Margaret B. Kabat

Margaret B. Kabat, LCSW-C, CCM
Chief of Staff

Enclosure

Enclosure

Department of Veteran Affairs (VA) Comments to
the Government Accountability Office (GAO) Draft Report
Biomedical Research: Improvements to the Quality of Information about DOD and VA Contributions to Drug Development Needed
(GAO-24-107061)

Recommendation 3: The Under Secretary of Health at VA should direct ORD to take steps to better ensure that VA investigators conducting ORD-funded clinical trials submit results to ClinicalTrials.gov within 1 year of the primary completion date. Such steps could include improving procedures for notifying VA investigators of the trial result submission deadlines and collecting and analyzing data to determine how to address factors causing delays.

VA Response: Concur. VA appreciates GAO's recognition that VA sets a high standard for transparency by requiring all its funded clinical trials to be registered; and report results on ClinicalTrials.gov, which goes beyond the legal requirements for reporting on only a subset of "Applicable Clinical Trials." VA views this high standard as a positive commentary on its commitment to get information to the public about all clinical trials funded by the Office of Research and Development (ORD). VA established requirements to register its clinical trials in 2005 and further promoted this high standard to include results reporting over 10 years ago in 2013, applied the requirements retroactively to trials that started in 2007 to coincide with the Food and Drug Administration Amendments Act (FDAAA) 801 timeframes, and continues these requirements today.

To address GAO's recommendation, ORD will continue its robust practices for tracking and monitoring extension requests and working with all Principal Investigators on navigating ClinicalTrials.gov reporting requirements, data entry, and quality assurance. ORD will focus on the subset of non-applicable clinical trials that are not subject to legal results reporting requirements but are expected to adhere to VA's ethically based reporting requirements. ORD is committed to continual improvement and informing Veterans and the public about its research and the outcomes of its trials and will expend additional resources to collect and analyze data to determine what factors are contributing to delays in result reporting for non-applicable clinical trials. ORD will develop and implement strategies to better ensure timely results reporting to ClinicalTrials.gov specifically for trials that are not compelled to report results under FDAAA 801.

Target Completion Date: August 2025

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgements

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), Emily Quick-Cole, Ana Barrios, Cindy Korir-Morrison, Alec McQuilkin, Won Lee, Virginia A. Chanley, Patrick Harner, Victoria Aysola, and Anika McMillon.