

Why GAO Did This Study

Clinical research—clinical trials and other studies involving human subjects—for drugs seeking FDA approval can occur in the U.S. or overseas. During inspections, FDA goes on-site, such as to hospitals or other health care settings, to examine research protocols and records as well as the entity and facility involved in the research. Challenges in other FDA inspection programs contributed to GAO placing FDA medical product oversight on its High-Risk List in 2009.

GAO was asked to review FDA’s inspections of clinical research. This report, among other objectives, describes inspections FDA conducted from fiscal years 2012 through 2023; describes the frequency with which FDA identified serious deficiencies during inspections; and examines FDA’s efforts to maintain its investigator workforce. For this work, GAO examined FDA data and documents and interviewed FDA officials. GAO also interviewed 15 out of about 100 investigators, selected to represent diversity among the different investigator positions and tenure with FDA.

What GAO Recommends

GAO is making one recommendation that FDA evaluate its recruitment and retention efforts to determine their effectiveness and incorporate results, as appropriate, to help ensure the agency is using the most appropriate tools to maintain its investigator workforce. The Department of Health and Human Services, of which FDA is a part, agreed with GAO’s recommendation.

View [GAO-24-106383](#). For more information, contact Mary Denigan-Macauley at (202) 512-7114 or deniganmacauleym@gao.gov.

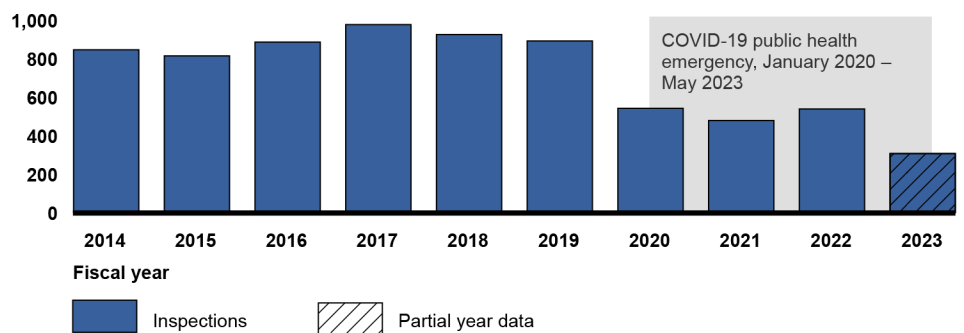
CLINICAL RESEARCH

FDA Should Evaluate Its Efforts to Recruit and Retain Its Inspection Workforce

What GAO Found

The Food and Drug Administration (FDA) conducts inspections to, among other things, help ensure the quality and integrity of clinical research used to support drugs seeking marketing approval in the U.S. FDA’s clinical research inspections peaked in fiscal year 2017 but have since declined. FDA officials attributed this decrease to the COVID-19 pandemic and not having enough investigators.

Number of FDA Clinical Research Inspections Related to Drugs, Fiscal Year 2014 through March 1, 2023



Source: GAO analysis of Food and Drug Administration (FDA) inspection data. | GAO-24-106383

From fiscal years 2012 through 2020, FDA classified 3 percent of clinical research inspections as having serious deficiencies that would warrant regulatory actions. Investigators GAO spoke with were frustrated that problems they identified (e.g., failure to follow research protocols) did not result in more serious classifications. FDA is limited in its ability to cite serious deficiencies for a common type of study supporting generic drugs. Specifically, the regulations for these studies do not include certain requirements for basic study conduct, such as record retention and following study protocols. FDA has started the process of revising these regulations. Having effective requirements will be important to help ensure high-quality research.

FDA has faced challenges recruiting and retaining investigators, resulting in fewer inspections and a less experienced workforce. For example, FDA was unable to complete about 30 percent of one type of common inspection within the requested time frames from fiscal year 2018 through July 2023, according to agency information. FDA officials and the investigators GAO spoke with identified low compensation and high amounts of travel as contributing to these challenges. FDA has taken steps to increase recruitment and retain investigators, such as increased compensation and student loan repayment. The agency recently made progress recruiting new investigators, but attrition has been a persistent problem and it can take new investigators up to a year to independently conduct inspections. Although FDA made progress, the agency has not formally evaluated its efforts to determine their effectiveness. Such an evaluation could help FDA determine whether it is using the most appropriate tools to maintain its workforce. GAO has cited workforce as a concern across multiple FDA programs and sustained attention in this area will be critical.