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

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.

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BIOMEDICAL RESEARCH

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

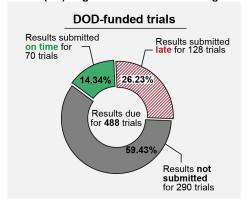
What GAO Found

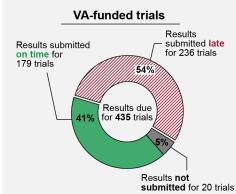
The Departments of Defense (DOD) and Veterans Affairs (VA) fund biomedical research and development (R&D) that can lead to new drugs and medical devices. DOD and VA dedicated about \$20 billion and \$10 billion respectively to such R&D in fiscal years 2019 through 2023. Multiple DOD components fund biomedical 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