



February 2024

CLINICAL RESEARCH

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

Accessible Version

GAO Highlights

Highlights of [GAO-24-106383](#), a report to congressional requesters

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.

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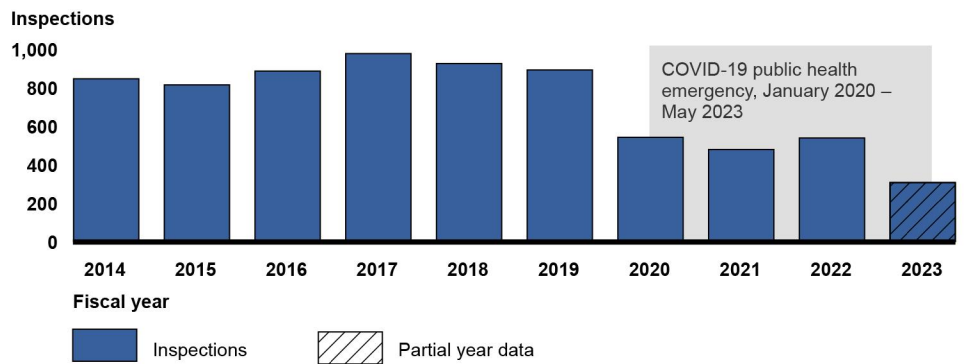
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What GAO Found

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

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

Fiscal Year	Inspections
2012	685
2013	698
2014	845
2015	813
2016	885
2017	976
2018	924
2019	891
2020	541
2021	477
2022	537
2023 (partial year)	306

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.

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Abbreviations

BA/BE	bioavailability/bioequivalence
BIMO	bioresearch monitoring
CDER	Center for Drug Evaluation and Research
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
IRB	institutional review board
ORA	Office of Regulatory Affairs

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February 22, 2024

Congressional Requesters

Clinical research—which includes clinical trials and other studies involving human subjects—provides information that may support the safety and efficacy of both brand and generic drugs. For drugs seeking approval from the Food and Drug Administration (FDA), clinical research can occur in sites all over the world, wherever there may be patients that are reflective of those living in the U.S. who would take the specific drug under development. Often this research happens in hospitals or clinics, conducted by physicians who are simultaneously providing care to their patients while also participating in clinical trials.

FDA, through its Bioresearch Monitoring (BIMO) program, is responsible for overseeing the quality and integrity of clinical research used to support drug marketing applications submitted to FDA. It also works to protect the rights, safety, and welfare of the human subjects involved in that research. FDA generally carries out this oversight through inspections in which its BIMO investigators go on-site to assess compliance with statutory and regulatory requirements governing the conduct of clinical research. This may include examining research protocols and records as well as the entity and facility involved in the research. These inspections can identify deficiencies in the conduct of the research that could call the integrity or interpretability of marketing application data into question, thereby affecting an approval decision. The inspections can also identify research conduct that may pose risks to the human subjects.

During the COVID-19 pandemic, FDA faced difficulties conducting these in-person inspections and often used alternative tools to gather needed information, according to agency documents. These tools include remote regulatory assessments, which could include document reviews, as well as information sharing with other foreign regulatory agencies performing similar oversight work.

Our work and work by others have raised questions about FDA's oversight of clinical research. For example, in 2010, the Department of Health and Human Services' (HHS) Office of Inspector General reported that FDA faced challenges conducting inspections of foreign clinical

trials.¹ In 2023, we examined one part of FDA’s BIMO program—its oversight of institutional review boards (IRB), which are groups that review ethical and safety considerations for human subject research—and found that FDA inspects relatively few IRBs and had not conducted a risk-based assessment to determine whether it is conducting an adequate amount.² In addition, as early as 1998, we identified weaknesses in another of FDA’s inspection programs—the oversight of drug manufacturing.³ FDA has since taken some steps to improve its information on manufacturing facilities and to increase the frequency of foreign inspections. However, based in part on this work, we placed FDA’s oversight of drugs and other medical products on our High-Risk List in 2009.⁴

You asked us to conduct a review of FDA’s BIMO program as it relates to ensuring that drugs approved for marketing in the U.S. are safe and effective. In this report we

1. describe how FDA identifies and prioritizes clinical research for inspection,
2. describe the inspections FDA conducted and alternative tools it has used from fiscal years 2012 through 2023 to oversee clinical research,
3. describe the frequency with which FDA identified serious deficiencies during clinical research inspections that warranted regulatory action, and
4. examine FDA’s efforts to maintain its BIMO investigator workforce.

For all four objectives, we reviewed relevant federal laws, regulations, or other documentation related to the agency’s oversight of clinical

¹See Department of Health and Human Services Office of Inspector General, *Challenges to FDA’s Ability to Monitor and Inspect Foreign Clinical Trials*, OEI-01-08-00510 (June 2010) and *The Food and Drug Administration’s Oversight of Clinical Trials*, OEI-01-06-00160 (Sept. 2007).

²GAO, *Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness*, [GAO-23-104721](#) (Washington, D.C.: Jan. 17, 2023).

³See, for example, GAO, *Food and Drug Administration: Improvements Needed in the Foreign Drug Inspection Program*, [GAO/HEHS-98-21](#) (Washington, D.C.: Mar. 17, 1998) and *Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program*, [GAO-22-103611](#) (Washington, D.C.: Jan. 7, 2022).

⁴See GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to be Maintained and Expanded to Fully Address All Areas*, [GAO-23-106203](#) (Washington, D.C.: Apr. 20, 2023).

research.⁵ We also interviewed FDA officials from the Center for Drug Evaluation and Research (CDER), which identifies and prioritizes clinical research for inspection as part of its oversight of drugs, and the Office of Regulatory Affairs (ORA), which is responsible for conducting the inspections. We also interviewed a nongeneralizable selection of 15 BIMO investigators (out of about 100 BIMO investigators) to identify challenges the agency faces in conducting clinical research inspections. We selected these investigators to represent diversity among the different investigator positions, such as domestically based investigators and those in the foreign BIMO cadre, and tenure with FDA and the BIMO program. The views of these investigators cannot be generalized to other investigators.

To describe the inspections FDA conducted to oversee clinical research, we analyzed data from FDA's Field Accomplishments and Compliance Tracking System, which contains information on BIMO inspections. Specifically, we examined FDA data from fiscal year 2012 through March 1, 2023, the most recent data available at the time of our review. We chose this time frame to examine historical trends from the period prior to the COVID-19 pandemic. We examined the number of clinical research inspections conducted by FDA, the locations in which the inspections were conducted, the types of entities that were inspected, and the frequency with which FDA identified deficiencies during inspections. We also reviewed FDA data on its use of alternative tools from fiscal year 2020, when the COVID-19 pandemic started, through March 1, 2023, the most recent available at the time of our review.

To examine FDA's efforts to maintain its BIMO investigator workforce, we analyzed FDA data on the number of authorized, filled, vacant, newly hired, and departing investigator positions for fiscal years 2018 through 2023. Fiscal year 2018 was the first full fiscal year after FDA reorganized

⁵We focused this report on FDA's inspections of clinical research conducted for human prescription drugs regulated by the Center for Drug Evaluation and Research and not on most biological products, veterinary medicines, or other items or products regulated by other FDA centers for which FDA also conducts inspections. Clinical research inspections of certain biological and biosimilar products that are regulated by CDER are also included in our analysis of inspections.

We included the following entities that are involved in clinical research in this report: clinical investigators, contract research organizations, IRBs, sponsors, and entities that conduct bioavailability/bioequivalence studies. We did not include preclinical studies in our analysis, which do not include research on human subjects, or certain post-market safety monitoring activities that are also included in FDA's BIMO program (i.e., Postmarketing Adverse Drug Experience and Risk Evaluation and Mitigation Strategies).

its inspection workforce to create a specialized BIMO program; fiscal year 2023 was the most recently available full year of data to use when we conducted our analysis. We also compared FDA's efforts to address vacancies against key principles we identified in prior work for strategic workforce planning.⁶

To assess the reliability of the data on inspections and alternative tools, we reviewed related documentation, interviewed knowledgeable agency officials, conducted electronic data testing for missing data and outliers, and compared the data to published information from the same sources. To assess the reliability of the data on investigator staffing, we interviewed knowledgeable agency officials. Based on these steps, we found these data sufficiently reliable for the purposes of our reporting objectives.

We conducted this performance audit from November 2022 to February 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.

Background

Drug Development and Approval Process

Drug sponsors (sponsors)—such as a pharmaceutical company—initiate clinical research to demonstrate the safety and effectiveness of drugs they propose to market in the U.S., among other reasons. Before clinical research for new drugs, or for new uses for existing drugs, can be started in the U.S., sponsors must submit investigational new drug applications notifying FDA of the impending clinical research.⁷ Upon completion of that research, sponsors then must submit a marketing application that includes clinical research data to obtain FDA approval if they want to market the drugs in the U.S.

⁶GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, [GAO-04-39](#) (Washington, D.C.: Dec. 11, 2003).

⁷See 21 C.F.R. part 312.

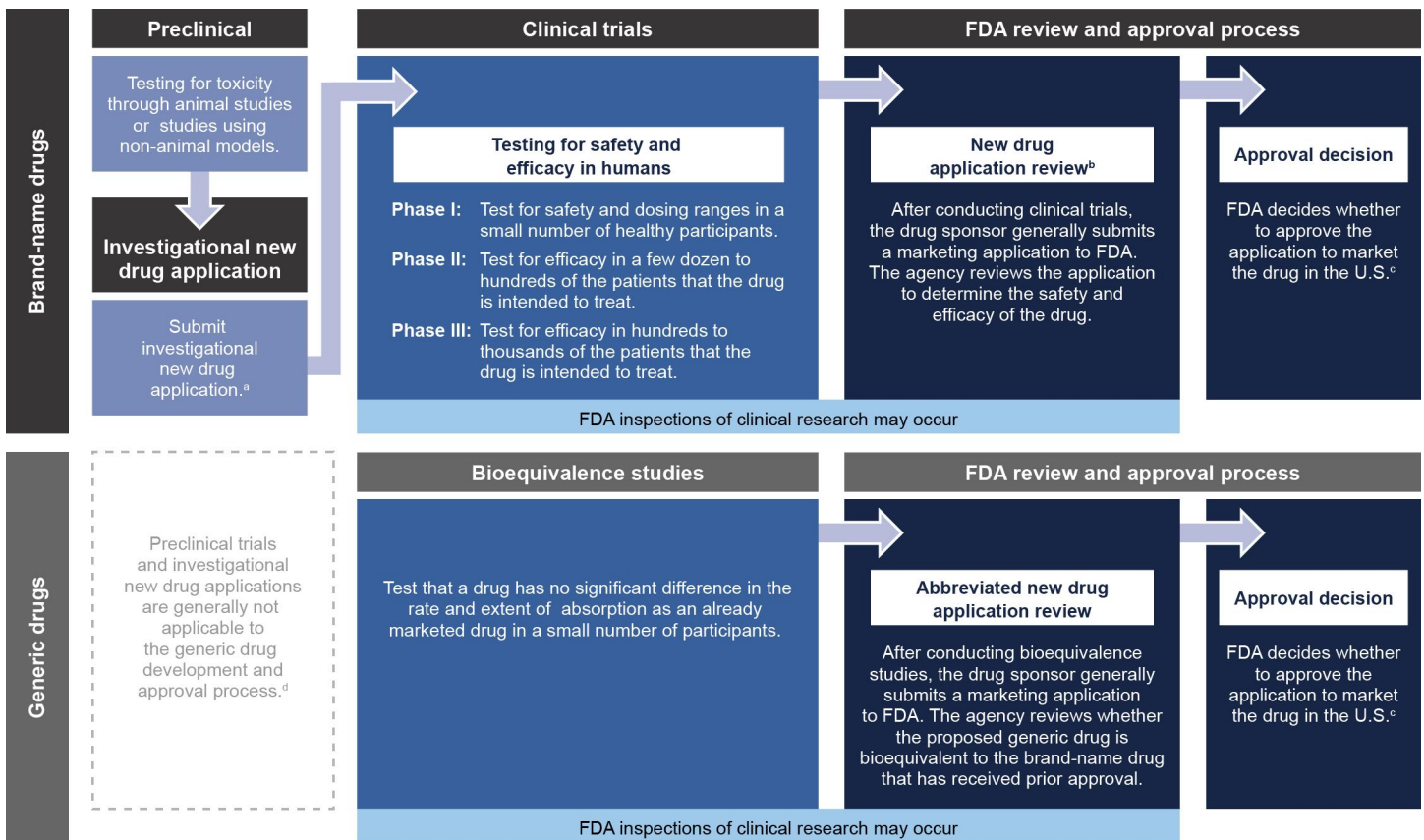
- **Brand-name drugs.** Applications for brand-name drugs typically include the results of clinical trials in humans to support the safety and efficacy of the drug.⁸ Additionally, these applications may include data from other studies involving human subjects, such as bioavailability studies that measure the extent and rate to which the active drug ingredient is absorbed in the body, among other things.
- **Generic drugs.** Applications for generic drugs typically present the results of bioequivalence studies to demonstrate that the generic drug is bioequivalent (i.e., no difference in the extent and rate of absorption) to a previously approved brand-name drug.⁹

See figure 1 for a simplified illustration of the brand-name and generic drug development and approval processes related to clinical research.

⁸For the purposes of this report, we are including the applications and development processes associated with brand-name and generic drugs in our categorization along with the approval process. Brand-name drugs are those drug products that have been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(c). Supplemental applications for brand-name drugs may also be submitted if there are subsequent changes to the drugs that sponsors would like to pursue. When we use the term marketing, brand-name drug, or generic drug applications, we include supplemental applications.

⁹For the purposes of our report, a generic drug is approved by FDA as the same—or bioequivalent—to a previously approved brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use under section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

Figure 1: Simplified Brand-Name and Generic Drug Development and FDA Approval Processes Related to Clinical Research



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

Accessible Text for Figure 1: Simplified Brand-Name and Generic Drug Development and FDA Approval Processes Related to Clinical Research

Category	Step	Step information
Brand-name drugs	Preclinical	Testing for toxicity through animal studies or studies using non-animal models.
Brand-name drugs	Investigational new drug application	Submit investigational new drug application. ^a

Letter

Category	Step	Step information
Brand-name drugs	Clinical trials	<p>Testing for safety and efficacy in humans</p> <ul style="list-style-type: none"> Phase I: Test for safety and dosing ranges in a small number of healthy participants. Phase II: Test for efficacy in a few dozen to hundreds of the patients that the drug is intended to treat. Phase III: Test for efficacy in hundreds to thousands of the patients that the drug is intended to treat. <p>note: FDA inspections of clinical research may occur</p>
Brand-name drugs	FDA review and approval process (one of two)	<p>New drug application review^b</p> <p>After conducting clinical trials, the drug sponsor generally submits a marketing application to FDA. The agency reviews the application to determine the safety and efficacy of the drug.</p> <p>note: FDA inspections of clinical research may occur</p>
Brand-name drugs	FDA review and approval process (two of two)	<p>Approval decision</p> <p>FDA decides whether to approve the application to market the drug in the U.S.^c</p>

Category	Category information	Step	Step information
Generic drugs	Preclinical trials and investigational new drug applications are generally not applicable to the generic drug development and approval process. ^d	na	na
Generic drugs	na	Bioequivalence studies	<p>Test that a drug has no significant difference in the rate and extent of absorption as an already marketed drug in a small number of participants.</p> <p>note: FDA inspections of clinical research may occur</p>

Letter

Category	Category information	Step	Step information
Generic drugs	na	FDA review and approval process (one of two)	Abbreviated new drug application review After conducting bioequivalence studies, the drug sponsor generally submits a marketing application to FDA. The agency reviews whether the proposed generic drug is bioequivalent to the brand-name drug that has received prior approval. note: FDA inspections of clinical research may occur
Generic drugs	na	FDA review and approval process (two of two)	Approval decision FDA decides whether to approve the application to market the drug in the U.S. ^c

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

Notes: This presents a simplified example of a process for drugs regulated by the Center for Drug Evaluation and Research (CDER). For the purposes of our report, brand-name drugs are those drug products that have been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(c). A generic drug is approved by FDA as the same—or bioequivalent—to a previously approved brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use under section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

^aSponsors must generally submit an investigational new drug application before beginning any clinical research on a new drug, or a new use of an approved drug, in the U.S. See 21 C.F.R. part 312. Sponsors conducting clinical research exclusively in foreign countries are not required to submit an investigational new drug application to FDA. However, this research must be conducted in accordance with FDA's good clinical practice requirements in order to be considered in support of a drug marketing application. See 21 C.F.R. § 312.120(a)(1).

^bAlong with the results of the preclinical research and clinical trials, sponsors also generally include the results of bioavailability studies in their new drug applications, among other things.

^cFDA may approve the drug for marketing in the U.S. or issue a complete response letter identifying the need for further information. 21 C.F.R. § 314.110.

^dSponsors of generic drugs do not need to submit an investigational new drug application to notify FDA of planned bioequivalence studies if certain criteria are met. See 21 C.F.R. § 320.31(d).

FDA's review of brand-name and generic drug marketing applications is funded in part by user fees that drug sponsors pay when they submit a marketing application to the agency.¹⁰ In negotiating the user fees with the drug industry, FDA commits to meeting certain performance goals,

¹⁰Federal law authorizes FDA to collect user fees to supplement the annual funding that Congress provides for the agency for the purposes of conducting specified activities. Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts. The Prescription Drug User Fee Act of 1992 authorized user fees for brand-name drugs. Pub. L. No. 102-571, tit. I, 106 Stat. 4491. The Generic Drug User Fee Amendments of 2012 authorized user fees for generic drugs. Pub. L. No. 112-144, tit. III, 126 Stat. 1008. Each must be reauthorized every five years.

such as reviewing marketing applications within a specified time frame.¹¹ For example, for brand-name drug applications, FDA's goal is to meet internally to discuss its review plan, including identifying any sites FDA plans to inspect, within 45 days of receiving an application, and to complete its review, including any inspections, within 10 months of filing the application.¹² Likewise for generic drug applications, FDA's goal is to complete its review of those applications, including conducting any inspections, within 10 months of submission. FDA's review times may be accelerated if a brand-name or generic drug application is deemed a priority, such as if the drug represents a significant therapeutic improvement over currently available drugs.¹³

FDA's BIMO Program and Inspections of Clinical Research

FDA's BIMO program oversees clinical and other research for all product areas regulated by the agency and involves multiple centers and offices within FDA.¹⁴ For clinical research involving CDER regulated drugs, CDER selects which sites and studies should be inspected, including the entity on which to focus. Then, ORA's BIMO investigators generally

¹¹These goals are outlined in a commitment letter, which covers the 5-year user fee authorization period, that is transmitted to Congress at the time user fees are authorized. See, for example, *Prescription Drug User Fee Act Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*, accessed Nov. 30, 2023, <https://www.fda.gov/media/151712/download?attachment>.

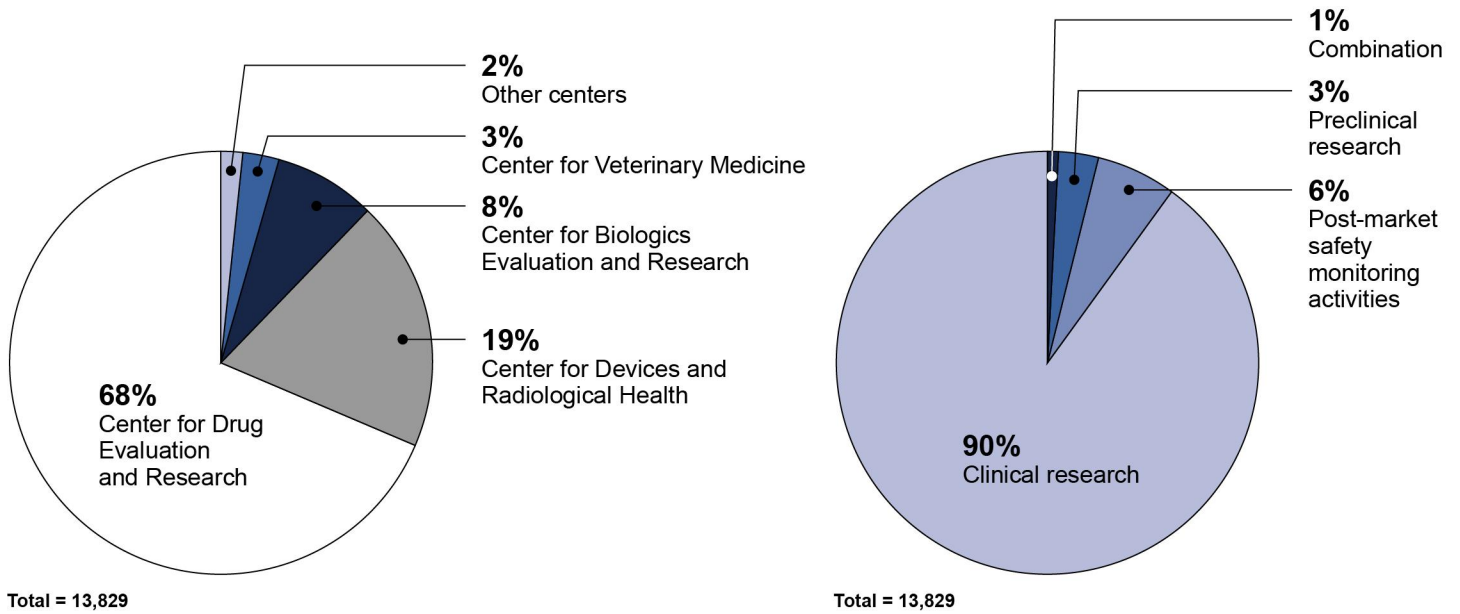
¹²Food and Drug Administration, *CDER 21st Century Review Process Desk Reference Guide*, accessed Nov. 8, 2023, <https://www.fda.gov/media/78941/download>.

¹³See Food and Drug Administration, *Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review*, accessed Dec. 15, 2023, <https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review>. For priority brand-name drug applications, FDA's goal is to meet internally to discuss the review plan within 30 days of receiving the application and complete its review within 6 months of filing the application. For certain priority generic drug applications, FDA's goal is to complete its review within 8 months from submission. FDA's goals for reviewing application supplements are similar to the goals for reviewing applications.

¹⁴FDA has six product centers that reflect product areas overseen by the agency. These are the: Center for Biologics Evaluation and Research, CDER, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Center for Tobacco Products.

conduct the inspections.¹⁵ The vast majority of FDA’s BIMO inspections are in support of products overseen by CDER and are of clinical research (see fig. 2).

Figure 2: BIMO Inspections by FDA Center and Type of Research, Fiscal Year 2012 through March 1, 2023



Total = 13,829
 Source: GAO analysis of Food and Drug Administration (FDA) inspection data. | GAO-24-106383

Accessible Data for Figure 2: BIMO Inspections by FDA Center and Type of Research, Fiscal Year 2012 through March 1, 2023

Category	Percentage
Other centers	2%
Center for Veterinary Medicine	3%
Center for Biologics Evaluation and Research	8%
Center for Devices and Radiological Health	19%
Center for Drug Evaluation and Research	68%
Total	13829

Category	Percentage
Combination	1%
Preclinical research	3%

¹⁵In some instances, CDER staff may accompany a BIMO investigator on an inspection or conduct the inspection independently, such as for entities conducting certain bioavailability or bioequivalence studies.

Category	Percentage
Post-market safety monitoring activities	6%
Clinical research	90%
Total	13829

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

Notes: Data through March 1, 2023, were the most recent data available at the time of our analysis. FDA's Bioresearch Monitoring (BIMO) inspections of clinical research entities include clinical trials and other studies involving human subjects. Preclinical research includes studies involving animals or non-animal models and does not include research in human subjects. Post-marketing safety monitoring activities include research involving humans that occurs after a drug is already marketed in the U.S.

FDA may inspect any of the multiple different types of entities that participate in clinical research at the sites where they conduct their work. See figure 3 for FDA's categorization of entities that oversee or conduct clinical research and are subject to inspection. FDA's clinical research inspections typically focus on the entity overseeing or conducting a particular clinical research study and not on the larger site. For example, a hospital may have many employees who are both providing clinical care and serving as clinical investigators conducting clinical research studies. However, an FDA inspection would focus on a single clinical investigator and the specific study they conducted in support of a drug application at the hospital and not on the hospital itself. FDA has authority to inspect entities that oversee and conduct clinical research; however, there are no regulatory or statutory requirements for FDA to conduct inspections of these entities.¹⁶

¹⁶FDA documentation states the agency will usually conduct inspections every 1 or 5 years for IRBs depending on the outcomes of previous inspections. See Food and Drug Administration, *Compliance Program 7348.809*, Chapter 48: Bioresearch Monitoring (Sept. 26, 2018).

Figure 3: FDA’s Categorization of Entities That Oversee or Conduct Clinical Research and Are Subject to FDA Inspection



Source: GAO analysis of Food and Drug Administration (FDA) documentation (text); iiierlok_xolms/stock.adobe.com (icons). | GAO-24-106383

Accessible Text for Figure 3: FDA’s Categorization of Entities That Oversee or Conduct Clinical Research and Are Subject to FDA Inspection

Category	Category information	Category level
Drug sponsors	Companies that initiate and take responsibility for clinical research in investigational new drug or marketing applications.	One
Institutional review boards	Groups that oversee clinical research involving human subjects by reviewing ethical and safety considerations for each study.	One
Contract research organizations	Companies that oversee or conduct certain parts of the clinical research, if contracted by the sponsor.	Two
Clinical investigators	Individuals that generally conduct clinical research.	Three

Category	Category information	Category level
Entities that conduct bioavailability/bioequivalence studies	Entities conduct these studies to (1) measure the extent and rate to which the active drug ingredient is absorbed in the body for brand-name drugs, or (2) demonstrate that a drug has no difference in the rate and extent of absorption as an already marketed drug, often in support of generic drugs.	Three

Source: GAO analysis of Food and Drug Administration (FDA) documentation (text); iierlok_xolms/stock.adobe.com (icons). | GAO-24-106383

A drug sponsor, such as a pharmaceutical company, oversees the clinical research needed to support a drug it is seeking to market in the U.S. Sponsors are responsible for ensuring that the research is conducted in accordance with good clinical practice and clinical investigators follow the research protocols created for each specific study. A sponsor may transfer its research responsibilities to a contract research organization.

Within a given clinical trial, the research may be conducted at dozens or hundreds of sites, each of which has a clinical investigator (generally a physician) who conducts the research at that site. In addition, bioavailability/bioequivalence (BA/BE) studies can be conducted to support drug approval, such as to demonstrate bioavailability for a brand-name drug or support that a generic drug is bioequivalent to a brand-name drug already on the market.¹⁷ BA/BE studies can be conducted by a variety of different entities, including sponsors or contract research organizations.

The conduct of this research is also overseen by IRBs, which are entities separate from the sponsors and clinical investigators, that assess the ethical and safety considerations for research involving humans. IRBs review and approve research protocols and periodically review the ongoing studies to ensure human subject protections. Most IRBs are based at universities, health care organizations (such as hospitals), or independent organizations.

Clinical Research Inspection Process

FDA's inspections vary based on the entity it is inspecting, but inspections generally include an ORA BIMO investigator going on site to examine

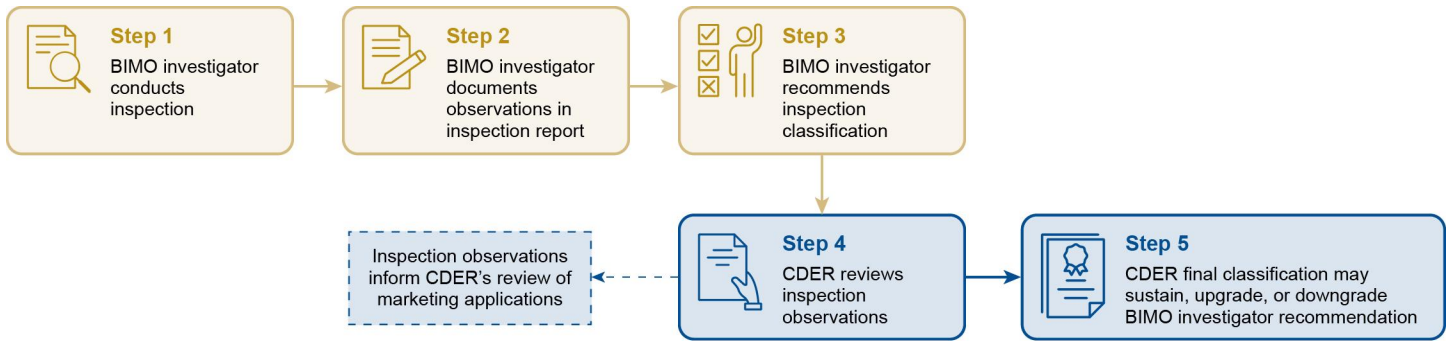
¹⁷For the purposes of our report, we use the same terminology as FDA in describing the agency's inspections of the entities conducting BA/BE studies. Specifically, we use the term BA/BE studies to include studies only involving bioavailability, only involving bioequivalence, or involving both bioavailability and bioequivalence.

research protocols and records. The purpose of the inspection is to identify any issues that could affect the quality of the clinical research data or result in risk to the human subjects and to assess compliance with applicable regulations. For example, FDA documents direct a BIMO investigator to inspect patient enrollment and informed consent documents; examine data sources and subject records for accuracy and completeness; and assess the clinical investigator's compliance with the study protocol and good clinical practice through discussions with the clinical investigator or other staff and reviewing records, among other things.

After an inspection, CDER reviews observations from the inspection report written by the BIMO investigator and classifies the inspection into one of three categories based on whether any observations are considered serious deficiencies.¹⁸ (See fig. 4.) When making a classification decision for an inspection, FDA officials stated that CDER reviewers consider several factors. Specifically, FDA officials said reviewers consider whether 1) the evidence supports the observations, 2) the observations are regulatory violations, and 3) the observations have an effect on data reliability or present a significant risk to study participants. Each of these factors can vary considerably for each study based on the study design and protocols, the target population, and other elements.

¹⁸CDER finalizes the inspection classification into one of three categories based on its determination of whether any deficiencies identified during the inspection are serious enough to warrant regulatory action. "No action indicated" means that insignificant or no deficiencies were identified during the inspection; "voluntary action indicated" means that deficiencies were identified during the inspection, but the agency is not prepared to take regulatory action, so any corrective actions are left to the inspected entity to take voluntarily; and "official action indicated" means that serious deficiencies were found that warrant regulatory action.

Figure 4: FDA Process for Classifying Inspections for Clinical Research



Source: GAO review of Food and Drug Administration (FDA) information (text); keenan/stock.adobe.com (icons). | GAO-24-106383

Accessible Text for Figure 4: FDA Process for Classifying Inspections for Clinical Research

Step	Step information
One	BIMO investigator conducts inspection
Two	BIMO investigator documents observations in inspection report
Three	BIMO investigator recommends inspection classification
Four	CDER reviews inspection observations
Five	CDER final classification may sustain, upgrade, or downgrade BIMO investigator recommendation
Dotted line from step four	Inspection observations inform CDER's review of marketing applications

Source: GAO review of Food and Drug Administration (FDA) information (text); keenan/stock.adobe.com (icons). | GAO-24-106383

Notes: Bioresearch monitoring (BIMO) investigators within FDA's Office of Regulatory Affairs summarize observations in an establishment inspection report.

Based in part on the inspection report, FDA's Center for Drug Evaluation and Research (CDER) finalizes the inspection classification into one of three categories based on its determination of whether any deficiencies identified during the inspection are serious enough to warrant regulatory action. "No action indicated" means that insignificant or no deficiencies were identified during the inspection; "voluntary action indicated" means that deficiencies were identified during the inspection, but the agency is not prepared to take regulatory action, so any corrective actions are left to the inspected entity to take voluntarily; and "official action indicated" means that serious deficiencies were found that warrant regulatory action.

Some investigators may identify observations due to concerns over the quality of the data used in a study, but these issues may not violate the study protocol or applicable regulations. Therefore, such observations would not affect the final classification. However, CDER reviewers could use the observation to inform drug marketing application review decisions. For example, a BIMO investigator in ORA may identify that the clinical investigator is inconsistently applying the research study protocol at their site. If the study protocol is vaguely worded, the clinical investigator's actions could be adhering to the protocol and would not be considered a deficiency for the purpose of classifying the inspection. The

observation, however, could result in the CDER reviewer taking further action to examine data quality, such as excluding data from the entity with the concerns during the review of the marketing application.

FDA may take regulatory action to promote compliance for significant regulatory violations. This action may include issuing warning letters describing conditions requiring correction or initiating disqualification proceedings against a clinical investigator.¹⁹ For example, FDA issued one clinical investigator a warning letter for failing to follow study protocols, including improperly enrolling subjects that did not meet eligibility requirements and improperly administering doses of the study drug outside of the required schedule. FDA makes most inspection classifications and regulatory actions publicly available through an online, searchable inspection dashboard.²⁰

FDA Generally Identifies Clinical Research Entities for Inspection through Drug Marketing Applications and Prioritizes Inspections Based on Risk

FDA generally identifies clinical research entities for inspection when sponsors submit individual drug marketing applications to the agency. FDA determines the total number of inspections it plans to conduct each year in an annual BIMO workplan, based on available staffing resources and historical trends, and prioritizes inspections based on risk.

¹⁹For this report, we use the term “regulatory action” to refer specifically to the advisory, administrative, or legal actions that FDA may take to promote or require compliance when an inspection identifies regulatory violations. FDA officials noted that the decision to approve a marketing application can also be considered a regulatory action; however, we are not including this decision when we refer to regulatory actions taken in response to inspections that identify serious deficiencies because it does not need an inspection to occur and does not directly address compliance by the inspected entity.

²⁰The dashboard also includes inspection observations that are cited on the FDA form 483, which may be issued to the inspected entity at the end of an inspection; see <https://datadashboard.fda.gov/ora/cd/inspections.htm>. The form 483 typically only cites those observations which the investigator believes may be significant violations of regulation or law and may not be issued for every inspection if no significant reportable violations are observed.

FDA Generally Identifies Clinical Research Entities for Inspection Using Drug Marketing Applications

FDA primarily identifies clinical research entities for inspection when sponsors submit individual drug marketing applications to the agency, according to agency officials. FDA officials said the agency also identifies entities through any referrals it receives alleging potential noncompliance.

Marketing applications. FDA uses marketing applications to identify the majority of entities that participate in clinical research conducted in the U.S. and globally that could be subject to inspection. As the clinical research studies are submitted in marketing applications, this generally represents research that has already been completed.

FDA Information about Clinical Research Entities

The Food and Drug Administration (FDA) does not maintain comprehensive catalogs of the entities involved in clinical research and does not require clinical research entities to register with the agency, according to agency officials. FDA officials said that doing either would not be an efficient use of agency resources as there are a large number of entities involved—over 350,000 clinical investigators conducting research according to one FDA database that has captured a subset of clinical investigators since the 1990s—and many clinical investigators often participate in only one study. FDA officials also said that given the large volume of clinical investigators conducting research compared to the number of inspections conducted annually, FDA would still need to primarily identify clinical research entities for inspections through marketing applications regardless of whether such a list existed.

In contrast, FDA has a registration requirement and a catalog for drug manufacturing establishments, which it also inspects. In comparison to clinical research entities, there were approximately 4,800 such manufacturing establishments as of October 2022, and they consistently manufacture drugs year after year. FDA is also required to conduct inspections of these establishments based on risk.

Source: GAO analysis of FDA information. | GAO-24-106383

In the case of brand-name drug applications, FDA officials said that a single application can include many entities involved in clinical research, including dozens or hundreds of clinical investigators. FDA officials said that it historically took a long time to go through the applications to identify entities for inspection, which officials told us resulted in the agency not completing inspections in the past within its user fee goals for reviewing

applications.²¹ To help address this challenge, the agency is working to finalize draft guidance that will require sponsors of brand-name drug applications to submit standardized electronic information about clinical investigators involved in conducting major studies used to support safety and efficacy claims supporting their applications.²²

Although the guidance is not yet finalized, FDA officials estimate that sponsors of 65 to 85 percent of original brand-name drug applications are currently submitting information in accordance with it. As a result, FDA officials indicated that CDER has more quickly selected and inspected entities and been better able to meet its user fee goals for completing application reviews since the draft guidance was issued in 2018. FDA officials expect the guidance to be finalized in 2024, and the submission requirements would go into effect 24 months after the final guidance is issued.

For generic drug applications, FDA provides guidance and other documents for how sponsors of generic drug applications are to submit BA/BE studies electronically to the agency.²³ FDA officials said that sponsors typically include one to two BA/BE studies in a marketing application.

²¹FDA's goal is to complete its review of brand-name drug and generic drug applications, including any inspections, within 10 months of filing the application for brand-name drugs and within 10 months of submitting the application for generic drugs. For those applications that are deemed a priority, FDA's goal is to complete review, including any inspections, within 6 months of filing the application for brand-name drugs and within 8 months of submitting the application for generic drugs.

²²Congress provided FDA with explicit authority to specify in guidance the electronic format for such submissions. Food and Drug Administration Safety and Innovation Act, Pub. L. No. 112-144, § 1136, 126 Stat. 993, 1123 (2012). See Food and Drug Administration, *Draft Guidance for Industry: Standardized Format for Electronic Submission of New Drug Application and Biologic Licensing Application Content for the Planning of BIMO Inspections for CDER Submissions*, (Silver Spring, Md.: Feb. 2018). The agency's BIMO Technical Conformance Guide also provides specific, nonbinding guidance on how sponsors are to submit information on all sites involved in major clinical research in brand-name drug applications. See Food and Drug Administration, *BIMO Technical Conformance Guide*, (Aug. 11, 2022). This guide also applies to certain investigational new drug applications as well.

²³See, for example, Food and Drug Administration, *Guidance for Industry – Abbreviated New Drug Application Submissions – Content and Format* (Silver Spring, Md.: June 2019) and "Abbreviated New Drug Application Forms and Submission Requirements," accessed Dec. 6, 2023, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/abbreviated-new-drug-application-anda-forms-and-submission-requirements>.

Referrals. FDA also identifies clinical research entities for inspection through referrals it receives about potential noncompliance, including any alleged or potential misconduct, of a particular entity overseeing or conducting any ongoing or completed clinical research, according to agency officials. The referrals may come through required reports submitted by sponsors overseeing this clinical research, IRBs, or other mechanisms, such as complaints from the public or whistleblowers.²⁴ CDER receives about 600 to 800 referrals annually, the majority of which are required reports from IRBs. Though FDA can receive referrals about any of the entities involved in clinical research, the officials said that most are about clinical investigators. For example, a complaint could involve a clinical investigator's non-compliance with study protocol requirements that resulted in a serious adverse event for a participant, an investigator's alleged falsification of study data, or failure to obtain informed consent for the participant to be in the study.

FDA Uses Staffing and Historical Trends to Determine the Number of Inspections, Prioritizing Them Based on Several Risk Factors

Purpose of FDA Inspections of Clinical Research

Marketing application inspections are conducted in support of the agency's review of marketing applications to evaluate the reliability and integrity of study data after research is generally complete.

Surveillance inspections are conducted as part of the agency's routine oversight of clinical research to assess compliance with applicable regulations and can occur at any time.

For-cause inspections are conducted in response to referrals alleging potential noncompliance of any type of clinical research entity. For-cause inspections can occur at any time.

Source: GAO analysis of FDA information. | GAO-24-106383

FDA determines the total number of inspections it plans to conduct each year in an annual BIMO workplan based on available staffing resources and historical trends. FDA uses historical trends of inspections conducted each year in its estimates because there are no clear trends in the number of applications submitted to the agency each year, according to FDA officials. If there are not enough staffing resources to conduct the planned inspections, FDA officials said the agency prioritizes inspections

²⁴Sponsors that are overseeing research conducted under an investigational new drug application are required to submit annual and intermittent reports that include information on serious adverse experiences and deaths, among other things. IRBs are also required to submit reports to FDA on noncompliance with good clinical practice, among other things.

related to marketing applications, which are tied to user fee performance goals, to avoid delaying an approval decision. FDA officials added that they can delay conducting surveillance inspections, which relate to IRB oversight of ongoing clinical research, as they are not time sensitive. In January 2023, we reported on FDA's surveillance inspections of IRBs and recommended that FDA conduct an annual risk assessment to determine whether the agency is conducting an adequate number of such inspections each year.²⁵

In its review of each marketing application, FDA applies risk-based criteria to help reviewers prioritize among the clinical research studies and sites listed to identify entities needing inspection.²⁶ These criteria vary somewhat depending on the entity involved in the clinical research or the type of study conducted and may consider the number of human subjects enrolled or reports of serious adverse events or deaths. The criteria for each entity are as follows.

- **Clinical investigators.** FDA developed a site selection tool for prioritizing clinical investigators for inspection. Agency officials said a tool was developed for these inspections because each brand-name drug application could include dozens or hundreds of clinical investigators and meeting the user fee performance goals takes a high degree of efficiency. The tool ranks clinical investigators named in the application based on 23 risk attributes, including enrollment, the efficacy outcome, incidence of severe adverse events or deaths, and any complaints. CDER staff then determine which of the ranked clinical investigators should be inspected. FDA officials said that the reviewers select a small number of clinical investigators from each marketing application to inspect (generally between three and five).
- **Sponsors and contract research organizations.** FDA determines whether or not sponsors or contract research organizations should also be inspected during its review of marketing applications. These decisions may be made at the time the application is filed or based on

²⁵We also recommended that HHS's Office of Human Research Protections, another office that oversees IRBs, conduct a risk assessment to determine whether it is conducting an adequate number of inspections. Additionally, we recommended that HHS should ensure that both FDA and the Office of Human Research Protections convene stakeholders to examine approaches for measuring IRB effectiveness in protecting human subjects and implement the approaches as appropriate. HHS agreed with our recommendations but has not yet provided an update on its progress. See [GAO-23-104721](#).

²⁶Marketing application inspections include inspections of clinical investigators, sponsors, contract research organizations, and entities that conduct BA/BE studies.

findings from inspections of clinical investigators. According to FDA documentation, the agency considers the complexity of the study design, patient population involved in the study, last inspection date and classification of the inspection, any allegations of non-compliance, or systematic concerns with the study, among other things, in selecting which entity to inspect.

- **Entities that conduct BA/BE studies.** FDA does not have a formal tool for selecting entities conducting BA/BE studies for inspection. FDA officials said this was because applications typically include a small number of BA/BE studies. Instead, FDA manually determines whether to conduct an inspection based on criteria such as the level of risk of the drug or when the site conducting the BA/BE study was last inspected.

FDA also uses risk-based criteria to prioritize other clinical research entities for inspection that are not tied to individual marketing applications, either for surveillance inspections of IRBs or for-cause inspections for investigating referrals tied to any entity.²⁷

- **IRBs.** FDA uses a selection tool that aggregates information from the list of IRBs maintained by HHS's Office of Human Research Protections, FDA inspection data, and FDA's Bioresearch Monitoring Information System, among other sources, to which criteria is then applied.²⁸ The tool prioritizes IRBs for inspection based on factors including an IRB's last inspection date, the findings from prior inspections, and the number of study protocols the IRB reviews.²⁹
- **Referrals.** Lastly, FDA evaluates referrals, including any complaints, on a case-by-case basis to determine whether the account is credible and whether a for-cause inspection is warranted. FDA officials said

²⁷Surveillance inspections are typically of IRBs, while for-cause inspections are conducted for any entity participating in clinical research.

²⁸The Bioresearch Monitoring Information System includes information from each form 1572—Statement of Investigator—voluntarily submitted to FDA by drug sponsors along with an investigational new drug application. According to the agency's website, many sponsors submit the form 1572 to FDA because it collects, in one place, information that must be submitted to FDA under the investigational new drug application regulations.

²⁹Unlike other types of BIMO inspections, FDA documentation indicates that IRBs will usually be reinspected every 1 or 5 years depending on the outcome of the previous inspection. Our 2023 report found that FDA is not tracking whether it is inspecting IRBs with this frequency, and agency officials said that the number of inspections they conduct is driven by resources. We recommended that FDA should conduct an annual risk assessment to determine whether the agency is conducting an adequate number of inspections. The agency concurred with our recommendation. See [GAO-23-104721](#).

that the agency prioritizes complaints related to significant public health concerns, such as for potential data falsification, subject harm due to non-compliance, or studies involving vulnerable populations. FDA may combine these for-cause inspections with marketing application inspections if the investigator would be inspecting the same entity.

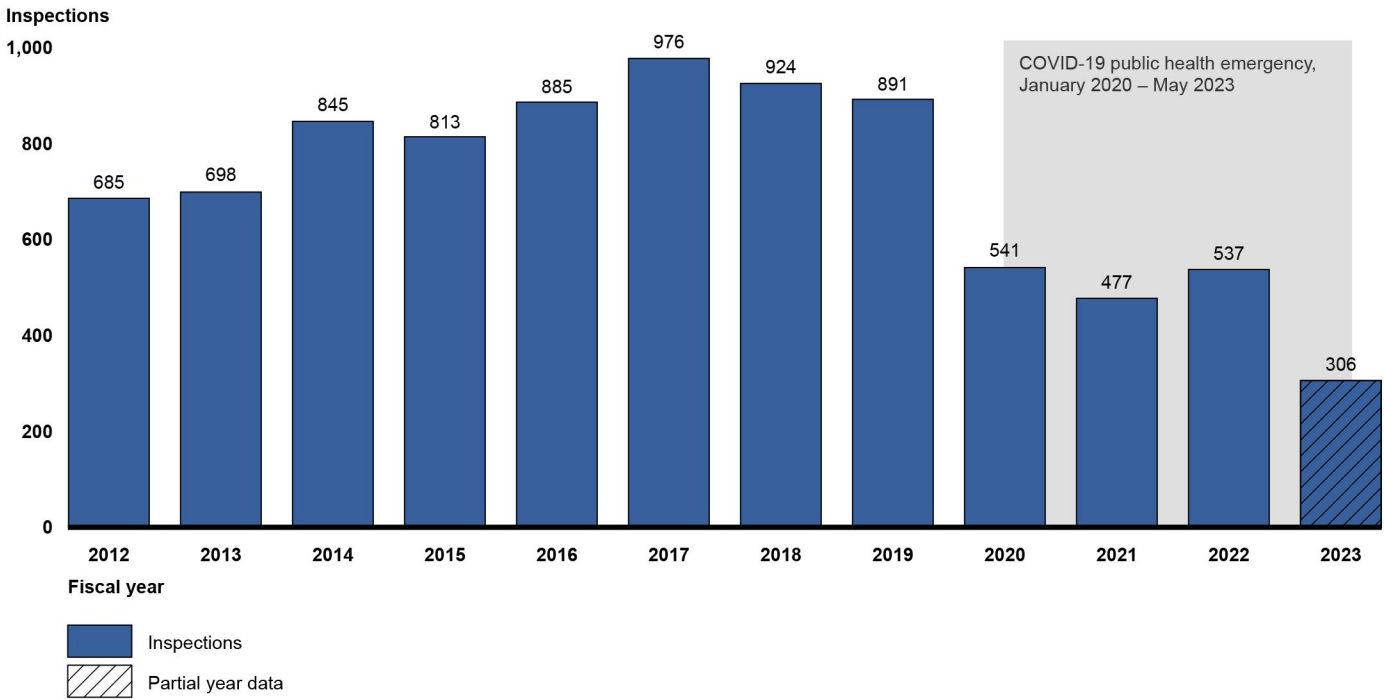
FDA's Clinical Research Inspections Declined in Recent Years and FDA Increasingly Used Alternative Oversight Tools such as Remote Regulatory Assessments

FDA's clinical research inspections have declined since fiscal year 2017 with substantially fewer inspections starting in fiscal year 2020. In response to the COVID-19 pandemic, the agency began using remote regulatory assessments in addition to existing alternative oversight tools to help counteract the decreased inspections. FDA is exploring the continued use of such remote tools.

FDA's Clinical Research Inspections Declined by Nearly Half Since 2017, Especially during the COVID-19 Pandemic, and Were Primarily of Research Conducted in the U.S.

Inspection decline. Our analysis of FDA data shows that FDA's clinical research inspections peaked in fiscal year 2017, with large decreases starting in fiscal year 2020. (See fig. 5.) FDA officials attribute this decrease in inspections mostly to the COVID-19 pandemic and not having enough investigators. As FDA does not have a comprehensive catalog of all clinical research entities eligible for inspection, it is not possible to determine whether there were fewer clinical research entities eligible for inspection over this time period. However, according to FDA officials, the number of marketing applications received by FDA for review has not changed, which is generally how FDA identifies and prioritizes clinical research for inspection.

Figure 5: Number of FDA Clinical Research Inspections, Fiscal Year 2012 through March 1, 2023



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

Accessible Data for Figure 5: Number of FDA Clinical Research Inspections, Fiscal Year 2012 through March 1, 2023

Fiscal year	Inspections
2012	685
2013	698
2014	845
2015	813
2016	885
2017	976
2018	924
2019	891
2020	541
2021	477
2022	537
2023 (partial year)	306

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

Notes: Data through March 1, 2023, were the most recent data available at the time of our analysis. Our analysis includes FDA clinical research inspections conducted for drugs regulated by the Center for Drug Evaluation and Research.

FDA suspended all inspections except those deemed mission critical in March 2020, after the public health emergency was declared for the COVID-19 pandemic. The agency resumed normal operations for domestic inspections in July 2021 and began resuming normal operations for foreign inspections in March 2022, according to officials.

Despite the large decrease, FDA conducted more clinical research inspections during the first year of the COVID-19 pandemic than other FDA inspection programs for medical products (e.g., drug or medical device manufacturing).³⁰ FDA officials stated that clinical research inspections for many drug marketing applications were considered mission critical, such as those for COVID-19-related products and for lifesaving or life-extending drugs. Therefore, FDA continued conducting these types of inspections during the COVID-19 pandemic, while it paused those deemed not mission critical, such as surveillance inspections of IRBs.³¹ In addition, FDA officials reported that, starting in July 2020, the agency was able to conduct several non-mission-critical domestic inspections when it resumed conducting non-mission-critical inspections in areas of low COVID-19 risk.³²

While FDA began its return to standard operations for all domestic inspections in July 2021 and, according to officials, began resuming non-mission-critical foreign inspections in March 2022, clinical research inspections had not returned to pre-pandemic levels as of March 1, 2023. For example, in fiscal year 2022, FDA conducted 354 fewer inspections than fiscal year 2019, the last full fiscal year prior to the start of the COVID-19 pandemic. FDA officials attributed the decrease in inspections primarily to not having enough BIMO investigators available to conduct inspections, and the agency not conducting many foreign inspections that were not considered mission critical for the first half of fiscal year 2022.

³⁰For example, more than half (172) of all mission-critical inspections conducted from March 2020 through September 2020 were for the BIMO program, according to FDA documents. In comparison, FDA conducted two mission-critical medical device manufacturing inspections and 25 mission-critical drug manufacturing inspections during that same time period. See Food and Drug Administration, *Resiliency Roadmap for FDA Inspectional Oversight* (May 2021).

³¹FDA announced in March 2020 that, in light of the COVID-19 pandemic, the agency would temporarily halt any foreign or domestic inspections other than those deemed mission critical. FDA identified mission-critical inspections on a case-by-case basis by considering many factors including the importance of patient access to the product subject to inspection, as well as considering the safety of its inspection staff and employees of the establishment to be inspected.

³²In July 2020, FDA resumed certain domestic inspections under a COVID-19 Advisory Rating system, which used real-time data to assess the COVID-19 risk by county, and a year later FDA announced it was resuming standard operations for all domestic inspections.

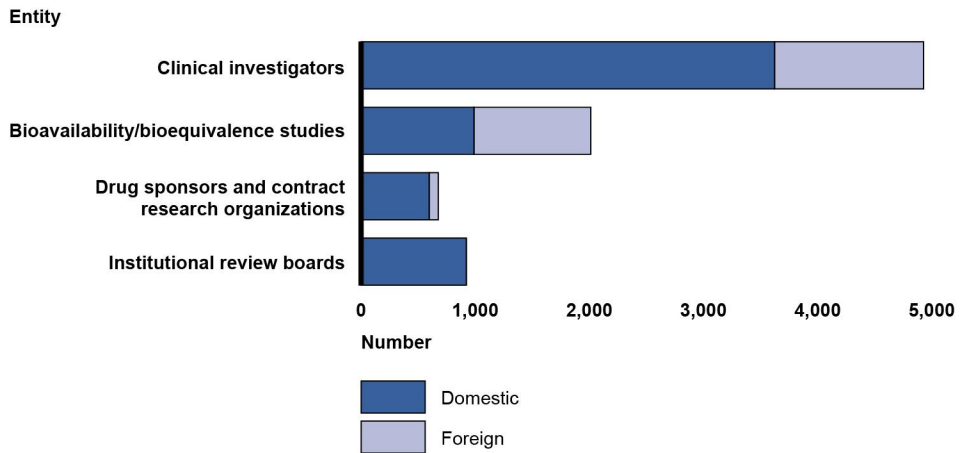
As a result of conducting fewer inspections, FDA may have less information to inform its review of marketing applications and surveillance of ongoing clinical research.

Locations and entities inspected. Overall, most clinical research inspections were of domestic entities rather than foreign entities (72 percent and 28 percent, respectively). FDA most frequently conducted foreign clinical research inspections in India, followed by Canada and several European countries, such as Poland, Germany, and France.³³ Half of FDA's inspections of entities conducting BA/BE studies were of foreign entities, often located in India. (See fig. 6.) Regarding the entities that FDA most frequently inspected from fiscal year 2012 through March 1, 2023, 57 percent of FDA clinical research inspections were of clinical investigators and nearly 25 percent were of BA/BE studies.³⁴ The majority of FDA's inspections of entities conducting BA/BE studies—70 percent—were related to BA/BE studies supporting generic drug applications.

³³From fiscal year 2012 through March 1, 2023, the 10 countries in which FDA most frequently conducted inspections (and the numbers of inspections conducted there) were: India (730), Canada (192), Poland (140), Germany (133), France (98), United Kingdom (74), Italy (66), Spain (57), Romania (47), and China (46). Fewer foreign inspections were conducted in fiscal years 2020 through 2022 as a result of the COVID-19 pandemic; however, the effect of these years on the overall percentage of foreign and domestic inspections was minimal.

³⁴Eight percent of inspections were of drug sponsors or contract research organizations, and 11 percent were of IRBs. For the purposes of this report, we include inspections of radioactive drug research committees with inspections of IRBs. Radioactive drug research committees, which accounted for 26 inspections during this time period, are separate from IRBs but perform a similar function of reviewing and overseeing a certain type of clinical research.

Figure 6: Total FDA Inspections by Clinical Research Entity and by Inspection Location, Fiscal Year 2012 through March 1, 2023



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

Accessible Data for Figure 6: Total FDA Inspections by Clinical Research Entity and by Inspection Location, Fiscal Year 2012 through March 1, 2023

Entities	Domestic	Foreign
Clinical investigators	3623	1305
Bioavailability/bioequivalence studies	989	1023
Drug sponsors and contract research organizations	596	80
Institutional review boards	922	0

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

Notes: Data through March 1, 2023, were the most recent data available at the time of our analysis. This analysis includes entities that conduct or oversee clinical research for drugs regulated by the Center for Drug Evaluation and Research. Clinical investigators are individuals who conduct the research. Bioavailability/bioequivalence studies are conducted by entities to determine the extent and rate the drug is absorbed or if a drug has no difference in the rate and extent of absorption as an already marketed drug. Drug sponsors are companies that initiate and take responsibility for clinical research for a drug product, while contract research organizations oversee or conduct certain parts of the clinical research, if contracted by the sponsor. Institutional review boards provide oversight of clinical research by reviewing ethical and safety considerations.

Because FDA does not maintain a comprehensive list of clinical research entities eligible for inspections, it is difficult to compare the ratio of FDA’s inspections in foreign countries to the amount of clinical research conducted in those countries. Data from a subset of brand-name drug applications indicates that approximately two thirds of those clinical

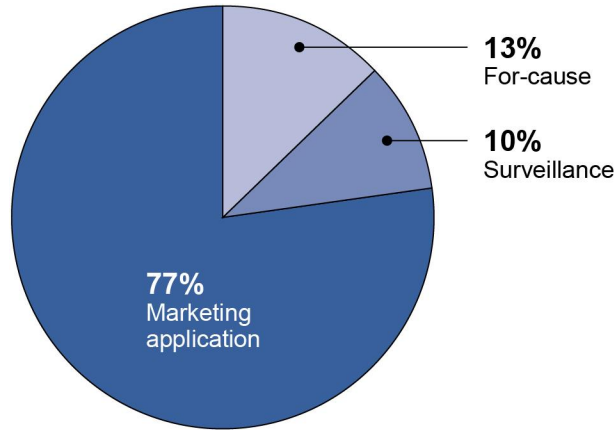
investigators were located in foreign countries.³⁵ However, most FDA inspections of clinical investigators were conducted at domestic locations. FDA officials stated that when a drug marketing application includes both domestic and foreign data, which is frequently the case, inspecting clinical research in the U.S. population is of greater interest because domestic research demonstrates the efficacy and safety of the drug when used in conjunction with other standards of care common in the U.S. Additionally, officials stated that domestic inspections are a more efficient use of time and finite inspection resources. FDA officials also noted that these data on the location of clinical investigators do not represent information from all clinical investigators that are included in marketing applications.

Consistent with how FDA identifies and selects clinical research entities for inspection, we estimate that 77 percent of clinical research inspections were conducted to support the review of a marketing application, rather than to conduct surveillance of ongoing research or for cause.³⁶ (See fig. 7.) FDA documents note that prioritizing the completion of marketing application inspections over surveillance inspections maximizes the agency's ability to meet its goals for reviewing marketing applications and prevents delays in marketing application approval decisions.

³⁵This includes data on clinical investigators conducting major clinical research for those brand-name drug applications that included standardized electronic information. According to FDA officials, this represents approximately 65 to 85 percent of recently submitted original brand-name drug applications for fiscal years 2021 and 2022 and fewer original brand-name drug applications for prior years.

³⁶Marketing application inspections include inspections of clinical investigators, sponsors, contract research organizations, and entities conducting BA/BE studies. Surveillance inspections are typically of IRBs, while for-cause inspections are conducted for any type of clinical research entity. As this report is focused on inspections of clinical research, we did not include the small percentage of inspections FDA conducts of preclinical studies in our analysis, which do not include research in human subjects, or certain post-market safety monitoring activities that are also included in FDA's BIMO program (i.e., Postmarketing Adverse Drug Experience and Risk Evaluation and Mitigation Strategies), all of which could be conducted for surveillance purposes.

Figure 7: Estimated Percentage of Total FDA Clinical Research Inspections Conducted in Support of a Marketing Application, Surveillance, or For-Cause, Fiscal Year 2012 through March 1, 2023



Total = 8,578

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

Accessible Data for Figure 7: Estimated Percentage of Total FDA Clinical Research Inspections Conducted in Support of a Marketing Application, Surveillance, or For-Cause, Fiscal Year 2012 through March 1, 2023

Category	Percentage
For-cause	13%
Surveillance	10%
Marketing application	77%
Total	8578

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

Notes: Data through March 1, 2023, were the most recent data available when we conducted our analysis. This figure represents an estimate of marketing application, surveillance, and for-cause inspections of clinical research for CDER regulated products, as FDA's inspection data does not directly identify which inspections were associated with marketing application reviews. We classified a marketing application inspection based on the clinical research entity inspected. Marketing application inspections are conducted as part of the agency's review of marketing applications to evaluate the reliability and integrity of study data. Surveillance inspections are conducted as part of the agency's routine oversight of clinical research to assess compliance with applicable regulations, including ongoing research. For-cause inspections are conducted per referrals alleging potential noncompliance and can be conducted for any type of clinical research entity.

FDA Began Using Remote Regulatory Assessments during the COVID-19 Pandemic in Addition to Existing Alternative Tools

Remote Regulatory Assessments

Remote regulatory assessments include a variety of activities, such as requesting and reviewing documents, virtual meetings with personnel at the inspected site, or livestream video of the inspected site.

The Food and Drug Administration (FDA) does not consider remote regulatory assessments to be inspections. FDA investigators typically write a narrative summary of the information reviewed and any observations of concern.

Prior to fiscal year 2023, sites voluntarily participated in remote regulatory assessments of clinical research. The Consolidated Appropriations Act, 2023, gave FDA the authority to require sites to provide documents and information in advance of or in lieu of inspections, similar to authority which already existed for drug manufacturing establishments subject to FDA inspection. Participation in other types of remote regulatory assessments, such as use of video, is still voluntary.

Source: GAO analysis of FDA information. | GAO-24-106383

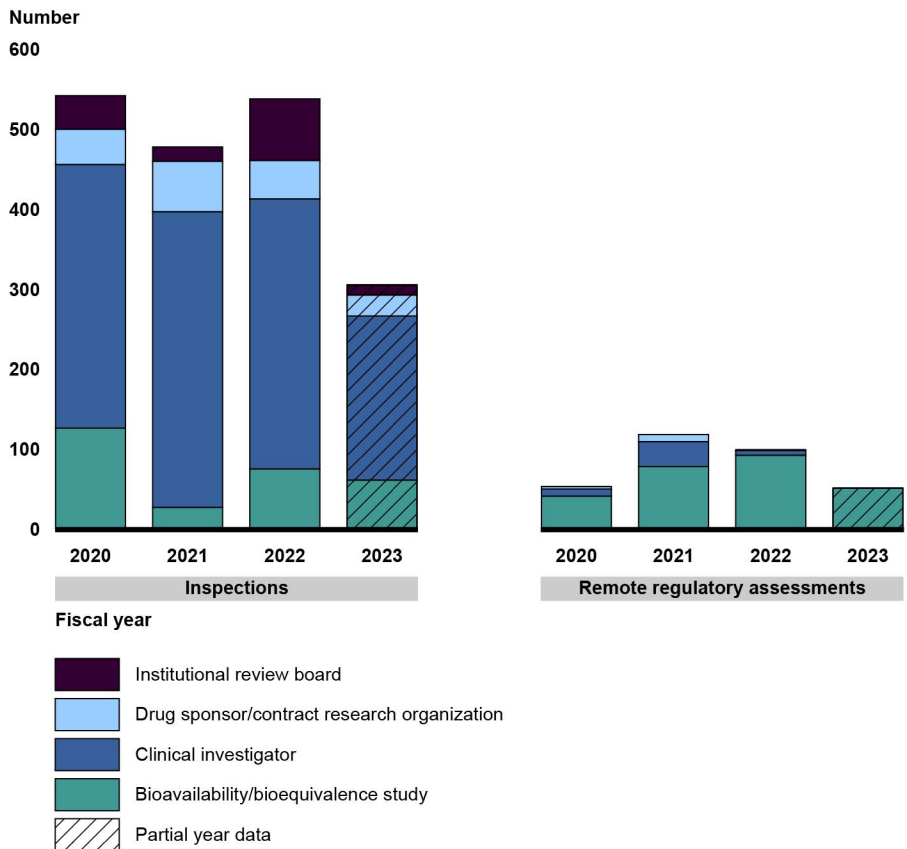
FDA began using remote regulatory assessments in fiscal year 2020 to conduct oversight of clinical research when non-mission-critical inspections were paused during the COVID-19 pandemic. These assessments added to other alternative tools that FDA was already using. Remote regulatory assessments are any of a variety of assessment activities that are conducted entirely remotely. (See sidebar.) While FDA began using these assessments specifically for clinical research oversight after the COVID-19 pandemic started, FDA documents state that the agency is exploring their continued use. FDA has also used information from foreign regulators in its review of drug marketing applications since 2009.

Remote regulatory assessments during the pandemic. According to FDA data, the agency conducted 321 remote regulatory assessments of clinical research entities from fiscal year 2020 through March 1, 2023.³⁷ The majority of these were entities conducting BA/BE studies. FDA officials stated that, because many BA/BE inspections for generic drug marketing applications were not considered mission critical during the COVID-19 pandemic, FDA did not conduct an inspection and instead used remote regulatory assessments to inform the agency's reviews.

³⁷FDA did not begin tracking remote regulatory assessments conducted by BIMO investigators until August 31, 2020.

This trend is supported by our analysis of FDA inspection and remote regulatory assessment data during this time (see fig. 8). Although FDA has indicated that remote regulatory assessments are not a substitute for an inspection, it may utilize them to inform its review of marketing applications, as FDA determines whether an inspection is needed during its review. According to agency officials, FDA approved four marketing applications for brand-name drugs (such as an oncology product) and additionally evaluated entities conducting BA/BE or other laboratory studies for 285 generic or brand-name drugs using information collected through remote regulatory assessments and other alternative tools.

Figure 8: FDA Inspections and Remote Regulatory Assessments for Clinical Research from Fiscal Year 2020 through March 1, 2023, by Entity



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

Accessible Data for Figure 8: FDA Inspections and Remote Regulatory Assessments for Clinical Research from Fiscal Year 2020 through March 1, 2023, by Entity

Fiscal year	Bioavailability/bioequivalence study (inspections)	Clinical investigator (inspections)	Drug sponsor/contract research organization (inspections)	Institutional review board (inspections)
2020	126	329	44	42
2021	27	369	63	18
2022	75	337	48	77
2023 (partial year)	61	205	26	13

Fiscal year	Bioavailability/bioequivalence study (remote regulatory assessments)	Clinical investigator (remote regulator assessments)	Drug sponsor/contract research organization (remote regulator assessments)	Institutional review board (remote regulator assessments)
2020	41	9	3	0
2021	78	31	9	0
2022	92	6	1	0
2023 (partial year)	51	0	0	0

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

Notes: Remote regulatory assessments include any of a variety of assessment activities that are conducted entirely remotely, while inspections are generally conducted on site. FDA began conducting remote regulatory assessments in fiscal year 2020 and did not begin tracking data on certain remote regulatory assessments until August 31, 2020. These data include inspections and remote regulatory assessments FDA conducted through March 1, 2023, which were the most recent data available when we conducted our analysis.

This analysis includes entities that conduct or oversee clinical research for drugs regulated by the Center for Drug Evaluation and Research. Institutional review boards provide oversight of clinical research by reviewing ethical and safety considerations. Drug sponsors are companies that initiate and take responsibility for clinical research for a drug product, while contract research organizations oversee or conduct certain parts of the clinical research, if contracted by the sponsor. Clinical investigators are individuals who conduct the research. Bioavailability/bioequivalence studies are conducted by entities to determine the extent and rate the drug is absorbed or if a drug has no difference in the extent and rate of absorption as an already marketed drug.

Most of the 15 BIMO investigators we spoke with noted challenges with conducting remote regulatory assessments and most preferred conducting on-site inspections.³⁸ For example, four investigators described issues with conducting remote assessments, including

³⁸Many remote regulatory assessments of entities conducting BA/BE studies were done by CDER staff and not BIMO investigators. BIMO investigators we spoke with most frequently described the remote regulatory assessments they conducted as consisting of remote record reviews and virtual meetings with clinical research personnel to discuss records and clarify document requests. Few investigators described using livestream video to view the clinical research location. FDA may also use the term “remote interactive evaluation” to refer to the use of any such interactive remote tool.

accessing requested electronic documents, and seven noted that receiving and reviewing the documents can take as long or longer than conducting an on-site inspection. In addition, some investigators observed that, due to the delay between when a document is requested and when it is received for a remote assessment, the inspected site has time to edit documents or create new documentation before it is shared with FDA. Nine of the 15 BIMO investigators stated they preferred on-site inspections over remote regulatory assessments; none indicated that they preferred remote regulatory assessments, although some noted that such tools are useful in certain situations. For example, two investigators stated that remote regulatory assessments could be a good tool for oversight of IRBs because these inspections typically include verifying a standard set of required documents that FDA can request all at once.

Continued use of remote regulatory assessments. According to FDA documents and agency officials, the agency is exploring the continued use of remote regulatory assessments in the future, including both when on-site inspections are not feasible and for more regular use for certain entities. FDA officials said the agency generally prefers to conduct on-site inspections but noted that remote regulatory assessments will continue to be a part of routine operations moving forward, taking into consideration factors such as timing and the site location, as in the following examples.

- FDA may continue to use remote regulatory assessments when travel to a region is restricted for geopolitical reasons or civil unrest, such as with the conflict between Ukraine and Russia that started in 2022.³⁹
- FDA officials stated that the agency is considering how to refine the use of remote regulatory assessments, both in advance of an on-site inspection and in lieu of an inspection, in order to better leverage the agency's constrained inspection resources.
- FDA started a pilot program in 2023 exploring the use of remote regulatory assessments for conducting surveillance of IRBs instead of conducting on-site inspections. FDA officials said remote regulatory assessments could be an effective tool for IRB oversight, given that IRB inspections rely more heavily on document reviews relative to other clinical research inspections. As of September 2023, FDA indicated it had selected IRBs to participate in the pilot and was in the

³⁹According to FDA officials, prior to the COVID-19 pandemic, in instances where travel to the inspection location was not possible, the sponsor of the drug marketing application was responsible for facilitating the use of certain alternative tools. For example, the sponsor might make certified copies of the necessary documentation and study records available for the investigator to review at a safe alternative site in the U.S.

process of conducting the remote regulatory assessments. FDA officials said they did not have a specific timeframe for completing the pilot.

Information from other regulators. In addition to remote regulatory assessments, FDA gathers information to inform its review of drug marketing applications through its use of confidentiality commitments with regulators in Europe, Canada, Japan, and the United Kingdom. The first confidentiality commitment was signed in 2003, according to officials, and allowed FDA to share and receive non-public inspection information such as inspection reports, memos, and other documents. In 2009, FDA began a collaborative initiative to formally exchange clinical research information with foreign regulators using these confidentiality commitments. For example, in 2022, FDA received 20 documents from foreign regulators related to 11 marketing applications and shared 76 documents related to 52 marketing applications. According to officials, each country considers different regulatory requirements when conducting clinical research inspections. Thus, it would not be possible for FDA to recognize inspections conducted by other countries as meeting FDA's clinical research inspection requirements, as FDA has done for other inspection programs, such as drug manufacturing. However, the information other regulators gather during inspections can be useful to inform FDA marketing application reviews, according to agency officials.

FDA Classified Few Inspections as Having Identified Serious Deficiencies and Is Taking Steps to Address Limitations in Relevant Regulations

FDA classified few clinical research inspections as having serious deficiencies that would warrant regulatory action, though many of the 15 BIMO investigators we spoke with expressed frustrations that their classification recommendations were changed to a less serious classification. In addition, both BIMO investigators and FDA officials stated that, for certain types of studies supporting generic drug applications, agency regulations limit the deficiencies that can be cited in inspections. FDA is in the process of revising these regulations.

FDA Classified Three Percent of Clinical Research Inspections as Having Identified Serious Deficiencies;

Selected BIMO Investigators Noted Frustrations Over Classification Process

FDA classified few clinical research inspections as having serious deficiencies that warranted regulatory action. Specifically, FDA data show that from fiscal years 2012 through 2020, FDA classified 3 percent of clinical research inspections as official action indicated, meaning that it identified serious deficiencies and regulatory actions were warranted.⁴⁰ For example, one inspection was classified official action indicated because FDA found that the clinical investigator failed to follow protocol requirements for patient eligibility, report adverse events, and obtain informed consent from subjects prior to initiating screening procedures.

Starting in fiscal year 2018 through fiscal year 2020, FDA classified less than half as many inspections as official action indicated as in prior years—about 1 to 2 percent annually compared to 3 to 7 percent annually from fiscal year 2012 through fiscal year 2017. FDA officials could not state a specific reason for this change but noted several factors that could have led to it, including a reorganization in fiscal year 2017 that made BIMO a separate inspection program with its own dedicated investigators with more expertise in how to conduct clinical research inspections. FDA officials also noted an evolution with regards to good clinical practice monitoring that was occurring around this time, and which could have improved clinical research entities' compliance with clinical research best practices.⁴¹

According to FDA inspection data, BIMO investigators in ORA recommended that more clinical research inspections be given an official action indicated classification than eventually were, but reviewers in CDER classified many of these initial recommendations as a less serious final classification. Specifically, from fiscal years 2012 through 2020, CDER reviewers classified nearly 60 percent of clinical research inspections that BIMO investigators in ORA initially recommended for

⁴⁰We excluded fiscal years 2021 through 2023 from this analysis because many inspection classifications from those years were not yet finalized at the time that we received data from the agency. FDA officials told us that inspection classifications are not finalized until the associated marketing application review is complete and inspections that receive an official action indicated classification generally take longer to finalize.

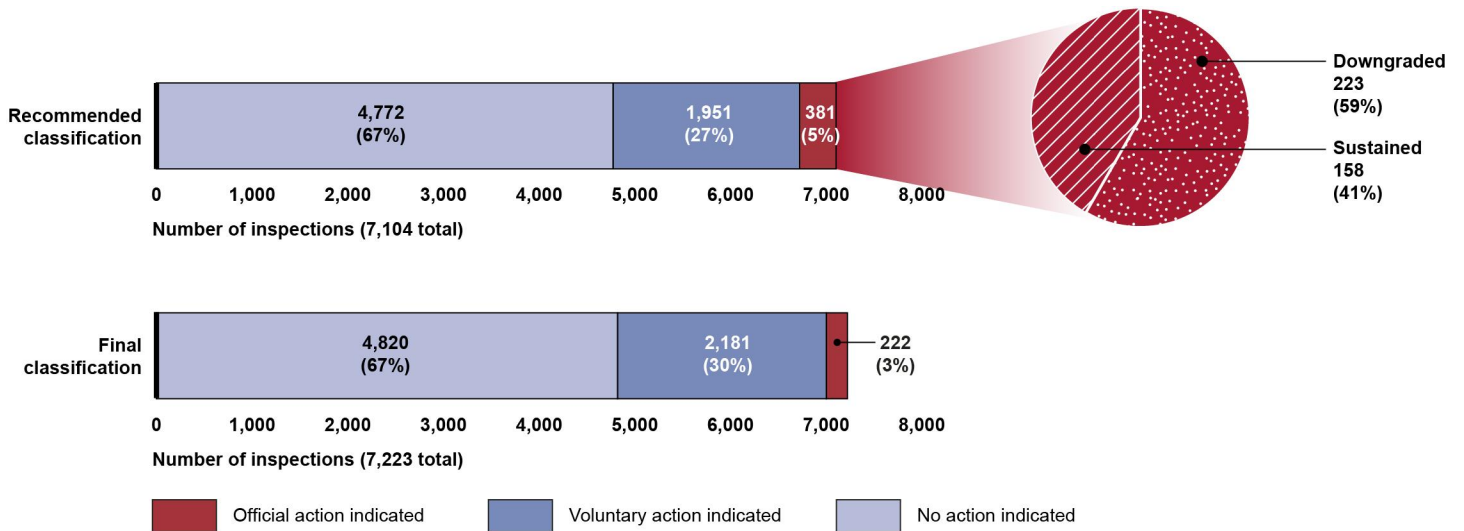
⁴¹For example, see Food and Drug Administration *E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) – Guidance for Industry*, OMB Control No. 0910-0843 (Silver Spring, MD: March 2018).

Letter

official action indicated classification as a less serious final classification (see fig. 9).⁴²

⁴²Less than one percent of inspections recommended for a less serious classification had a final classification of official action indicated.

Figure 9: FDA Recommended and Final Classifications for Clinical Research Inspections, Fiscal Years 2012 through 2020



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

Accessible Data for Figure 9: FDA Recommended and Final Classifications for Clinical Research Inspections, Fiscal Years 2012 through 2020

Recommended classification	Number of inspections	Percentage	Inspection/percentage analysis
No action indicated	4772	67%	na
Voluntary action indicated	1951	27%	na
Official action indicated	381	5%	<ul style="list-style-type: none"> Downgraded: 223 (59%) Sustained: 158 (41%)
Total	7104		

Final classification	Number of inspections	Percentage
No action indicated	4820	67%
Voluntary action indicated	2181	30%
Official action indicated	222	3%
Total	7223	

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

Notes: FDA’s Center for Drug Evaluation and Research (CDER) finalizes the inspection classification into one of three categories based on its determination of whether any deficiencies identified during the inspection are serious enough to warrant regulatory action. “No action indicated” means that insignificant or no deficiencies were identified during the inspection; “voluntary action indicated” means that deficiencies were identified during the inspection, but the agency is not prepared to take

regulatory action, so any corrective actions are left to the inspected entity to take voluntarily; and “official action indicated” means that serious deficiencies were found that warrant regulatory action.

Percentages may not sum to 100 percent due to rounding. The total number of recommended classifications and the total number of final classifications are not equal because a small number of inspections (119) were submitted to CDER for review without a recommended classification. Thus, those inspections were included in the final classification counts but not the recommended classification counts. Additionally, for this analysis we did not include inspections which have not received a final classification of official action indicated, voluntary action indicated, or no action indicated.

Approximately one percent (104) of inspections initially recommended for voluntary action indicated classification received a less serious final classification. Two percent (170) of inspections recommended for a less serious classification received a more serious final classification, with less than one percent of these (55) receiving the most serious final classification—official action indicated.

Many of the 15 BIMO investigators we spoke with stated that inspection reclassifications can be frustrating due to the additional work that is required for them to support more serious classifications. For example, 10 investigators stated that they collect additional evidence or have multiple discussions with ORA or CDER reviewers to support an official action indicated recommendation. Further, four investigators noted they are allowed less time to complete their inspection report when a classification of official action indicated is recommended. Specifically, investigators noted they are expected to complete an inspection report for a recommended official action indicated classification in 5 days, including supervisory review, whereas investigators typically have 30 days to complete reports for inspections that are not recommended official action indicated.⁴³ In addition, six of the 15 BIMO investigators we spoke with felt that some clinical research entities were not being held accountable for observations the BIMO investigator found to be concerning, because they were not receiving official action indicated classifications and warning letters. While many investigators acknowledged that CDER reviewers have the final decision on the inspection classification, the majority also noted that reclassifications can affect morale.

FDA officials said that several factors can influence whether a BIMO investigator’s recommendation will receive a less serious final classification from CDER reviewers. For instance, officials stated that the clinical investigator may later provide a response with additional documentary evidence that they could not locate while the BIMO investigator was on-site, thereby addressing the BIMO investigator’s inspection observations. In addition, officials reiterated that the inspection

⁴³FDA guidance states that inspection reports should be completed in a timeframe commensurate with the action time frames for any potential regulatory action. Thus, an inspection report recommended for official action indicated should be written in time for CDER to review and complete any regulatory actions, such as issuing a warning letter, within FDA’s time frames for such an action.

classification can depend on the unique wording of each study protocol, and, as a result, the same type of observation identified as a deficiency in one inspection may not be cited as a deficiency for a different inspection under a different study protocol.⁴⁴ According to FDA officials, the final classification depends on whether the investigator's observations represent a regulatory violation, the significance of the violation, and its effect on the clinical research subjects or the validity of the data.

FDA officials also emphasized that their focus is on ensuring that the data supporting drug marketing applications are reliable and verifiable, which may be different from determining the final classification. FDA officials reiterated that, regardless of the inspection classification, the review team assessing the marketing application may take action in response to concerns raised by investigators. These actions could include excluding data generated by the entity with the concerns from FDA's review of the application, conducting a sensitivity analysis to determine the impact of concerning data on the overall clinical research findings, and requesting additional information or inspections.⁴⁵ One preliminary analysis from the agency indicated that CDER reviewers recommended actions, such as excluding data or requesting additional information, before making a final decision on 21 percent of brand-name drug marketing applications that received inspections from fiscal years 2015 through 2019.

Additionally, FDA officials noted that taking regulatory action to resolve deficiencies is separate from the primary inspection focus on ensuring the data supporting drug marketing applications are reliable and verifiable. This is in part because the inspected research has generally already been completed and the entities cannot correct the identified deficiencies. Entities can take steps in response to deficiencies to improve their conduct in any future clinical research. However, in the case of clinical investigators, which comprise most FDA clinical research inspections, FDA officials noted they often do not participate in multiple clinical studies. This differs from other inspection programs, such as drug

⁴⁴For example, one protocol might clearly require clinical investigators to take a certain action, such as administering a test at a certain time, while another might say they may take that action.

⁴⁵According to FDA officials, if the agency excludes data from its review of an application, a sensitivity analysis will be conducted to ensure that it does not alter the determination of the drug's safety and effectiveness. If the drug's safety and effectiveness is still supportable but excluding the data results in a smaller total study population, the agency may work with the applicant to address this, including decisions on what should be stated on the drug label.

manufacturing, where entities are continually manufacturing drugs and inspection classifications from any point in time and any resulting regulatory actions can help ensure drug products meet quality and safety in the future.

FDA's Citation of Serious Deficiencies in Clinical Research Is Limited by Regulation; FDA Began the Process of Revising these Regulations in 2020

FDA is limited in its ability to cite certain serious deficiencies identified during inspections as regulatory violations because most BA/BE studies in support of generic drugs are not subject to certain requirements. Specifically, FDA regulations generally exempt these BA/BE studies from study conduct requirements that apply to other types of clinical research inspected by the FDA.⁴⁶ (See sidebar.) Therefore, six investigators we spoke with stated that they may identify observations related to study conduct for BA/BE studies, but most cannot be cited as deficiencies for the purpose of classifying the inspection because there are no applicable regulations. While most BA/BE studies conducted in support of brand name drugs are also subject to other regulations governing clinical study conduct, up to 70 percent of FDA's inspections of entities conducting BA/BE studies are of generic drugs subject only to the limited regulations for BA/BE studies, according to our analysis of FDA inspection data. Such inspections are also frequently of studies conducted outside of the U.S.

⁴⁶All BA/BE studies are subject to regulations under 21 C.F.R. part 320. However, generally, any domestic research on a new drug or a new usage (i.e., brand name drug), including supporting BA/BE studies, is also subject to 21 C.F.R. part 312 and must be conducted under an investigational new drug application. In contrast, a BA/BE study for a drug that contains the same active ingredient as an already approved drug (i.e., a generic drug) is generally exempt from 21 C.F.R. part 312 if it meets the requirements under 21 C.F.R. part 320.31(d).

Regulatory Requirements for Clinical Research Conduct

All bioavailability/bioequivalence (BA/BE) studies are subject to the Food and Drug Administration's (FDA) regulations governing those studies, but BA/BE studies for brand-name drugs are also subject to additional study conduct requirements.

- BA/BE studies supporting most brand-name drugs are subject to the same regulations that govern all clinical research conducted under an investigational new drug application, which require that research is conducted according to the study protocol, is reviewed by an institutional review board (IRB), includes informed consent from subjects, and that clinical research records are maintained and made available to FDA for inspection, among other requirements.
- In contrast, BA/BE studies supporting generic drugs are generally only subject to the regulations governing BA/BE studies, which have no specific requirements related to following study protocols or retention of study records. These regulations specifically require that entities conducting such studies 1) keep samples of the product being tested, 2) obtain informed consent from subjects and IRB review of the study, and 3) report serious adverse events.

Source: GAO analysis of FDA information. | GAO-24-106383

As a result, for most generic drugs, FDA is unable to classify inspections of BA/BE studies that do not meet study conduct requirements as having identified serious deficiencies, because the study conduct regulations do not apply. Furthermore, the agency has limited options for regulatory action. For example, current BA/BE regulations do not give FDA the regulatory authority to disqualify an entity conducting BA/BE studies from participating in future clinical research.⁴⁷ Furthermore, the inability to cite a deficiency for most issues observed during an inspection of these BA/BE studies may limit public and sponsor awareness of concerns. For example, since many observations that investigators identify during BA/BE study inspections are not regulatory violations, they are typically not included on the inspection dashboard that makes public information about FDA's inspections.⁴⁸

FDA acknowledged the limitations with its BA/BE regulations and is in the process of making revisions. The agency first included plans to update these regulations in its 2020 agenda of upcoming regulatory actions. According to officials, the regulation revision process can typically take 3

⁴⁷FDA can disqualify any clinical investigator conducting research under an investigational new drug application from participating in future clinical research. 21 C.F.R. § 312.70. However, as BA/BE studies for generic drugs are generally exempt from these requirements, FDA cannot take the same action for entities conducting BA/BE studies for most generic drugs. FDA can, however, use inspection observations to inform its review of a generic drug marketing application.

⁴⁸FDA makes investigator citations from the FDA form 483s public on the agency's inspection dashboard, see <https://datadashboard.fda.gov/ora/cd/inspections.htm>. As many observations that investigators identify during inspections of BA/BE studies are not regulatory violations they would not typically be cited on the FDA form 483s if one were to exist.

to 5 years and may take up to 10 years from when the agency initiates the rulemaking to the publication of the final rule.

According to FDA's regulatory agenda, the agency plans to issue a draft of the revised regulations, known as a notice of proposed rulemaking, in April 2024.⁴⁹ The agency has included notice of their intention to update these regulations in public agency plans since fall 2020 but has pushed back the anticipated issue date five times. FDA officials noted that it is not uncommon for the timeline for issuing draft regulations to be delayed or adjusted. Factors that can affect that timing include competing agency priorities and the time required to complete reviews both inside and outside of FDA, as well as the effect of the COVID-19 pandemic. According to FDA, the regulations governing BA/BE studies limit the agency's ability to ensure these studies are reliable and valid.⁵⁰ Further, the agency reports that revising these regulations should improve BA/BE study quality and could result in fewer studies being rejected, thus promoting faster drug marketing application approvals and increasing the speed at which these drugs are available to patients. Having requirements to ensure BA/BE studies meet study conduct regulations is important for FDA to ensure the reliability and validity of BA/BE studies.

FDA Has Not Evaluated the Effectiveness of Its Efforts to Address Its Declining BIMO Inspection Workforce

Since fiscal year 2018, FDA has faced challenges maintaining its BIMO investigator workforce, both in terms of recruiting and retaining investigators, leading to a less experienced workforce and fewer inspections being conducted. FDA officials and BIMO investigators we spoke with identified compensation and amount of travel as contributing to some of the challenges with recruitment and retention. FDA has taken steps to increase recruitment of BIMO investigators and recently reduced

⁴⁹See 88 Fed. Reg. 48,553 (July 27, 2023). In general, FDA must publish a notice of proposed rulemaking in the Federal Register for each regulation and allow for public comment. After the comment period has closed, FDA must publish another notice in the Federal Register to terminate the process, issue a new proposal, or issue a final regulation. 21 C.F.R. § 10.40. As of December 2023, FDA has not yet published a notice of proposed rulemaking.

⁵⁰See 87 Fed. Reg. 5,066 (Jan. 31, 2022).

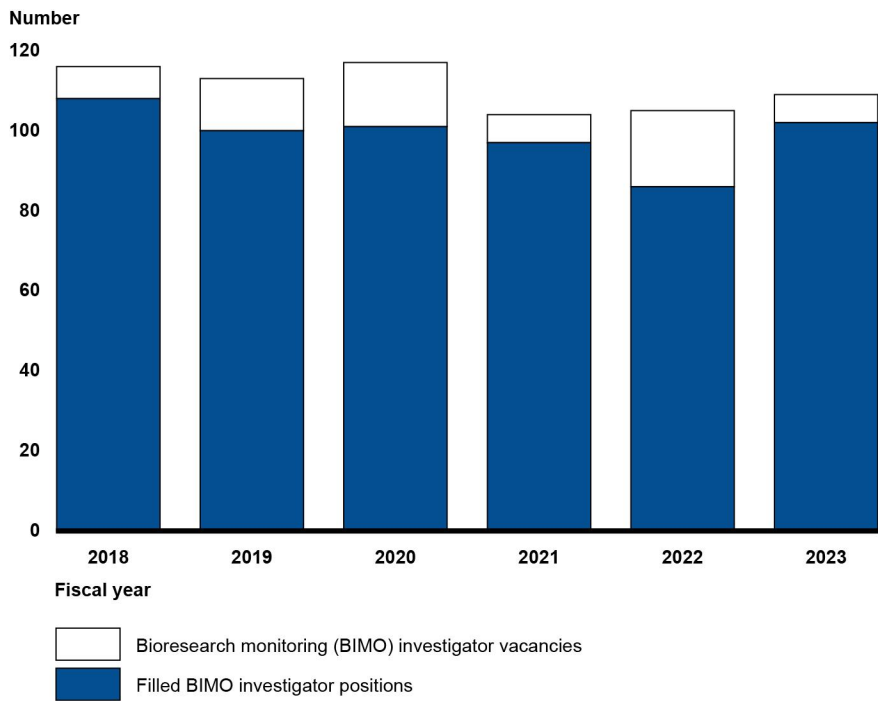
vacancies, though challenges with attrition have been persistent. The agency has not evaluated these efforts to know which are most effective.

FDA's BIMO Inspection Workforce Has Declined Since 2018, Mainly due to Continued Attrition

FDA has faced challenges maintaining its BIMO investigator workforce, which it relies on to ensure the quality and integrity of clinical research data. Since fiscal year 2018, the first fiscal year after FDA created a BIMO-specific workforce, through fiscal year 2023, the number of BIMO investigators has declined (see fig. 10).⁵¹ During this period, the BIMO program had an average vacancy rate of 11 percent with the highest vacancy rate, 18 percent, in fiscal year 2022. As of November 2023, there were six BIMO investigator vacancies and ORA has selected candidates to fill each vacancy, according to FDA officials.

⁵¹In 2017, FDA reorganized its inspection workforce to create a specialized BIMO program to conduct clinical research and other types of BIMO inspections. Prior to this, all FDA investigators could conduct a BIMO inspection. The BIMO inspection workforce consists of U.S.-based investigators who conduct domestic and foreign inspections, a U.S.-based dedicated foreign cadre of investigators, national experts, and an investigator assigned to a foreign office.

Figure 10: FDA BIMO Investigator Workforce, Fiscal Years 2018 through 2023



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

Accessible Data for Figure 10: FDA BIMO Investigator Workforce, Fiscal Years 2018 through 2023

Fiscal year	Filled BIMO investigator positions	Bioresearch monitoring (BIMO) investigator vacancies
2018	108	8
2019	100	13
2020	101	16
2021	97	7
2022	86	19
2023	102	7

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

Vacancies in the BIMO investigator workforce can be attributed to persistent attrition that has generally outpaced FDA’s recruitment of new investigators each fiscal year. While the agency increased hiring in recent years, it often lost more BIMO investigators than it was able to replace. Specifically, data from the past 6 fiscal years show the agency had an

average attrition rate of 13 percent (see table 1).⁵² In fiscal year 2023, the agency hired a large number of BIMO investigators to help fill most of its ongoing vacancies.

Table 1: Bioresearch Monitoring (BIMO) Investigator Staffing Levels, Fiscal Years 2018 through 2023

Fiscal year	Number of authorized BIMO investigators	Number of filled BIMO investigator positions	Number of BIMO investigators hired	Number of BIMO investigator departures
2018	116	108	3	11
2019	113	100	7	13
2020	117	101	12	4
2021	104	97	13	14
2022	105	86	9	20
2023	109	102	23	11

Source: GAO analysis of documentation from the Food and Drug Administration. | GAO-24-106383

Despite recruiting more BIMO investigators to fill vacancies, in fiscal year 2023 there were fewer BIMO investigators than in fiscal year 2018. In part, this is because the number of authorized positions for the BIMO program has decreased from 116 positions in fiscal year 2018 to 109 in fiscal year 2023, resulting in a smaller BIMO investigator workforce. FDA officials attributed the decrease in authorized positions to stagnant funding for ORA, which includes the BIMO program, and the agency offering higher salaries for BIMO investigators. In contrast, FDA officials noted that the BIMO investigator workforce would need to double in size to approximately 220 BIMO investigators to fully meet the agency’s needs for clinical research inspections.

FDA officials said the loss of experienced investigators through attrition had several negative effects. Specifically, officials said that this loss, along with the COVID-19 pandemic, led to the decline in the number of clinical research inspections completed annually. Additionally, officials told us the agency has not been able to complete all the clinical research inspections it planned to conduct. According to information from FDA, approximately 6 percent of all clinical research inspections assigned to

⁵²According to FDA officials, the attrition rate is similar across other inspection programs within ORA.

BIMO investigators from fiscal year 2018 through July 2023 were unable to be completed.⁵³

Additionally, the workforce is less experienced overall due to attrition and a large influx of new BIMO investigators. For example, as a result of the hiring in fiscal year 2023 alone, more than 20 percent of the workforce in that year consisted of newly hired BIMO investigators. Agency officials told us that newer staff take longer to complete clinical research inspections and are often trained on the job. The extra time needed to train a new BIMO investigator during a clinical research inspection or to write the associated inspection report also affects the number of inspections that experienced investigators can conduct, according to agency officials. FDA officials also told us that, due to the amount of training and specialized requirements for BIMO investigators, it can take up to a year before a new hire can conduct basic domestic inspections independently and it can take 2 to 3 years before they can conduct foreign inspections independently.

Lastly, FDA officials also said that these workforce challenges can make it difficult to conduct inspections within the time frames for completing application reviews FDA established as part of its user fee performance goals.⁵⁴ For example, according to information provided by CDER, approximately 30 percent of clinical investigator inspections—which accounts for the majority of clinical research inspections the agency conducted—needed extensions beyond the CDER requested due date from fiscal year 2018 through July 2023. Information from FDA also shows that there have been delays in inspections of other entities such as IRBs, which are inspected for surveillance purposes rather than from the review of marketing applications.

⁵³In addition to staffing issues and the COVID-19 pandemic, the officials also mentioned conflict due to civil unrest near an inspection site as another reason for why inspections were not completed.

⁵⁴FDA's goal is to complete its review of brand-name drug and generic drug applications, including any inspections, within 10 months of the sponsor filing the application (brand-name drugs) or submitting the application (generic drugs). For those applications that are deemed a priority, FDA's goal is to complete review, including any inspections, within 6 months of the sponsor filing the brand-name drug application or within 8 months of the sponsor submitting the generic drug application.

FDA and Selected BIMO Investigators Identified Compensation and Amount of Travel as Contributing to Challenges Recruiting and Retaining Staff

FDA officials and the 15 BIMO investigators we spoke to noted several factors that have affected the agency's ability to recruit and retain its BIMO inspection workforce. These challenges include the following.

Compensation. FDA officials and eight BIMO investigators we interviewed said low compensation was a major contribution to recruitment and retention challenges. For example, two BIMO investigators stated that a number of BIMO investigators left FDA for higher-paying jobs in industry after gaining several years of experience in the BIMO program. While the agency has made changes to increase salaries for new hires, FDA officials acknowledged that compensation continues to be a challenge for existing BIMO investigators because the agency is not able to match industry salaries.

Travel. Seven BIMO investigators we interviewed stated the amount of travel required for domestic inspections can be challenging, with some BIMO investigators noting that the amount of travel can affect their work-life balance. For example, three BIMO investigators said that travel to local sites can take several hours a day in addition to the time spent conducting the inspection at the site.⁵⁵ Agency officials said that prospective applicants may not continue with the interview process once they understand how much travel is involved. FDA's hiring announcements state that BIMO investigators travel 50 percent of the time, which may be difficult for people to sustain, according to agency officials.

Non-specific vacancy announcements. FDA officials said that recruitment efforts were limited by vacancy announcements that were not specific to the BIMO inspection program. Instead, they were shared among all of FDA's inspection programs (such as drug manufacturing or medical devices), and the BIMO program was not able to target recruits specifically interested in clinical research.

Retirements. FDA officials told us that, historically, investigators needed to have about 10 years of inspection experience to be eligible for the

⁵⁵BIMO investigators we interviewed did not cite the amount of foreign travel as a challenge that affected their workload.

BIMO program. Therefore, when the BIMO-specific workforce was established in fiscal year 2017, the majority of investigators assigned to the program were later in their career. As a result, many BIMO investigators have recently retired or are currently or soon to be eligible for retirement. For example, about 30 percent (21) of the 73 BIMO investigators who have left the program from fiscal year 2018 through fiscal year 2023 retired, and officials noted that 30 percent of the current BIMO investigator workforce are eligible to retire as of October 2023.

FDA Instituted Efforts to Recruit and Retain BIMO Investigators, but Has Not Evaluated These Efforts

FDA has implemented a variety of efforts to recruit and retain BIMO investigators. Many of these are outlined in the agency’s Strategic Hiring Plan for the Office of Regulatory Affairs for fiscal years 2022 through 2024, which includes a number of recruitment and retention strategies to increase hiring and reduce investigator attrition, including for BIMO investigators.⁵⁶

For recruiting, FDA officials said that the agency was able to make recent progress recruiting BIMO investigators by using authorities granted from the 21st Century Cures Act, which was enacted in 2016, and other sources.⁵⁷ (See table 2 for more information on FDA’s recruitment efforts.)

Table 2: FDA Efforts to Recruit BIMO Investigators

Category	Category information
Increased pay	FDA set a higher pay rate for qualified scientific, technical, or professional positions that support the development, review, and regulation of medical products. Since April 2022, FDA has posted three hiring announcements for Bioresearch Monitoring (BIMO) investigators at a higher pay rate equivalent to a General Schedule 11 level rather than the typical General Schedule 7 through General Schedule 9 level.
Location-based incentives	FDA may pay incentives for newly hired BIMO investigators in certain geographic areas where it is difficult to hire investigators.
Tailored recruitment strategies	FDA used direct-hire authority and other initiatives—including a program for recent graduates—to provide additional pathways for recruiting new investigators directly to the BIMO program.
Outreach	FDA coordinated with universities that have relevant academic programs and posted targeted hiring announcements to relevant industry organizations to reach a larger pool of qualified candidates.

Source: GAO description based on Food and Drug Administration (FDA) documentation and interviews with agency officials. | GAO-24-106383

⁵⁶We previously reported on vacancies in another FDA inspection program, the foreign drug investigator workforce. See [GAO 22-103611](#).

⁵⁷Pub. L. No. 114-255, 130 Stat. 1033 (2016).

Note: These efforts include authorities granted to FDA under the 21st Century Cures Act, which, among other things, provides additional hiring and pay flexibilities to the Department of Health and Human Services to facilitate FDA's recruitment of qualified candidates to scientific, technical, or professional positions that support the development, review, and regulation of medical products. Pub. L. No. 114-255, § 3072(a), 130 Stat. 1033, 1134 (2016).

For retention, FDA officials noted the agency has two main types of financial incentives to help retain existing BIMO investigators.

- **Student loan repayment.** Through this program, FDA may make payments to the loan holder of up to a maximum of \$10,000 for an employee in a calendar year (for a total of not more than \$60,000 for any one employee). Employees receiving this benefit must sign an agreement to remain in the service of the agency for at least 3 years.
- **Monetary incentives.** FDA offers cash incentives for domestic-based BIMO investigators who complete foreign inspections. For example, domestic investigators can receive between \$300 and \$700 in incentives per foreign inspection trip, depending on the length of the foreign inspection and how many are completed in a fiscal year.

In addition, FDA officials stated that ORA initiated an employee-led effort to identify strategies to improve the retention of BIMO investigators using the results of the Federal Employee Viewpoint Survey.⁵⁸ This effort identified seven strategies, including the following.

- **Informal rewards.** BIMO investigators identified the need for more recognition. In response, the agency created an informal reward incentive, "BIMO Bucks," that supervisory staff can use to give BIMO investigators recognition for their work, according to FDA officials. This reward can be used for additional paid time off.
- **Career planning.** BIMO investigators identified the need for more career advancement opportunities.⁵⁹ In response, agency officials created an interactive visual for different positions within the BIMO program that illustrates potential career pathways for BIMO investigators and details potential routes for professional advancement within the BIMO program. This visual is available to all BIMO investigators.

⁵⁸The Federal Employee Viewpoint Survey is a web-based survey administered annually by the U.S. Office of Personnel Management. The National Defense Authorization Act for Fiscal Year 2004 requires all Federal Government agencies to conduct annual surveys of employees to assess their satisfaction with leadership policies and practices. Pub. L. No. 108-136, § 1128, 117 Stat. 1392, 1641 (2003); 5 C.F.R. §§ 250.301–03.

⁵⁹The lack of career advancement was also noted by four BIMO investigators that we interviewed as a reason for why BIMO investigators have left for other opportunities.

- **BIMO suggestion box.** To better address areas for improvement, FDA implemented a suggestion box allowing BIMO investigators to anonymously submit suggestions for improvements every quarter. The suggestions are reviewed by management and discussed with staff during brown bag sessions.

Although FDA has taken steps to increase recruitment and address retention, the agency does not know which of the various efforts have been effective. We have identified key principles for effective strategic workforce planning.⁶⁰ These state that agencies should evaluate progress toward reaching their human capital goals and the contribution of human capital activities toward achieving programmatic goals. Agency officials told us they discuss recruitment efforts weekly to determine which efforts are working and have started to look into employee exit survey data to give them more insight into reasons why BIMO investigators have left. However, FDA officials said the agency has not formally evaluated these recruitment and retention efforts to determine their effectiveness or where additional efforts may be necessary. According to FDA officials, ORA had directed staffing resources to recruiting new BIMO investigators to fill vacancies and did not have the staffing resources available to conduct an evaluation simultaneously. As many BIMO investigator vacancies have recently been filled, conducting an evaluation could help FDA officials determine the effectiveness of the agency's current recruitment and retention efforts for these positions—such as increased pay, student loan repayment, and other financial incentives—and ensure the agency is using the most appropriate tools to maintain its BIMO investigator workforce.⁶¹ Having a sufficient number of BIMO investigators and a more experienced workforce is important for the oversight of the clinical research that helps to assure the quality of the data used to approve the brand and generic drugs that Americans consume every day.

⁶⁰See [GAO-04-39](#).

⁶¹We made multiple related recommendations to FDA in January 2022 to address the agency's challenges in recruiting and retaining qualified staff to meet its workforce needs. Specifically, we recommended that FDA (1) develop and implement an agency-wide strategic workforce plan, (2) update its plan on an ongoing basis, and (3) develop tailored strategies focused on recruiting and retaining current FDA investigators conducting foreign inspections of drug manufacturing establishments. FDA concurred with these recommendations and is taking steps to address them. See GAO, *FDA Workforce: Agency-Wide Workforce Planning Needed to Ensure Medical Product Staff Meet Current and Future Needs*, [GAO-22-104791](#) (Washington, D.C.: Jan. 14, 2022), and [GAO-22-103611](#), respectively. Additionally, FDA's challenges recruiting and retaining staff has also contributed to the agency's continued inclusion on GAO's high-risk list, see [GAO-23-106203](#).

Conclusions

FDA's BIMO inspections are a key tool to ensure the quality and integrity of the clinical research informing the agency's approval of brand-name and generic drugs and the protection of human subjects in that research. The agency has already taken steps to strengthen its inspection oversight by beginning an update of key regulations. However, the agency continues to conduct many fewer inspections than it did during its peak in fiscal year 2017, despite identifying a high need for these inspections. Further, attrition over several years has left it with a less experienced workforce and less capacity to conduct needed inspections.

The agency has implemented retention efforts—such as student loan repayment and other financial incentives—and has recently had success recruiting BIMO investigators. However, given the persistence of these challenges, evaluating these efforts would help FDA ensure it is using the most appropriate tools to fill vacancies and reduce attrition. Using the most appropriate tools would also allow the agency to increase the number of BIMO inspections it conducts to better meet the agency's needs to ensure the brand and generic drugs that Americans consume every day are safe and effective. These challenges are not unique to the BIMO program, and workforce has been a concern across multiple FDA programs, contributing to FDA's oversight of drugs and other medical products being included on our High-Risk List. Therefore, sustained attention from the agency in this area will be critical.

Recommendation for Executive Action

The Commissioner of FDA should evaluate its recruitment and retention efforts for BIMO investigators—such as increased pay, student loan repayment, and other financial incentives—to determine their effectiveness and incorporate results of this evaluation as appropriate to help ensure the agency is using the most appropriate tools to maintain its BIMO investigator workforce. (Recommendation 1)

Agency Comments

We provided a draft report to HHS for comment, of which FDA is a part. In its written comments, reproduced in appendix I, HHS concurred with our recommendation. HHS said that FDA is committed to reviewing and

evaluating current and recently used recruitment and retention efforts and exploring if additional incentives could be utilized. It also said FDA will incorporate the results of such an evaluation, as appropriate, to ensure the agency is using the most appropriate tools to maintain its BIMO investigator workforce. HHS also provided technical comments, which we incorporated as appropriate.

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

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.

A handwritten signature in black ink that reads "Mary Denigan-Macauley". The signature is written in a cursive style with a long horizontal flourish at the end.

Mary Denigan-Macauley
Director, Health Care

List of Requesters

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
House of Representatives

The Honorable Brett Guthrie
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable H. Morgan Griffith
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

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

**Appendix I: Comments from the Department of
Health and Human Services**



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

February 2, 2024

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mary Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"CLINICAL RESEARCH: FDA Should Evaluate its Efforts to Recruit and Retain its Inspection Workforce" (GAO-24-106383)**.

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

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH & HUMAN SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – CLINICAL RESEARCH: FDA SHOULD EVALUATE ITS EFFORTS TO RECRUIT AND RETAIN ITS INSPECTION WORKFORCE (GAO-24-106383)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and provide comments on the Government Accountability Office's (GAO) draft report.

GAO Recommendation

The Commissioner of FDA should evaluate its recruitment and retention efforts for BIMO investigators—such as increased pay, student loan repayment, and other financial incentives—to determine their effectiveness and incorporate results of this evaluation as appropriate to help ensure the agency is using the most appropriate tools to maintain its BIMO investigator workforce.

HHS Response

FDA concurs with the recommendation to evaluate retention and recruitment efforts for BIMO investigators. FDA is committed to reviewing and evaluating current hiring and retention efforts, evaluating hiring and retention tools that have been utilized in the last three years, and other existing data to assess the effectiveness of efforts. FDA will also determine if there are additional incentives that could be applied within the BIMO program to aid in future recruitment and retention efforts. FDA will incorporate the results of the evaluation, as appropriate, into our hiring and retention efforts to ensure the agency is using the most appropriate tools to maintain its BIMO investigator workforce.

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

February 2, 2024

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Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

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GAO Contact

Appendix II: GAO Contact and Staff Acknowledgments

Mary Denigan-Macauley, (202) 512-7114 or
DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the contact named above, William Hadley (Assistant Director), Rebecca Hendrickson (Analyst-in-Charge); Presley Cannon-Stewart, Taneeka Hansen, and Ashley Nurhussein made key contributions to this report. Also contributing were Sonia Chakrabarty, David Jones, Laurie Pachter, and Dan Ries.

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