



December 2022

CANCER CLINICAL TRIALS

Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients

GAO Highlights

Highlights of [GAO-23-105245](#), a report to congressional committees

Why GAO Did This Study

Diverse representation in clinical trials is important to ensure the safety and efficacy of treatments for the patient population likely to use the treatment being studied. It is also important from an equity perspective as these trials often represent the best available health care. Despite more than 3 decades of government policies intended to improve clinical trial diversity, certain groups remain consistently underrepresented in cancer clinical trials. Those groups include certain racial and ethnic groups, adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities.

The Henrietta Lacks Enhancing Cancer Research Act of 2019 and House Appropriations Report 116-450 each included a provision that GAO study diverse representation of patients in cancer clinical trials. This report describes (1) actions federal agencies have taken to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials and (2) practices used by selected non-federal cancer centers to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials.

GAO interviewed officials and reviewed documents from federal agencies that fund or conduct cancer clinical trials. GAO also identified 17 cancer centers with a history of enrolling diverse populations in cancer clinical trials and asked them to describe relevant practices that facilitated such enrollment. GAO identified practices facilitating diverse enrollment that were described by or about these centers.

View [GAO-23-105245](#). For more information, contact John E. Dicken 202-512-7114, dickenj@gao.gov

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CANCER CLINICAL TRIALS

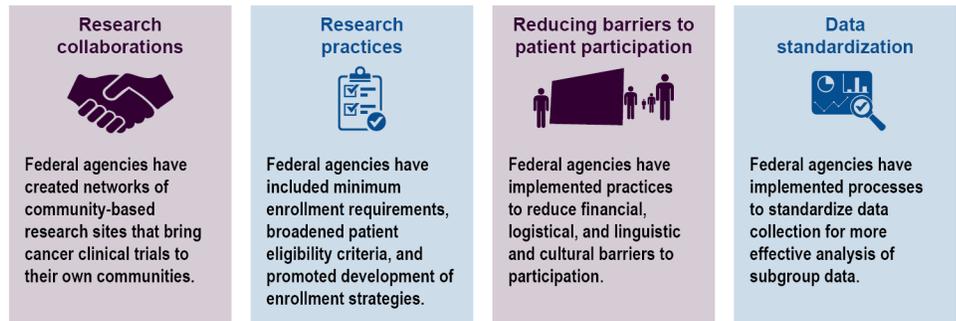
Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients

What GAO Found

GAO found that both federal agencies and selected non-federal cancer centers took actions to facilitate participation of patients from diverse backgrounds in cancer clinical trials. Generally, these actions addressed a variety of barriers to participation that are often cited in the literature.

The Department of Health and Human Services, Department of Defense, and Department of Veterans Affairs took actions that have the goal of increasing the proportion of patients from diverse backgrounds enrolled in federally funded cancer clinical trials. These efforts are focused on developing research collaborations, modifying research practices, reducing barriers to patient participation, and collecting and sharing data.

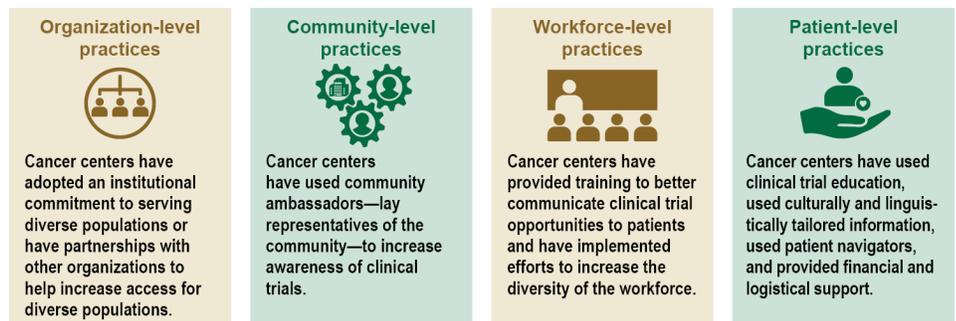
Federal Actions to Facilitate Diversity in Cancer Clinical Trials



Source: GAO analysis of information from the Department of Defense, Department of Health and Human Services, and Department of Veterans Affairs. | GAO-23-105245

The 17 non-federal cancer centers in GAO's review implemented practices to facilitate the enrollment of patients from diverse backgrounds that were focused on four areas: organization, community, workforce, and patients. Fifteen of the centers implemented practices in at least three of these four areas.

Selected Cancer Center Practices to Facilitate Diversity in Cancer Clinical Trials



Source: GAO analysis of information about the 17 selected cancer centers. | GAO-23-105245

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Abbreviations

CDMRP	Congressionally Directed Medical Research Programs
CMS	Centers for Medicare & Medicaid Services
DOD	Department of Defense
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NCI	National Cancer Institute
NIH	National Institutes of Health
VA	Department of Veterans Affairs

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December 19, 2022

Congressional Committees

Diverse patient representation in clinical trials is important to ensure the safety and efficacy of treatments for the population likely to use the treatment being studied.¹ Ideally, these trials analyze differences in the safety or efficacy of a treatment amongst different groups to identify biological and social factors that may affect health. For some drugs, these differences have resulted in population-specific information in labeling about dosage or warnings.² In addition, diverse representation among patients in clinical trials is important to ensure equity, such that all individuals have access to clinical research, which in many settings, represents the best available health care.³

The federal government has made increasing diversity in clinical trials a policy focus for more than 3 decades, yet numerous groups remain underrepresented. For example, the National Institutes of Health (NIH) was mandated to include women and persons from racial and ethnic groups other than non-Hispanic White populations in clinical trials.⁴ However, an analysis that searched NIH's clinical trials data base in January 2013 found that NIH's National Cancer Institute (NCI) sponsored or co-sponsored 10,000 clinical trials, and that less than 2 percent of these trials focused on racial or ethnic groups other than non-Hispanic

¹The National Institutes of Health (NIH) defines a clinical trial as a research study in which one or more human subjects are prospectively assigned to one or more interventions that may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. In other words, patients or participants are assigned to a treatment option (which may include one that is actually no treatment, such as with a pill that has no medical component. NCI notes that its definition of clinical trials includes trials to test new methods of screening, prevention, diagnosis, or treatment.

²See B. E. Bierer et al., *Achieving Diversity, Inclusion, and Equity in Clinical Research: Guidance Document Version 1.1* (Cambridge and Boston, MA: Multi-Regional Clinical Trials (MRCT) Center of Brigham and Women's Hospital and Harvard, 2021). accessed July 6, 2021 <https://mrctcenter.org/diversity-in-clinical-trials/>

³National Academies of Sciences, Engineering, and Medicine, *Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups* (Washington, DC: The National Academies Press, 2022) accessed May 17, 2022, <https://doi.org/10.17226/26479>.

⁴National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 131, 107 Stat. 122, 133-35.

White.⁵ Further, a study that examined all cancer drug approvals granted by the Food and Drug Administration (FDA) from July 2008 through June 2018 found that Black and Hispanic patients in the U.S. were consistently underrepresented in the clinical trials supporting those drug applications when compared to the proportion of cancer incidence and mortality among Blacks and Hispanics in the U.S.⁶ Other groups, such as adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities have also been underrepresented in cancer clinical trials.

The Henrietta Lacks Enhancing Cancer Research Act of 2019 and House Appropriations Report 116-450 each included a provision that we study the diverse representation of patients in cancer clinical trials.⁷ This report describes

1. actions federal agencies have taken to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials and
2. practices used by selected cancer centers to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials.

In this report, we focused on groups of patients from diverse backgrounds in terms of racial and ethnic groups, adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities because they were either specified in the legislation or had been cited in scientific literature as underrepresented groups in clinical trials.

To describe actions federal agencies have taken to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials, we interviewed officials from federal agencies that fund or conduct cancer clinical trials,

⁵The review notes that other trials may have included patients from a variety of racial and ethnic groups, but such groups were not the primary focus. M. S. Chen et al., "Twenty Years Post-NIH Revitalization Act: Renewing the Case for Enhancing Minority Participation in Cancer Clinical Trials," *Cancer*, vol. 120, no. 7 (2014).

⁶J. M. Loree et al., "Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals from 2008 to 2018." *JAMA Oncology*, vol. 5, no. 10 (2019).

⁷Pub. L. No. 116-291, § 3, 134 Stat. 4894, 4895 (2021); H.R. Rep. No. 116-450, at 93 (2020). The Henrietta Lacks Enhancing Cancer Research Act of 2019 includes a Congressional finding that scientists used tumor cells from Henrietta Lacks for more than 20 years, without her or her family's consent. The cells have contributed to many scientific advances such as the development of the polio vaccine and other drug treatments.

and develop and maintain policies related to such trials. Specifically, we interviewed officials from agencies within the Department of Health and Human Services (HHS)—including NIH, FDA, and the Centers for Medicare & Medicaid Services (CMS)—the Department of Veterans Affairs (VA), and the Department of Defense (DOD). We also reviewed and analyzed documents from these agencies outlining relevant policies, procedures, and programs related to clinical trial participation.

To describe practices used by selected cancer centers to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials, we first identified non-federal cancer centers that have been effective at enrolling such patients or recognized in published literature for enrolling diverse populations in cancer trials.⁸ To do so, we conducted a literature search and interviewed stakeholders. We used the literature search to identify articles demonstrating the ability to enroll patients from diverse groups in cancer clinical trials, or review articles that recognized such centers. We also asked stakeholders to identify cancer centers that have been effective in enrolling patients from diverse backgrounds in cancer clinical trials or articles that might provide such information. Based on this, we identified 17 cancer centers that met our selection criteria and focused on cancer clinical trials. We use the word “centers” to describe these cancer centers and institutes.⁹ We asked officials from the 17 selected centers to identify relevant practices that facilitate enrollment of patients from diverse backgrounds in cancer clinical trials through a questionnaire we provided. We did not independently verify the information reported by the centers in their response to the questionnaires we sent them. We also reviewed documents provided by the centers and published literature about the centers.

To address both objectives, we also conducted interviews with a range of stakeholders who could provide a variety of perspectives on issues related to diversity in cancer clinical trials, actions taken by the federal government, and practices for facilitating enrollment of diverse groups of patients in cancer clinical trials. Specifically, we interviewed representatives from four organizations that represent a variety of perspectives in patient advocacy, six that represent clinical research, and

⁸For the purposes of this report, cancer centers are health care organizations and groups of health care organizations that provide care for people with cancer and conduct cancer clinical trials.

⁹The centers we identified for this report do not constitute all cancer centers that have had increased enrollment of diverse populations into cancer clinical trials.

three that represent the pharmaceutical industry. We identified these stakeholders through our review of literature and these interviews. The information we obtained from these interviews with stakeholders is not generalizable; however, it provides insight into issues related to diversity in cancer clinical trials. (A detailed description of our scope and methodology is in app. I.)

We conducted this performance audit from May 2021 to December 2022 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

Clinical Trials

Clinical trials are studies to test new drugs, already approved drugs, devices, or other forms of treatment, prevention, or supportive care. Clinical trials provide data about the safety and effectiveness of medical products and health care interventions. Funders of clinical trials are also referred to as clinical trial sponsors. Generally, trial sponsors evaluate the design of a clinical trial, often using a technical review process such as peer review, and with require the approval of an Institutional Review Board.¹⁰

Clinical trial settings. Clinical trials can take place in a variety of settings (e.g., academic hospitals, community hospitals, and specialty treatment centers) and geographic locations. Some clinical trials may be led by a particular research institution, such as a cancer center, but also have multiple community sites that enroll and treat patients in the trial.

Clinical trial funding. Most clinical trials that lead to drug approvals are funded by pharmaceutical companies, and most participants in cancer clinical trials are enrolled outside of the U. S. For example, one study found that of the trials funded in 2014, the number of clinical trials funded

¹⁰Institutional Review Boards are formal groups that review and monitor research involving human participants. The groups have the power to approve, require modifications to, or disapprove research. The groups serve to protect the rights and welfare of the participants.

by the pharmaceutical industry was more than 6 times greater than the number funded by NIH.¹¹ In the case of cancer clinical trials, those not funded by pharmaceutical companies are typically funded by federal agencies, academic institutions, and other organizations. The American Cancer Society Cancer Action Network reported that the trials funded by NCI tend to compare one treatment approach against another, whereas those funded by pharmaceutical companies are designed to receive FDA approval for either new drugs or new uses of an already approved drug.¹² FDA has reported that for clinical trials used to support new drugs from 2015 through 2019, 65 percent of clinical trial participants are enrolled in trial settings outside of the U.S.¹³

Clinical trial staff. Clinical trials are led by a principal investigator who is typically a physician. We refer to these principal investigators as “researchers” in this report. These researchers generally have control over the details of the trial, including how participants are recruited and enrolled into the trial, and the data that the trial will gather. They also are responsible for providing oversight of the trial to ensure it is conducted in accordance with the plans. The clinical trial staff may include staff such as research nurses who educate patients about a trial; doctoral-level researchers—such as statisticians and population scientists—who provide expertise in developing the trial structure; staff who manage the collection of data throughout the trial; and physicians, nurses, and other health care providers who provide medical care to clinical trial patients as needed.

Clinical trial participants. Clinical trial participants are those people who enroll in a clinical trial. They may be people with a particular disease or they may be healthy volunteers. Participants may learn about trials from their doctor or from online clinical trial databases. They must meet certain eligibility criteria set by the trial to participate; these criteria can include characteristics such as age, sex, the type and stage of their disease, their

¹¹S. Ehrhardt, L. J. Appel, and C. L. Meinert, “Trends in National Institutes of Health Funding for Clinical Trials Registered in ClinicalTrials.gov,” *JAMA*, vol. 314, no. 23 (2015).

¹²American Cancer Society Cancer Action Network, *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report*, 2018. Accessed June 7, 2021 <https://www.fightcancer.org/policy-resources/barriers-patient-enrollment-therapeutic-clinical-trials-cancer>

¹³Food and Drug Administration, *2015-2019 Drug Trials Snapshot: Summary Report*, November 2020.

previous medical treatment, and other medical conditions. For purposes of this report, we refer to clinical trial participants as “patients.”

Federal Agencies That Fund and Conduct Cancer Trials

Federally funded cancer clinical trials are primarily funded by HHS agencies such as NIH, and within NIH, specifically NCI. Other agencies that fund or conduct cancer trials include DOD, through the Congressionally Directed Medical Research Programs (CDMRP) and the John P. Murtha Cancer Center; and VA. The agencies may award funds to researchers outside of the federal government through a competitive process whereby researchers submit grant applications to the funding agency, or they may provide those funds to agency researchers within the federal government to conduct the trials. For some agencies, competitive grants may be renewed by the agencies, sometimes requiring a renewal application. CDMRP, on the other hand, requires that all research funding be openly competed, so those wishing to apply for follow-on or additional funding must submit new applications to be evaluated through a review process.

NIH

NIH’s NCI is the federal government’s principal agency for cancer research and training. NCI has 30 divisions, offices, and centers that work together on its cancer research agenda and the institute supports trials through a number of different trial networks and programs. For example, NCI supports the National Clinical Trials Network, a collection of organizations and clinicians that coordinates and supports cancer clinical trials at more than 2,200 sites worldwide. NCI also supports the NCI Community Oncology Research Program, a national network of sites that expands the reach of the National Clinical Trials Network and provides infrastructure for conducting clinical trials focused on cancer prevention, screening, supportive care and symptom management, surveillance, health-related quality of life, and cancer care delivery. These sites then operate more than 1,000 research sites to bring cancer clinical trials and care delivery studies to people in their own communities. In fiscal year 2021, NCI received \$6.35 billion in funding.

DOD

DOD has two primary organizations that fund cancer research.

- CDMRP originated via a Congressional appropriation in 1992 to foster novel approaches to biomedical research. CDMRP is located within the U.S. Army Medical Research and Development Command, which is the largest medical research enterprise within DOD. CDMRP administers research programs targeting specific cancers or cancer topics as directed by Congress. Awards of these CDMRP funds must be openly competed and may be made to both DOD and non-DOD

organizations. In fiscal year 2022, CDMRP received \$1.54 billion in appropriations for all 35 of its research program areas. Of those funds, \$585 million were directed to its 10 cancer research program areas; however, these funds support more than just clinical trials.

- John P. Murtha Cancer Center at the Walter Reed National Military Medical Center is the DOD Cancer Center of Excellence. DOD provides \$30 million in direct funding to Murtha Cancer Center to conduct state-of-the-art clinical care and innovative research, including clinical trials for the military and its beneficiaries.

VA

VA's Office of Research and Development has a strategic priority to increase veterans' access to high-quality clinical trials. Within VA's Office of Research and Development, the VA Cooperative Studies Program plans and conducts large, multicenter clinical trials and epidemiological studies, including those for cancer. The Cooperative Studies Program received more than \$104 million in funding in fiscal year 2021.

Federal Agencies with Roles Other Than Funding or Conducting Clinical Trials

FDA, NIH, and CMS, all within HHS, have a role related to clinical trials other than funding or conducting trials. This includes the issuance of guidance and regulations, and development of policies for those conducting clinical trials.

- One of FDA's roles is to help ensure the safety and efficacy of drugs. It does so by reviewing applications for new drugs, and issuing guidance and regulations related to the study of drugs, including clinical trials.
- NIH issues guidance and policies related to the conduct of clinical trials it funds. (A list of FDA and NIH guidance and policy related to diversity in clinical trials is in app. II.)
- Since 2000, CMS has paid for routine patient care costs for Medicare beneficiaries participating in clinical trials.¹⁴ Generally, CMS defines routine costs as those items or services provided to an individual under a qualifying clinical trial, including those provided to diagnose or treat complications resulting from participation in the trial, if they would have been otherwise covered outside of the trial.

¹⁴Medicare is the federally financed health insurance program for persons aged 65 and over, certain individuals with disabilities, and individuals with end-stage renal disease.

-
- CMS also pays for routine patient care costs for Medicaid beneficiaries participating in clinical trials.¹⁵ In December 2020, a law was enacted requiring Medicaid coverage of routine costs associated with clinical trial participation.¹⁶ Prior to this, states had flexibility to limit such coverage, and some states chose not to cover such services. As of January 2022, states are required to cover routine costs associated with participation in clinical trials.

Barriers Affecting Patient Enrollment in Cancer Trials

The multitude of barriers that affect the enrollment of patients into clinical trials has been described in published research. Some of the barriers frequently mentioned include the following.

- **Unconscious bias.** Unconscious bias is when stereotypes or cultural concepts influence behavior without realization. Unconscious bias can influence all stages of the clinical trial process, beginning with which patients are told about the availability of a clinical trial. One report found that this bias, based on misconceptions or assumptions about race, ethnicity, socioeconomic status, or other patient characteristics can affect a health care provider’s decision to mention the option of clinical trial participation to a patient.¹⁷
- **Mistrust and historical discrimination.** Research has shown that many patients from underrepresented racial and ethnic groups have a general mistrust of medical research stemming from historical and contemporary instances of racism and research misconduct.¹⁸ Research has shown that a lack trust in research, investigators, and

¹⁵Medicaid is a joint federal-state health care financing program for certain low-income and medically needed individuals.

¹⁶Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, div. CC, tit. II, § 210, 134 Stat. 1182, 2989-92.

¹⁷Case Comprehensive Cancer Center, “*Unconscious Bias: An Introduction*” (Cleveland, OH: Case Western University, 2015), accessed December 16, 2021, <https://case.edu/cancer/research/clinical-research-office/minority-accrual-committee/cultural-inclusion-and-awareness/unconscious-bias-introduction>

¹⁸M. Awidi and S. A. Hadidi, “Participation of Black Americans in Cancer Clinical Trials: Current Challenges and Proposed Solutions,” *JCO Oncology Practice*, vol. 17, no. 5 (2021); B. Nazha, M. Mishra, R. Pentz, and T. K. Owonikoko, “Enrollment of Racial Minorities in Clinical Trials: Old Problem Assumes New Urgency in the Age of Immunotherapy,” *ASCO Educational Book* (2019). J. G. Ford et al., “Barriers to Recruiting Underrepresented Populations to Cancer Clinical Trials: A Systematic Review,” *Cancer*, vol. 112, no. 2 (2008).

Availability of prostate cancer trials by county and population

One study of Black men—whose incidence rate of prostate cancer is 70 percent greater than that of White men and whose mortality rate is 2.5 times higher than White men—looked at availability of prostate cancer clinical trials by county and population. It found that the counties with a higher proportion of Blacks were less likely to have access to both cancer facilities and prostate cancer trials.

Source: W-J. Wang, S. D. Ramsey, C. S. Bennette, and A. Bansal, "Racial Disparities in Access to Prostate Cancer Clinical Trials" A County-Level Analysis." *JNCI Cancer Spectrum*, vol. 6, no. 1 (2022). | GAO-23-105245

Importance of location and setting

One study reported engaging Black patients in health interventions in community barbershops or predominately Black-serving churches was a key to success. The authors noted that the locations provided the patients with a familiar setting and trusted individuals and that location convenience was essential.

Source: C. R. Rogers et al., "Barriers to and Facilitators of Recruitment of Adult African American Men for Colorectal Cancer Research: An Instrumental Exploratory Case Study," *JCO Oncology Practice*, vol. 17, no. 5 (2021) | GAO-23-105245

the research system, and fear of being treated "as a guinea pig" can be a barrier to participation in clinical trials.¹⁹

- **Location.** A clinical trial's location may also be a barrier for a variety of reasons. First, clinical trials are often at major cancer centers or other sites where individuals from traditionally underrepresented groups are less likely to receive care, and may not be near where certain patients live.²⁰ For example, one study assessing the economic burden of cancer patients in early-phase clinical trials from a cancer center in Houston, Texas, found that half of the patients studied lived more than 300 miles from the clinic conducting the trial, and another 27 percent lived more than 101 miles away.²¹

For many reasons, it may be important to have trials be conducted where patients and caregivers are in order to improve awareness, access, and trust, all of which have been cited as barriers to participation.²²

- **Inclusion and exclusion criteria.** A clinical trial's inclusion and exclusion criteria—the factors that determine whether a patient is eligible to participate—may have bias embedded in them. Such criteria might include biological factors that result in bias toward certain individuals. For example, some of these eligibility factors (such as blood pressure) may vary between racial and ethnic groups and may therefore result in the exclusion of certain groups.

¹⁹B. E. Bierer et al., *Achieving Diversity*.

²⁰See Awidi and Hadidi, "Participation of Black Americans;" American Society of Clinical Oncology, *Improving Diversity in Clinical Trial Participation: Policy Brief*, (Oct. 2020), accessed July 7, 2022, <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020-CTDiv-Brief.pdf>; J. M. Unger et al., "Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation." *JNCI: Journal of the National Cancer Institute* Vol. 111 (2019), 245-255.

²¹Early-phase clinical trials are the first tests of a particular treatment and usually involve small groups of people. R. W. Huey et al., "Patient-Reported Out-of-Pocket Costs and Financial Toxicity During Early-Phase Oncology Clinical Trials," *The Oncologist*, vol. 26 (2021).

²²The Deloitte Center for Health Solutions and Pharmaceutical Research and Manufacturers of America, "Enhancing Clinical Trial Diversity: Stakeholder Perspectives on Advancing Research Through Representative Clinical Trials" (2021).

Lessons in cultural competence

One study identified lessons learned with increasing participation of American Indian/Alaska Natives in genetic research that can increase diverse representation in other research. Understanding that a lack of cultural competence can be a barrier, the authors recommended approaches that use cultural sensitivity to foster trust through the following:

- Becoming familiar with tribal governance and structure because each tribe is unique and culturally distinct
- Building trust with the community by learning the tribe's history of involvement with research; including by spending time in the community, and engaging stakeholders throughout the research process
- Becoming culturally attuned
- Being straightforward with expectations and ideal communication strategies
- Developing a research agreement and plan for using data
- Ensuring the study is review by the tribe for ethical and cultural considerations
- Providing the tribe with resources and personnel to support the study
- Balancing the need for scientific knowledge with the benefit to the community

Source: D. M. Carroll et al., "Recommendations to Researchers for Aiding in Increasing American Indian Representation in Genetic Research and Personalized Medicine," *Personalized Medicine*, vol. 18, no. 1 (2021). | GAO-23-105245

- **Cultural competence, linguistic, and literacy factors.** Cultural competence includes understanding and respect of the diversity of a patient population, including factors such as language, communication styles, beliefs, attitudes and behaviors. Having staff of a trial that shares cultural characteristics with the patients can facilitate participation.²³ Other barriers have to do with language. For example, the language used in consent forms can be difficult for patients to understand. Further, trial materials may not be offered in the native language of a patient. At the same time, some have noted that translating consent forms can be costly and those costs are rarely covered in research budgets.²⁴
- **Costs and other logistical barriers.** The costs of participating in a clinical trial can reduce a patient's ability to enroll or continue participating. Such costs include:
 - Investigational care costs are costs associated with the drug being studied and related services that would not otherwise be required such as blood tests for safety data and are covered by the sponsor of the clinical trial.
 - Routine care costs are direct medical costs for those services that would have been provided to a patient even without their participation in a clinical trial such as services for therapy or prevention of complications. These costs are typically covered by insurance, or if denied by insurance or the patient lacks insurance, by the patient themselves.
 - The third type of costs are nonmedical, out-of-pocket costs, such as lodging and meals, transportation, and dependent care or childcare. These costs are typically the responsibility of the patient.

²³Bierer et al., *Achieving Diversity*.

²⁴J. M. Kahn et al., "Strategies to Improve Diversity, Equity, and Inclusion in Clinical Trials," *Cancer*, (Jan. 15, 2022).

Out-of-pocket costs

One study found that overall, 48 percent of the patients in cancer clinical trials had monthly out-of-pocket costs of at least \$1,000. They also found that patients used a variety of sources to pay those costs including using savings, withdrawing money from retirement accounts, borrowing money from friends and family, having a fundraiser, and working extra hours or an additional job.

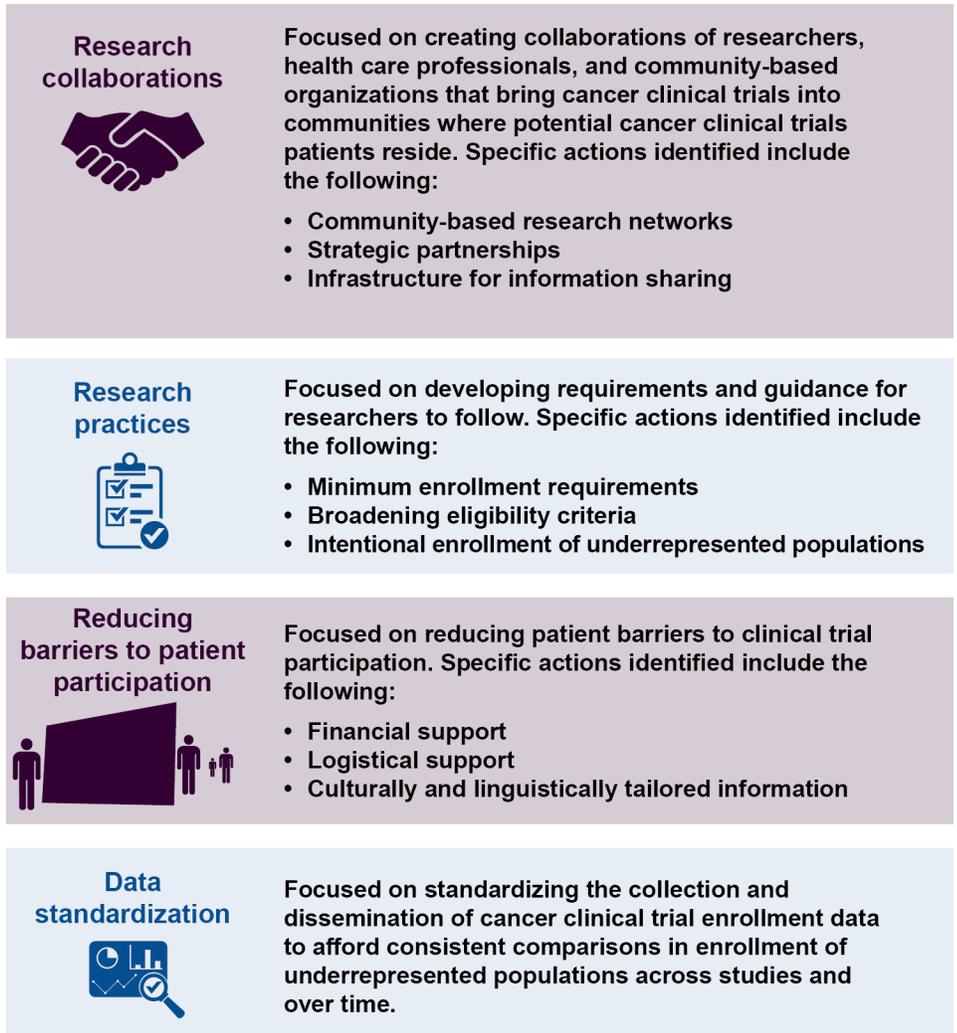
Source: R. W. Huey et al., "Patient-Reported Out-of-Pocket Costs and Financial Toxicity During Early-Phase Oncology Clinical Trials," *The Oncologist*, vol. 26 (2021). | GAO-23-105245

Logistical barriers that have indirect costs for patients include the time commitment, loss of income, and family considerations. As certain racial and ethnic groups are affected more by lower incomes and are more likely to have jobs based on an hourly wage, these costs make it harder for them to fit clinical trial participation into their schedule. However, many trials do not provide reimbursement for nonmedical costs of participating in a trial because of concerns that reimbursement for costs may be seen as an inducement to participation in a clinical trial.

A Range of Federal Actions Focus on Enrolling a Diverse Group of Patients in Cancer Clinical Trials

DOD, HHS, and VA are engaged in a range of actions that facilitate enrollment of a diverse group of patients in federally funded cancer clinical trials. These actions include developing research collaborations, modifying research practices, reducing barriers to patient participation, and collecting and sharing data. (See fig. 1 for a summary of federal actions within each category.)

Figure 1: Categories of Federal Actions to Facilitate Enrollment of a Diverse Group of Patients in Cancer Clinical Trials



Source: GAO analysis of information from the Department of Defense, Department of Health and Human Services, and Department of Veterans Affairs. | GAO-23-105245

Federal Actions Focused on Research Collaborations

According to agency officials and reviews of agency documentation, federal agencies have created collaborations of researchers, health care professionals, and community-based organizations that bring cancer clinical trials into communities where potential patients from underrepresented populations live. These collaborations have (1) created research networks in the communities where patients live, (2) developed strategic partnerships with institutions serving patients from

underrepresented populations, and (3) established an infrastructure for researchers to collaborate and share information.

Community-based research networks. NCI and VA have created networks of multiple clinical trial research sites placed within communities, which can enable sustained community interaction that has been shown to build trust and establish meaningful relationships with patients. Interacting directly with communities fosters the input of community stakeholders, which can help clinical trial teams incorporate community feedback into research design and identify individuals and organizations that can help facilitate the enrollment of a diverse group of patients in cancer clinical trials. Examples of community-based networks include the following:

- The NCI Community Oncology Research Program is a national network of seven research bases that provide scientific and statistical leadership in developing, implementing, and analyzing clinical trials. The program also includes 46 community sites that bring cancer clinical trials to patients in their own communities. One of the goals of the program is to bring clinical research studies to patients in their own communities so the evidence generated from clinical trials can contribute to improved patient outcomes for all people. One feature of the program is that 14 of the 46 sites are Minority/Underserved Community Sites, which are those for which at least 30 percent of the patient population is comprised of racial and ethnic groups other than non-Hispanic White or rural residents. The program enrolls patients in NCI-supported clinical trials at approximately 1,000 affiliate hospitals and cancer centers.
- The NCI and VA Interagency Group to Accelerate Trials Enrollment partnership between NCI and VA facilitates enrollment of veterans with cancer, including patients from diverse backgrounds, into NCI-funded clinical trials. This partnership helps bring NCI clinical trials to VA patients so that they do not have to seek treatment outside of the VA health care system. The goal is to build the capacity of VA Medical Centers with dedicated staffing and sustainable infrastructure so they can offer NCI clinical trials in the future. VA officials stated that this structure provides local support, which can help VA Medical Centers identify site-specific challenges related to clinical trial execution.

Strategic partnerships. DOD, FDA, and NCI have established strategic partnerships with organizations serving underrepresented populations, including health care and educational institutions and consumer advocacy organizations. Research has shown that the goal of these partnerships is

to create collaborations with organizations already working with patient communities to build trust and design clinical trials that are more inclusive of underrepresented communities. Examples of federal strategic partnerships include the following:

- According to officials, cancer programs managed by DOD's CDMRP have encouraged multi-institutional collaboration with institutions and outreach programs at university hospitals, cancer treatment centers, and minority-serving institutions. These types of collaborations may help increase diversity in the research community, which can reduce barriers affecting enrollment of certain underrepresented populations. Some CDMRP-funded cancer researchers also partner with patient advocates and consumer advocacy organizations throughout the clinical trial enrollment process to develop relationships and build trust. Some CDMRP cancer funding opportunities require such partnerships.
- FDA's Oncology Center of Excellence conducts an initiative called Project Equity to promote research practices and policies that facilitate enrollment of a diverse group of patients.²⁵ It does this through outreach and partnerships with oncology stakeholders, including academic organizations, pharmaceutical sponsors, regulatory agencies, and professional organizations. FDA officials stated that collaborations with stakeholders through Project Equity have explored ways to improve trial design and trial conduct that can generate clinical trial results across a diverse group of patients.
- NCI's Center to Reduce Cancer Health Disparities oversees the Partnerships to Advance Cancer Health Equity program that provides institutional awards for the development of partnerships between NCI-designated cancer centers and institutions focused on underrepresented populations. NCI officials stated that the partnerships are focused on increasing cancer research education for students and improving the effectiveness of cancer care in underserved communities. The program establishes partnerships through two funding mechanisms, one directly supporting researchers and one focused on building long-term relationships with institutions.

Infrastructure for information sharing. DOD, NCI, and VA research networks provide an infrastructure for network members to share information, such as best practices for enrolling patients from

²⁵See <https://www.fda.gov/about-fda/oncology-center-excellence/project-equity>, accessed August 10, 2022.

underrepresented populations and feedback to clinical trial administrators. Examples of federal actions in this area include the following:

- Murtha Cancer Center officials told us that the center has an Oversight Committee comprised of senior leadership and external federal experts from VA and NCI that reviews clinical trial participation data and provides trial recommendations based on their findings. The Oversight Committee has made recommendations for ensuring the proper inclusion of eligible military and veteran patients. Agencies officials noted they serve populations with high proportions of persons from racial and ethnic groups other than non-Hispanic White.
- NIH officials stated that the NCI Community Oncology Research Program’s seven research bases and the NCI National Clinical Trials Network membership organizations each hold periodic meetings, which serve as a forum for NCI officials and local researchers to share research best practices that address clinical trial participation gaps.²⁶
- VA officials stated that the NCI and VA Interagency Group to Accelerate Trials Enrollment program coordinates clinical trial researchers by hosting monthly conference calls, sharing information via newsletters, and providing central logistical support. This allows researchers to share issues with trial administrators as they arise. For example, researchers and officials learned through these information-sharing meetings that existing trial inclusion and exclusion criteria often restricts participation of those with hearing loss, more common in veterans. VA officials were able to escalate this issue to NCI in an effort to make trial eligibility criteria more inclusive.

Federal Actions Focused on Research Practices

Federal agencies have undertaken actions to modify research practices with the goal of increasing the enrollment of a diverse group of patients. Federal actions include making recommendations for clinical trials researchers on setting minimum requirements for clinical trial enrollment, broadening patient eligibility criteria, and intentional enrollment of underrepresented populations.

Minimum enrollment requirements. The DOD CDMRP’s prostate and kidney cancer programs require consortium-led clinical trials to enroll a minimum of 5 percent of their patients from a diverse background, which includes factors such as race, geography, and socioeconomic status.

²⁶The National Clinical Trials Network consists of four adult cancer groups, one group focused solely on childhood cancers, and a Canadian Collaborating Clinical Trials Network.

DOD officials stated the programs monitor planned and actual enrollment annually through technical progress reports submitted by researchers. CDMRP officials noted that while there is no penalty for network sites that do not meet the 5 percent minimum, the minimum percentage provides encouragement to researchers to focus on enrollment of patients from diverse backgrounds. CDMRP officials told us that nine of 10 sites in the consortium have exceeded the 5 percent minimum enrollment of patients from underrepresented populations, with enrollment ranging from 9 to 42 percent.²⁷ For network sites under the minimum, CDMRP science officers meet with researchers and discuss strategies to increase enrollment for underrepresented groups.

Broadening eligibility criteria. FDA and NCI have developed guidance for researchers for developing inclusion and exclusion criteria that facilitate enrollment of a diverse group of patients. Broadening eligibility criteria can increase the potential pool of clinical trial patients, particularly those from diverse backgrounds, such as older adults and those from certain racial and ethnic groups historically underrepresented in clinical trials, without affecting the safety of patients or effectiveness of the trial.

FDA published guidance in 2020 to help facilitate the broadening of eligibility criteria so that patients enrolled in trials will better reflect the population most likely to use the drug if it is approved.²⁸ The guidance recommended research practices that include to avoid unnecessarily excluding patients, to adapt research studies based on ongoing findings, and to recruit patients with different levels of disease severity. As a result, this guidance promotes understanding of important safety and effectiveness information for all patients who may benefit from the drug after approval. FDA also published guidance regarding the inclusion of older adults in cancer clinical trials.²⁹

NCI, using recommendations from the American Society of Clinical Oncology and Friends of Cancer Research, developed guidance,

²⁷The only Clinical Consortium site under 5 percent had an underrepresented enrollment rate of 3.7 percent.

²⁸Food and Drug Administration, Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, *Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs, Guidance for Industry* (Silver Spring, Md.: Nov. 2020).

²⁹Food and Drug Administration, *Inclusion of Older Adults in Cancer Clinical Trials – Guidance for Industry*. (Silver Spring, Md.: Mar. 2022).

effective as of 2018, that includes recommendations for researchers to broaden clinical trial eligibility related to patients with multiple medical conditions and adolescent patients.³⁰ NCI merged these recommendations into a Generic Protocol Template that some NCI funding programs require clinical trials to use when developing eligibility criteria. NCI added additional criteria to the guidelines in response to recommendations made in May 2021 by American Society of Clinical Oncology and Friends of Cancer Research that sought to identify additional criteria that can pose significant barriers to clinical trial enrollment.³¹

Intentional enrollment of underrepresented populations. DOD, FDA, NIH, and VA have implemented practices that support strategies for enrolling a more diverse group of patients in clinical trials. Research has shown that considering recruitment goals and strategies for enrolling underrepresented populations early in a clinical trial can improve the effectiveness of increasing the enrollment of those patients.³² Some agencies have required researchers to include intentional enrollment strategies as a separate attachment to their funding applications. In addition, VA has provided a toolkit to help research teams incorporate these strategies into their clinical trials.

- Since October 2020, DOD’s CDMRP policy has required all applicants for clinical research funding to submit a proposed strategy for the recruitment of women and underrepresented populations, including enrollment estimates by sex and race/ethnicity, at the time they apply. CDMRP officials told us they created the requirement as a separate

³⁰National Cancer Institute, Cancer Therapy Evaluation Program, *Broadening/Modernizing Eligibility Criteria for National Cancer Institute (NCI) Sponsored Clinical Trials* (Bethesda, Md.: Dec. 2021). The continued use of commonly accepted eligibility criteria has been found to exclude certain populations (e.g., racial and ethnic groups other than non-Hispanic White, older adults) without strong clinical or scientific justification.

³¹The American Society for Clinical Oncology and Friends of Cancer Research published a paper that recommends the broadening of additional eligibility criteria. The recommendations seek to promote the inclusion of all populations who are anticipated to benefit from a therapy while excluding patients only where safety concerns warrant exclusion of patients with certain characteristics. See E. S. Kim et al., “Continuing to Broaden Eligibility Criteria to Make Clinical Trials More Representative and Inclusive: ASCO–Friends of Cancer Research Joint Research Statement,” *Clinical Cancer Research*, vol. 27, no. 9 (2021): 2394–2399.

³²S. H. Javid et al., “A prospective analysis of the influence of older age on physician and patient decision-making when considering enrollment in breast cancer clinical trials,” *Oncologist*, vol. 17, no. 9 (2012):1180–1190.

attachment in most of the funding opportunities to stress the importance of this part of the application.

- Murtha Cancer Center officials stated that the center’s strategy to promote diversity and equity in DOD cancer studies directs research consent staff who are hired to enroll patients into clinical trials to prioritize recruitment of underrepresented groups. Finally, the strategy tasks administrative research staff to review incoming cancer patients from racial and ethnic groups other than non-Hispanic White, identify those who would be eligible for clinical trials, and purposefully approach these patients to determine their interest in participating.
- FDA developed draft guidance in April 2022 with recommendations that clinical trial researchers and funders develop race and ethnicity diversity plans.³³ The draft guidance recommends that researchers establish enrollment goals based on the population of patients who will use the treatment, details strategies to enroll and retain patients from diverse backgrounds, and describes how differences in safety and effectiveness can be assessed by race and ethnicity.
- NIH’s two inclusion policies require funding applicants to submit inclusion enrollment plans as a component of the application.³⁴ The first policy states that applications should describe the proposed study population in terms of sex/gender and race/ethnicity. A second similar policy describes recommendations for age. Both policies state that applicants should provide a rationale for the selection. Any exclusion based on sex/gender, race/ethnicity, or age must include a scientific or ethics-based justification.
- VA’s Women’s Health Research Network, in collaboration with the VA Cooperative Studies Program, developed a toolkit of resources that can be used to better support researchers in enhancing participation of women veterans in clinical trials. The toolkit includes recruitment

³³Food and Drug Administration, *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry, Draft Guidance* (Silver Spring, Md.: Apr. 2022); the 60-day comment period ended on June 13, 2022, and FDA officials said that when final, this guidance will reflect FDA’s current thinking on this topic.

³⁴National Institutes of Health, *NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research* (Bethesda, Md.: Oct. 2001); National Institutes of Health, *Revision: NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects* (Bethesda, Md.: Dec. 2017).

strategies, approaches to training research staff, and suggestions for local resources to support recruitment of women.

Federal Actions Focused on Reducing Barriers to Patient Participation

CMS, DOD, NCI, VA, and FDA have implemented actions focused on reducing financial, logistical, and cultural and linguistic barriers to patient participation in clinical trials.

Financial support. CMS, DOD, and NCI have taken action to address the financial barriers, which can contribute to low clinical trial participation rates for patients, particularly from underrepresented populations.³⁵ Agencies' actions to reduce financial barriers for clinical trial patients include compensation for routine costs associated with trial participation and reimbursement of patient out-of-pocket costs, such as transportation and dependent care.

- As previously described, Medicare and Medicaid cover routine patient care costs for beneficiaries participating in qualifying clinical trials. CMS officials stated that since Medicare coverage of such costs began in 2000, local Medicare administrators determine what routine costs are eligible for coverage for each separate qualifying clinical trial. Covered costs are those they deem reasonable and necessary and that are aligned with costs that would regularly be covered by Medicare.

Federal law required Medicaid coverage of routine patient costs associated with participation in qualifying clinical trials beginning January 1, 2022. According to CMS officials, state Medicaid administrators are responsible for establishing guidelines, within federal parameters, on coverage, reimbursement requirements, and processing reimbursements for costs related to clinical trials. Each state is required to submit a state plan amendment to CMS to implement the new benefit, and, as of June 2022, 44 state plan amendments had been approved.³⁶ Because Medicaid programs vary by state, Medicaid coverage for services that are within clinical trials

³⁵R. D. Nipp et al., "Recognizing the financial burden of cancer patients in clinical trials," *Oncologist*, vol. 20 (2015): 572-575.

³⁶A Medicaid state plan amendment is an agreement between a state and the federal government describing how that state administers its Medicaid program. The state plan amendment sets out groups of individuals to be covered, services to be provided, methodologies for providers to be reimbursed and the administrative activities that are underway in the state. When a state is planning to make a change to its program policies or operational approach, states send state plan amendments to CMS for review and approval.

also varies by state. CMS officials told us that the biggest challenge that clinical trial researchers may face are these state differences, particularly for those running clinical trials with patients from multiple states. In addition, state Medicaid programs are required to cover non-emergency transportation. According to CMS officials, this benefit covers the costs of necessary transportation for Medicaid-approved care, which includes approved care provided as part of clinical trials, and can cover other related travel expenses, including the cost of meals and lodging.

- According to officials, DOD's CDMRP allows cancer research budgets to cover out-of-pocket patient expenses associated with participation in clinical trials, including transportation, dependent care, food, and lodging. To increase patient awareness of this benefit, CDMRP has encouraged clinical trial researchers to state clearly to patients that these out-of-pocket costs will be reimbursed if they participate in that clinical trial. In addition, DOD's Murtha Cancer Center arranges travel and housing for active duty service members who are undergoing cancer treatment or participating in cancer clinical trials. Officials stated that this benefit allows patients to participate in cancer research without any additional cost to the patient.
- According to officials, NCI's Center for Cancer Research provides support to trial participants for travel expenses, food, lodging, and inpatient and outpatient medical treatment.³⁷ For example, NCI provides free lodging on the NIH campus for certain qualifying patients.

Logistical support. FDA, NCI, and VA have taken action to address logistical barriers, such as time commitments and distant research locations, which have been shown to deter patients from participating in clinical trials.³⁸ Related agency actions, which began in response to the COVID-19 pandemic, include using telemedicine for routine visits, shipping study medications to patients, and using local clinics and imaging centers for certain activities.

- FDA issued guidance that highlighted existing flexibilities for alternative locations or research processes for clinical trial activities,

³⁷The Center for Cancer Research is the largest division of NCI's intramural research program with nearly 250 basic and clinical research groups located on the NIH campus.

³⁸E. D., Giarelli et al., "Research participation among Asian American women at risk for cervical cancer: Exploratory pilot of barriers and enhancers," *Journal of Immigrant and Minority Health*, vol. 13, no. 6 (2011):1055–1068.

such as local imaging centers, virtual visits, and delivery of study medications that researchers could take during the COVID-19 pandemic.³⁹ This guidance is designed to help industry, researchers, and institutional review boards protect patient safety and facilitate continuing research. The guidance is in effect for the duration of the COVID-19 public health emergency, though agency officials said they could extend it beyond that date if needed. In 2022, FDA published draft guidance on using digital health technology to obtain data remotely from participants in clinical trials.⁴⁰

- NCI issued similar interim guidance that created flexibilities for continued clinical trial research during the COVID-19 pandemic.⁴¹ The interim guidance included alternative procedures, such as allowing shipment of study medications to patients and clarifying how researchers could work with local health care providers to perform certain trial activities. NCI officials stated that the agency is working to create permanent recommendations for these new processes.
- VA officials stated that researchers have incorporated telehealth in clinical trials to engage more veterans living in rural areas and reduce the burden of physically visiting a VA medical center. VA expanded telehealth into clinical trials as a way to enable continued patients' participation during the COVID-19 pandemic. VA has also made efforts to ship study medications to patients' homes to reduce the burden of traveling to a medical center. Stakeholders from a cancer advocacy association and a pharmaceutical company told us that continuing the use of telehealth may allow patients to overcome logistical barriers making it less burdensome to participate.

Culturally and linguistically tailored information. FDA and NIH have implemented actions to support developing culturally and linguistically appropriate materials to facilitate enrollment of a diverse group of patients in clinical trials. Research has shown that educational materials in different languages, with culturally relevant messages and images and

³⁹Food and Drug Administration, *Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency — Guidance for Industry, Investigators, and Institutional Review Boards* (Silver Spring, Md.: Aug. 2021).

⁴⁰Food and Drug Administration, *Digital Health Technologies for Remote Data Acquisition in Clinical Investigation (Draft Guidance for Industry, investigators, and Other Stakeholders)*, (Silver Spring, Md.: Jan. 2022).

⁴¹National Cancer Institute, *Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)* (Bethesda, Md., Mar. 2020).

clear language, are important in increasing the enrollment of patients across many racial and ethnic backgrounds.⁴² Examples of federal actions to address cultural and linguistic barriers include the following:

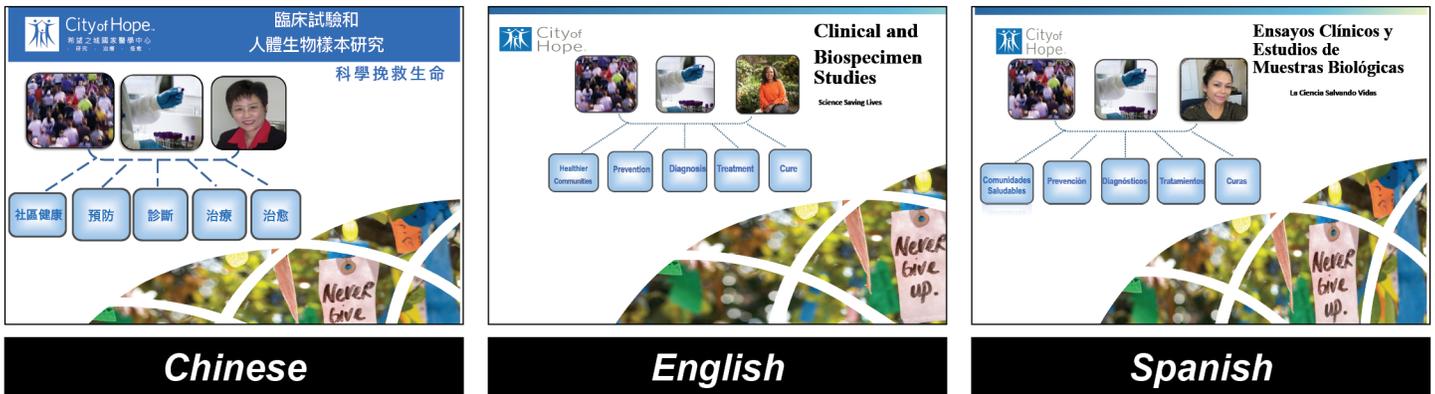
- FDA issued guidance on enhancing clinical trial diversity that includes recommendations for practices that increase cultural inclusiveness.⁴³ Recommendations include providing researcher cultural competency training and providing trial resources and documents in multiple languages and multilingual research staff and/or interpreters in order to encourage the participation and retention of individuals with limited English comprehension.
- NCI’s National Outreach Network employs community health educators at 24 NCI-designated cancer centers to develop and disseminate culturally appropriate, evidence-based, cancer information tailored to the specific needs and expectations of underrepresented populations. For example, the Beckman Research Institute’s City of Hope National Outreach Network program seeks to increase community knowledge of importance of clinical trials in ethnic minority communities, specifically Latino, African American, and Chinese. (See fig. 2.)
- According to officials, NIH developed “plain English” consent forms for clinical trial participation to reduce potential language barriers.⁴⁴

⁴²National Academies of Sciences, Engineering, and Medicine. Improving Representation.

⁴³Food and Drug Administration, *Enhancing the Diversity of Clinical Trial Populations*.

⁴⁴This effort aligns with work by the Plain Language Action and Information Network—a working group of federal employees from different agencies and specialties—that developed the Federal Plain Language Guidelines to assist agencies in developing documents with clear communication.

Figure 2: Clinical Trial Educational Materials Translated and Culturally Adapted through NCI’s National Outreach Network



Source: Beckman Research Institute’s City of Hope National Outreach Network Program. | GAO-23-105245

Federal Actions Focused on Data Standardization

DOD, FDA, NIH, and VA have implemented processes to standardize the collection of demographic data about clinical trial patients, which allows agencies to analyze results more effectively for patients from diverse backgrounds. Examples of federal actions include the following:

- DOD’s CDMRP implemented a policy in October 2020 requiring clinical trial researchers to use a standardized form to submit data annually about the demographics of the patients they enrolled in clinical trials. According to DOD officials, this form allows researchers to report information on patient demographics, including sex, race, and ethnicity to track progress in meeting the clinical study’s patient recruitment goals.
- FDA released guidance in 2016 to standardize the collection of demographic data in clinical trials.⁴⁵ The guidance established a standardized framework for consistency in the definition of race and ethnicity data.
- As stated in NIH policy, each NIH institute or center, including NCI, collects and reviews sex and gender, race, and ethnicity enrollment data, which are compiled as part of annual reports.⁴⁶ According to officials, NCI creates a triennial report using these data that describes enrollment in supported clinical research by sex and race/ethnicity.

⁴⁵Food and Drug Administration, *Guidance on Collection of Race and Ethnicity Data in Clinical Trials* (Silver Spring, Md.: Oct. 2016).

⁴⁶National Institutes of Health, *NIH Policy and Guidelines on the Inclusion of Women and Minorities*.

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- According to officials, all studies funded by VA’s Cooperative Studies Program—VA’s primary multisite clinical trial funding program—use a standard data collection template, which includes age, sex, location, and race/ethnicity.

Selected Cancer Centers Used a Variety of Practices to Facilitate Enrollment of Patients from Diverse Backgrounds in Cancer Clinical Trials

The 17 non-federal cancer centers in our review have implemented a variety of practices designed to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials. These practices fall into four categories: (1) organization-level practices, (2) community-level practices, (3) workforce-level practices, and (4) patient-level practices. Figure 2 describes the practices in each category.⁴⁷ Of the 17 cancer centers we reviewed, 15 centers noted implementing practices in at least three of the four categories.⁴⁸ (A description of selected cancer centers can be found in appendix III.)⁴⁹

⁴⁷These four categories generally align with categories identified in published literature. See, for example: O. Garrick, et al., “Advancing Inclusive Research: Establishing Collaborative Strategies to Improve Diversity in Clinical Trials.” *Ethnicity & Disease*, vol. 32, no. 1 (2022); J. M. Regnante et al., “US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials.” *Journal of Oncology Practice*, vol. 15, no. 4 (2019); American Cancer Society Cancer Action Network, *Barriers to Patient Enrollment in Therapeutic Clinical Trials for Cancer: A Landscape Report*, (2018); and A. M. Denicoff et al., “The National Cancer Institute-American Society of Clinical Oncology Cancer Trial Accrual Symposium: Summary and Recommendations.” *Journal of Oncology Practice*, vol. 9, no. 6 (2013).

⁴⁸Our review of the 17 selected cancer centers is based on our analysis of the descriptions provided by the 13 cancer centers that responded to a questionnaire we sent and publicly available information. For our review of the four cancer centers that did not respond to our questionnaire, we relied on publicly available information such as published literature and information available on the centers’ websites.

⁴⁹Appendix III includes descriptions of the 13 cancer centers that responded to a questionnaire we sent to the 17 cancer centers we identified.

Figure 3: Categories of Practices to Facilitate Diverse Patient Representation in Cancer Clinical Trials at Selected Cancer Centers



Source: GAO analysis of information about the 17 selected cancer centers. | GAO-23-105245

Organization-Level Practices

We found that all 17 selected cancer centers we reviewed noted implementing organization-level practices to help them understand the needs of diverse populations within their service area and enhance their ability to enroll a diverse patient population into cancer clinical trials.⁵⁰ Specifically, selected cancer centers have noted adoption of an institutional commitment to serving diverse populations in their service area or establishment of partnerships with other organizations to conduct or support clinical trials to increase access for diverse populations.

⁵⁰The term “service area” refers to the geographical area served by a cancer center.

Institutional commitment. Fourteen of the 17 selected cancer centers noted adopting an institutional commitment to diversity and serving diverse communities in their service area, including through cancer clinical trials. We found that centers have noted having a stated commitment to diversity in their mission and vision statements or strategic plans, or establishing leadership roles and programs, or initiatives focused on helping centers identify and address the needs of diverse communities in their service area. Research suggests that commitments from institutional leaders and infrastructure to support community engagement are important to identifying and addressing the research needs of communities and the barriers relevant to underserved communities.⁵¹

One example of this is Abramson Cancer Center's Community Outreach and Engagement Program, which is dedicated to helping the Center understand and address the needs of communities in the service area and has developed programs and strategies to help overcome barriers to the enrollment of patients with diverse backgrounds in cancer clinical trials. In 2014, the Center, through the Community Outreach and Engagement Program, implemented a 5-year initiative to increase the enrollment of Black patients into cancer clinical trials. As part of the initiative, the Center promoted clinical trials that address the cancer burden experienced by Black residents within the service area, required that each trial have a plan to recruit Black patients, developed marketing materials tailored to Black patients, and established a partnership with a transportation company to address transportation barriers. The efforts reached more than 10,000 individuals in communities across the service area and, by 2018, had more than doubled the Center's enrollment of Black patients in cancer clinical trials, according to Center officials.

Clinical trial partnerships. Eleven of the 17 selected cancer centers noted establishing partnerships with other organizations to conduct or support clinical trials. Clinical trial partnerships are intended to help centers develop and implement strategies to increase diverse participation in clinical trials, or make clinical trials more accessible to patients from diverse backgrounds by, for instance, expanding the number and types of locations that conduct trials. Examples of clinical trial partnerships at the selected cancer centers include the following:

⁵¹National Academies of Sciences, Engineering, and Medicine, *Improving Representation in Clinical Trials and Research Groups*.

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- The Benefis Sletten Cancer Institute is a member of the Montana Cancer Consortium, a clinical trial partnership that receives funding through the NCI Community Oncology Research Program. According to Institute officials, participating in the Montana Cancer Consortium enables the Institute to offer NCI trials to patients in its service area, which includes patients from rural and American Indian communities. Within the Institutes' service area, there are three reservations and one federally recognized landless tribe. Collectively, members of the Montana Cancer Consortium serve underrepresented communities across Montana, Idaho, and Wyoming—communities that previously had little access to clinical trials due to the vastness of the geography and a lack of academic treatment and research facilities. Since it was established in 1995, the Montana Cancer Consortium has enrolled more than 4,000 patients to NCI-funded clinical trials.
 - In 2008, the University of Illinois at Chicago, Rush University Medical Center, and John H. Stroger Hospital—three neighboring medical centers in Chicago—established a partnership to help ensure that adolescent and young adult patients at all three centers had access to NCI clinical trials and to increase the representation of patients from racial and ethnic minority groups in trials. Under the partnership, the three centers established a unified research team to share resources and manage trial logistics. Prior to 2008, one of the centers did not have access to NCI trials and the number of NCI trials at the other two centers were limited due to a lack of research resources to support their respective programs. Under the partnership, the overall number of cancer patients at the three sites who enrolled in NCI trials increased from 151 during the 6-year period from 2002 through 2008 to 825 during the 9-year period from 2008 through 2017, according to a study analyzing trial enrollment data before and after the group was formed.⁵² The study also found that the percentage of trial patients from a racial and ethnic group other than non-Hispanic White increased from 52 percent to 66 percent during those same time periods. The percentage of adolescent and young adult cancer patients enrolled in trials also increased, from 34 percent to 49 percent during those same time periods.

⁵²N. Mittal et al., "A Tri-Institutional Approach to Address Disparities in Children's Oncology Group Clinical Trial Accrual for Adolescents and Young Adults and Underrepresented Minorities.", *Journal of Adolescent and Young Adult Oncology*, vol. 8, no. 3 (2019).

Community-Level Practices

We found that 13 of the 17 selected cancer centers we reviewed noted implementing practices focused on engaging diverse communities within the cancer center service area. These practices include working with community ambassadors—representatives of the community—to increase awareness of clinical trials and working with community advisors representing diverse community stakeholders to help centers understand and address the needs and perspectives of diverse communities in their service area.

Community ambassadors. Seven of the 17 selected cancer centers noted working with community ambassadors to educate diverse communities on clinical trials and promote clinical trial participation. Educating communities on the role of clinical trials and the safeguards in place to protect trial participants may help cancer centers overcome some of the barriers to diverse representation in trials, such as a lack of awareness about clinical trials and a fear of participation in trials. Community ambassadors may serve as trusted messengers for communicating clinical trial information to diverse communities.⁵³ Examples of community ambassadors at the selected cancer centers include the following:

- The Yale Center for Clinical Investigation, as part of its Cultural Ambassador Program, works with leaders from two community organizations in historically underrepresented communities to help increase enrollment of Hispanic and Black patients in clinical trials.⁵⁴ Ambassadors help promote the Center’s clinical trials in the community and work with Center trial staff to create culturally tailored clinical trials information, among other things. Center officials told us that the proportion of patients from diverse backgrounds in clinical trials has increased since implementing the ambassador program in 2010. Specifically, officials reported the proportion of patients in trials from a racial and ethnic group other than non-Hispanic White increased from 3 percent in 2010 to 32 percent in 2021.
- The Fox Chase Cancer Center developed a 7-week community ambassador program to train individuals from Black communities to increase their knowledge of clinical trials and help them feel

⁵³Bierer et al., *Achieving Diversity*.

⁵⁴The Yale Center for Clinical Investigator Cultural Ambassador Program involves partnerships with Junta for Progressive Action—a organization dedicated serving the Hispanic community in greater New Haven—the Connecticut African Methodist Episcopal Zion Churches—one of the oldest Black congregations in the United States, and other community leaders.

comfortable discussing clinical trials in the community. The program includes training from Center staff on the history of clinical trials, barriers to participation, and the clinical trial process, including processes to protect patients enrolled in clinical trials. Ambassadors then disseminate clinical trial information within their networks and at community education events, according to officials.

Community advisors. Eleven of the 17 selected cancer centers noted working with community advisors to help them understand the needs of diverse communities within their service area. This is intended to help cancer centers prioritize and design clinical trials to meet the needs of the communities they serve, and help them increase access to trials. Additionally, we found that three cancer centers noted working with community advisors to develop targeted strategies to engage diverse communities within their service area. Examples of community advisors at the selected cancer centers include the following:

- The University of California Davis Comprehensive Cancer Center community advisory board includes cancer survivors and community members representing rural and urban counties across its service area, as well as community leaders representing racially and ethnically diverse communities. Center staff worked with the community advisory board to help enroll 20 patients from diverse backgrounds in a clinical trial for a new device. Board members provided suggestions to make advertisements for the trial more diverse, such as including images of individuals from diverse backgrounds in promotional videos. Center officials said that this input helped them more effectively enroll individuals from diverse backgrounds. The trial received more than 155 inquiries to fill 20 slots, helping them meet their diversity goals.⁵⁵
- The Meharry Medical College, Vanderbilt-Ingram Cancer Center, and Tennessee State University Cancer Partnership has worked with its community advisory board—which includes members from diverse racial and ethnic backgrounds who are cancer survivors, caregivers, and representatives of cancer-related organizations—to facilitate community input into its work. For example, the board developed materials for a clinical trial designed to reduce smoking-related cancer mortalities among racial and ethnic groups other than non-Hispanic White. Board members recommended changes to simplify the language used to describe the interventions to which patients may be

⁵⁵R. Badawi et al., “Diversifying the Subject Cohorts in Total-Body PET Research: A Feasibility Study,” *Journal of Nuclear Medicine*, vol. 63, no. S2 (2022).

assigned. Additionally, board members provided input regarding the tone of the language used to describe trial procedures and enhanced the design of trial materials in a culturally sensitive manner, according to an article describing the Partnership’s work with the board.⁵⁶

Workforce-Level Practices

We found that 13 of the 17 selected cancer centers we reviewed noted implementing practices focused on developing an inclusive and diverse health care workforce.⁵⁷ These practices include training for health care workers related to the inclusion of patients from diverse backgrounds in clinical trials and efforts to increase diversity within the cancer centers’ workforce.

Workforce training. Nine of the 17 selected cancer centers noted having training for health care workers related to the inclusion of patients from diverse backgrounds in clinical trials. Training in cultural competency—the ability to understand, interact, and work well with people of different cultures—can help health care workers better communicate with diverse patients to increase their awareness of clinical trials.⁵⁸ Additionally, training may help health care workers address unconscious biases—attitudes or stereotypes about race, ethnicity, socioeconomic status, or other patient characteristics that unknowingly alter an individuals’ perceptions, behavior interactions, and decision-making—that can otherwise lead to inequitable access to trials.⁵⁹ Examples of workforce training at the selected cancer centers include the following:

- Duke Cancer Institute’s “Just Ask” training program is designed to help health care workers and research teams communicate with patients from diverse backgrounds and ensure patients are aware and knowledgeable about research and clinical trial participation. The program helps workers recognize their own biases and also teaches strategies to mitigate the effects of unconscious biases on the patient experience and clinical trial participation, according to Institute

⁵⁶E. Connors et al., “Improving Community Advisory Board Engagement In Precision Medicine Research To Reduce Health Disparities.”, *Journal of Health Disparities Research and Practice*, vol. 12 : no. 6 (2018).

⁵⁷For the purposes of this report, the “health care workforce” includes both health care providers who provide cancer care, such as physicians and nurses, as well as clinical researchers and research team members, such as those who work on clinical trials.

⁵⁸Bierer et al., *Achieving Diversity*.

⁵⁹N. Barrett et al., “Assessing Feasibility and Utility of an Implicit Bias Training Program for Addressing Disparities in Cancer Clinical Trial Participation.” *Journal of Clinical Oncology*, vol. 40, no. 16 (2022).

officials. The American Society of Clinical Oncology and the Association of Community Cancer Centers have developed an unconscious bias training based on the Just Ask program that health care workers and research teams from other cancer centers can access online and complete independently.

- The Henry Ford Cancer Institute is developing unconscious bias training for its health care workforce. According to Institute officials, the goal of this training is to increase awareness about the effect of implicit biases on cancer disparities, including to improve clinical trial enrollment among diverse populations.

Diverse health care workforce. Eleven of the 17 selected cancer centers noted implementing practices focused on developing a diverse health care workforce.⁶⁰ A health care workforce that shares the demographic and other characteristics of the diverse communities in their geographic area has been shown to increase participation in clinical research, according to one report.⁶¹ Another report suggested that a diverse health care workforce may help cancer centers increase trust among underrepresented communities.⁶² Additionally, a diverse health care workforce can help ensure that clinical trials are designed and implemented to meet the needs of diverse communities, according to a joint statement issued by the American Society of Clinical Oncology and Association of Community Cancer Centers.⁶³ Examples of efforts to diversify the health care workforce by the selected cancer centers include the following:

- The Henry Ford Cancer Institute established a diversity, equity, inclusion, and justice committee made up of team members across the Institute. The group works to increase awareness and educational opportunities for the Institute’s leadership and staff, such as through quarterly learning sessions. It is also focused on increasing diversity in its team members, for example, by working with students from

⁶⁰For the purpose of this report, a “diverse health care workforce” refers to a workforce that includes individuals from backgrounds identified as underrepresented in the workforce, such women and racial and ethnic groups other than non-Hispanic White, or a workforce that shares the demographic and other characteristics of diverse communities in their geographic area.

⁶¹Bierer et al., *Achieving Diversity*.

⁶²Garrick et al., “Advancing Inclusive Research”.

⁶³R. A. Oyer et al., “Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement.” *Journal of Clinical Oncology* (2022).

underrepresented backgrounds to increase diversity in the field. The committee reviews the applicant pool to monitor the diversity of candidates and approves all hiring offers before they are made. Institute officials noted that hiring individuals from diverse backgrounds who reflect the diversity of communities in the Institute's service area has helped ensure its priorities incorporate the values and needs of all patients.

- The Hollings Cancer Center provides cancer research training and mentoring for students, with a focus on developing the careers of individuals from underrepresented backgrounds. For instance, the Center offers a 10-week summer research program for undergraduate students from three Historically Black Colleges and Universities in South Carolina, as well as the University of South Carolina. The program includes career mentoring from the Center's staff as well as hands-on laboratory research training. Since 2007, many of the students have been included as co-authors on peer-reviewed manuscripts.

Patient-Level Practices Implemented

We found that 15 of the 17 selected cancer centers we reviewed noted implementing practices that are designed to help patients overcome some of the barriers to clinical trial participation. These practices include educating patients about clinical trials, providing culturally and linguistically tailored information, using patient navigators, and providing financial and logistical supports.

Clinical trial education. Fourteen of the 17 selected cancer centers noted implementing practices to help educate patients about clinical trials. This includes practices that are intended to raise patient awareness of trials and trial opportunities, or help patients make informed decisions regarding clinical trial participation. Additionally, one of the centers noted providing clinical trial education to help address mistrust in medical research stemming from a history of racism and research misconduct—a reported barrier to enrolling patients from diverse backgrounds into clinical trials. Examples of clinical trial education for patients at the selected cancer centers include the following:

- Hollings Cancer Center's patient clinical trial education program—the "MOVENUP Train the Trainer Cancer Education Program"—discusses the importance of including diverse populations in cancer clinical trials and includes a focus on addressing mistrust of clinical trials among patients from diverse backgrounds. The program acknowledges previous research misconduct, such as the Tuskegee

Study, and then discusses the safeguards that have since been established to protect the rights of clinical trial participants.⁶⁴

- Fox Chase Cancer Center researchers developed an interactive tool called *mychoice* that is designed to address racial and ethnic inclusion in medical research. This web-based tool educates patients on clinical trials to help address their concerns related to participation, according to Center officials. As part of *mychoice*, patients can watch video interviews of cancer patients who have made decisions about participating in clinical trials to hear the concerns these patients had and their approach to deciding whether to participate. Additionally, *mychoice* provides a list of questions related to clinical trial processes and participation that patients can use to help facilitate discussions with their health care provider. The Center developed *mychoice* after finding that a lack of information about clinical trials was a barrier to participation for many of their Black patients.

Culturally and linguistically tailored information. Ten of the 17 selected cancer centers noted having clinical trial information that is tailored to meet the needs of culturally and linguistically diverse patients. To help people make informed decisions about trial participation, study materials must be culturally, linguistically, and ethnically appropriate, according a joint statement issued by the American Society of Clinical Oncology and Association of Community Cancer Centers.⁶⁵ We found that six centers have also used culturally and linguistically tailored information to help increase patient trust, awareness, and knowledge of trials. Examples of culturally and linguistically tailored information at the selected cancer centers include the following:

- The University of California Davis Comprehensive Cancer Center offers clinical trial education materials in English, as well as Hmong, Vietnamese, Cantonese, Mandarin, and Korean—languages the Center identified through a community needs assessment on clinical trial knowledge. Providing materials in a patient’s native language helps to increase trust and education among individuals with limited

⁶⁴The Syphilis Study at the Tuskegee Institute, known officially as the “Tuskegee Study of Untreated Syphilis in the Negro Male,” was a clinical study run by the U.S. Public Health Service designed to determine the natural course of untreated syphilis in Black men. The study, which ran from 1932 to 1972, followed 600 Black men in Alabama. Researchers did not obtain the patients’ consent and told the men they were being treated for “bad blood,” a term used to describe several ailments, including syphilis, anemia, and fatigue. Additionally, when penicillin became the standard treatment for the disease in 1943 the medicine was withheld from the patients.

⁶⁵Oyer et al., “Increasing Racial and Ethnic Diversity in Cancer Clinical Trials”.

English proficiency, and has played a critical role in the enrollment of Asian American cancer patients into clinical trials, according to Center officials. Additionally, Center officials reported that the center has translated research materials, such as information sheets and patient consent forms, into Spanish. These materials were reviewed by six bilingual and bicultural staff to ensure correct translation and that the materials are culturally appropriate for the Latino community, according to Center officials.

- As part of its “Help Us Discover” clinical trial awareness campaign, the Yale Center for Clinical Investigation developed culturally and linguistically tailored advertisements and education to promote its clinical research and encourage diverse participation. Specifically, the Center created education brochures that included photos of Black and Hispanic individuals and information describing why diverse representation in clinical trials is important. Additionally, the brochure was available in Spanish. (See fig. 4.)

Figure 4: Yale Clinical Trial Education Materials for Black and Hispanic Patients



IT'S IMPORTANT TO INCLUDE ALL TYPES OF PEOPLE IN CLINICAL STUDIES.

Human beings are very much alike. Only one-tenth of one percent of our genes varies from one person to the next. But even with these tiny differences, there are still people with different appearances and different health conditions. Illnesses affect each of us differently – as individuals, as families, as racial and ethnic groups, and as communities. Because of these differences, it's important to study different groups of people in order to understand which treatments work best for them. The best way to know that a particular medicine is right for someone is to test it in similar people.

MINORITIES HAVE HIGHER RATES OF CERTAIN DISEASES.

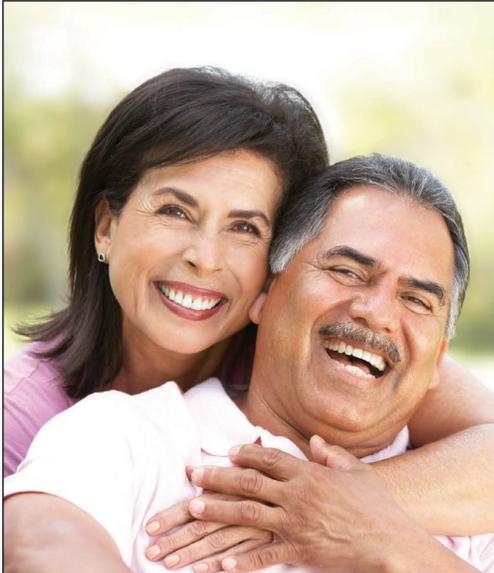
It is an unfortunate fact that minorities suffer disproportionately from such diseases as cancer, diabetes, cardiovascular disease, and HIV. The fastest and safest way to determine whether new treatments work for these and other diseases is through clinical research. Yet it's often difficult to find volunteers – especially minorities – willing to participate in clinical trials. There is a shortage of participants in clinical research – and minority participation is even lower than that of the general population.

NOT ALL DISEASES ARE CREATED EQUAL.

Many diseases affect African Americans more than people from other groups. For example:

- African Americans are more likely to have **stomach cancer** than other groups. Men have higher rates of **lung and prostate cancer**. **Breast cancer** is more common in African American women under 45, and they are more likely than other women to die from this disease.
- African Americans are twice as likely as non-Hispanic white adults to be diagnosed with **diabetes**. They are also more likely to have **kidney disease**, to be hospitalized, and to die from diabetes.
- African Americans have higher rates of **high blood pressure**. Men are more likely to die from **heart disease**. Women are more likely to be **obese**.
- African American infants are almost four times as likely to die from causes related to **low birth weight** compared to non-Hispanic white infants.
- African Americans are more likely than white adults to have a **stroke**. Men are 60 percent more likely to die from it. Survivors are more likely to become disabled and have difficulty with daily activities.

Courtesy of US Department of Health and Human Services Office of Minority Health.



ES IMPORTANTE INCLUIR TODO TIPO DE PERSONAS EN ESTUDIOS CLÍNICOS.

Los seres humanos son muy parecidos. Sólo una décima parte del uno por ciento de nuestros genes varían de una persona a otra. Pero incluso con estas pequeñas diferencias, todavía hay personas con diferentes apariencias y diferentes condiciones de salud. Las enfermedades afectan a cada uno de nosotros de manera diferente; como individuos, como familias, como grupos raciales y étnicos, y como comunidades. Debido a estas diferencias, es importante estudiar los diferentes grupos de personas con el fin de entender qué tratamientos funcionan mejor para ellos. La mejor manera de saber que un medicamento en particular es correcto para alguien es probarlo en personas similares.

LAS MINORÍAS TIENEN TASAS MÁS ALTAS DE CIERTAS ENFERMEDADES.

Es un hecho desafortunado de que las minorías sufren desproporcionadamente de enfermedades tales como cáncer, diabetes, enfermedades cardiovasculares y el VIH. La forma más rápida y segura de determinar si los tratamientos nuevos trabajan para éstas y otras enfermedades es a través de la investigación clínica. Sin embargo, a menudo es difícil encontrar voluntarios, en especial las minorías que están dispuestas a participar en ensayos clínicos. Hay una escasez de participantes en la investigación clínica y de las minorías es aún más baja que la de la población en general.

NO TODAS LAS ENFERMEDADES SON IGUALES.

Muchas enfermedades afectan a los hispanos más que a las personas de otros grupos. Por ejemplo:

- Los hombres y las mujeres hispanas tienen el doble de probabilidades de desarrollar y morir de **cáncer de bígado** que los blancos no hispanos. Las mujeres hispanas son más propensas a tener **cáncer de estómago y cáncer de cuello uterino** que otras mujeres.
- Los niños hispanos son más propensos a tener **asma** que otros niños.
- Las mujeres hispanas son más propensas a ser diagnosticadas con la infección por el VIH que las mujeres blancas no hispanas. Los hombres y mujeres hispanos son más propensos a tener **SIDA**, y son más propensos a morir de **VIH/SIDA**.
- Las mujeres hispanas tienen más probabilidades de sufrir un **accidente cerebrovascular** que otras mujeres.
- Los hispanos tienen el doble de probabilidades de morir a causa de la **hepatitis viral** que los blancos no hispanos. Ellos son dos veces más propensos a ser diagnosticados con **hepatitis A**, y adultos de 40 años y más son 30 por ciento más propensos a desarrollar la **hepatitis B**.

Courtesy of the Department of Health and Human Services of the HHS, U.S. Office of Health of the Minorities.

Source: Yale Center for Clinical Investigation. | GAO-23-105245

Patient navigators. Ten of the 17 selected cancer centers noted having patient navigators—center staff or lay health workers responsible for guiding a patient through the healthcare system—to support patients and educate them on clinical trials. Research suggests that patient navigators

may help cancer centers enroll diverse patients in clinical trials by providing practical support that enhances initial enrollment and continued support for participants enrolled in trials to enhance retention.⁶⁶ For instance, one report found that patient navigators can help identify whether there are barriers to patients' participation in a clinical trial and assist them in addressing those barriers, such as by helping with manage transportation and lodging.⁶⁷ Additionally, by educating patients on trials, patient navigators can raise awareness of trials and help ensure patients have the information they need to make informed decisions regarding clinical trial participation.

- One example of this is Avera Health's "Walking Forward" program, which includes two types of patient navigators—navigators who are based at the Center in Rapid City, and lay navigators who are members of American Indian communities. Navigators based in the Center assist American Indian patients with coordinating appointments, insurance issues, following up on tests, obtaining medications and specialty services or devices, facilitating transportation and lodging, and offer psychosocial support during treatment. Lay navigators work closely with the hospital staff and educate cancer patients on clinical trials, access to cancer screening and enrollment in community trials such as lung cancer screening and palliative care projects.

Financial and logistical support. Eight of the 17 selected cancer centers noted providing financial or logistical support for patients enrolled in trials. This may help cancer centers enroll patients from diverse backgrounds, as research suggests that patients from diverse backgrounds are more likely to be underrepresented in cancer clinical trials due to limited financial resources.⁶⁸ Logistical issues, such as having to take time off work and needing to find transportation to and from the trial site, can also be a barrier. Examples of financial and logistical support provided at the selected cancer centers include the following:

- Duke Cancer Institute patients, including those enrolled in clinical trials, who meet financial eligibility guidelines may receive support for

⁶⁶K. B. Cartmell et al., "Patient Barriers to Cancer Clinical Trial Participation and Navigator Activities." *Advances in Cancer Research*, vol. 146 (2020); M. N. Fouad et al., "Patient Navigation As a Model to Increase Participation of African Americans in Cancer Clinical Trials." *Journal of Oncology Practice*, vol. 12, no. 6 (2016).

⁶⁷K. B. Cartmell et al., "Patient Barriers and Navigator Activities".

⁶⁸R. D. Nipp et al., "Addressing the Financial Burden".

out-of-pocket expenses, including transportation and lodging, according to Institute officials. Patients may also receive lodging through community partners such as Caring House, a non-profit organization that provides supportive and affordable housing to patients.

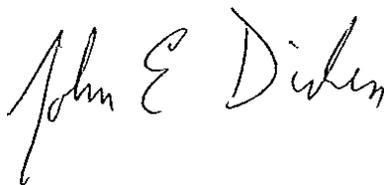
- Henry Ford Cancer Institute officials reported that the Institute uses its “Game On Cancer” campaign to support cancer patients. The campaign—a partnership between Henry Ford and the Detroit Lions football team, the Detroit Pistons basketball team, and other corporate partners—raises funds through special events to support patients and clinical research. According to Institute officials, this effort helps alleviate financial challenges cancer patients and their families may experience by providing the funds to pay for transportation, housing, prescriptions, medical supplies, and other expenses. Since the campaign started in 2015, Game On Cancer has raised more than \$5 million, according to officials.

Agency Comments

We provided a draft of this report to DOD, HHS, and VA for review. The agencies provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Veterans Affairs, and other interested parties. In addition, the report is 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 DickenJ@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 IV.



John E. Dicken
Director, Health Care

List of Committees

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor and Pensions
United States Senate

The Honorable Patty Murray
Chair
The Honorable Roy Blunt
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Rosa DeLauro
Chair
The Honorable Tom Cole
Ranking Member
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
House of Representatives

Appendix I: Objectives, Scope, and Methodology

Our report examined the following: (1) actions federal agencies have taken to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials and (2) practices used by selected cancer centers to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials. For the purposes of this report, we focused on diversity in terms of racial and ethnic groups, adolescents and young adults, older adults, women, low-income individuals, and individuals from rural communities because they were either specified in the legislation or had been cited in scientific literature as underrepresented groups in clinical trials. We used the National Cancer Institute’s definition of clinical trials, which includes those studies to test new methods of screening, prevention, diagnosis, or treatment. We use the word “centers” to describe cancer centers and institutes.

To address our research objectives, we

1. interviewed federal officials and stakeholders representing patient advocacy groups, pharmaceutical companies, and clinical research professionals and organizations;
2. reviewed relevant guidance and documents from federal officials;
3. conducted a review of relevant literature and publicly available information to identify cancer centers that enrolled a larger than average proportion of patients from diverse backgrounds in cancer clinical trials or been recognized in published literature for doing so; and
4. analyzed responses from questionnaires provided to selected cancer centers to identify the practices they have implemented.

We conducted this performance audit from May 2021 to December 2022 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.

Interviews with Federal Officials and Stakeholders

To address both objectives, we conducted semi-structured interviews with numerous federal officials and stakeholders who could provide a variety of perspectives on issues related to diversity in cancer clinical trials,

actions taken by the federal government, and their practices for facilitating enrollment of patients from diverse backgrounds in cancer clinical trials.

We interviewed officials from the following federal agencies with a role in cancer clinical trials.

- The Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, the Office of Minority Health, and the Centers for Medicare & Medicaid Services (CMS);
- The Department of Veterans Affairs (VA), including Veterans Health Administration; and
- The Department of Defense (DOD), including the Congressionally Directed Medical Research Programs (CDMRP) and Murtha Cancer Center.

We also interviewed 13 stakeholders that represent a variety of perspectives in patient advocacy, clinical research, and the pharmaceutical industry. These stakeholders provided various perspectives on the issues under study, as well as information about potential cancer centers to include in our review. We identified potential stakeholders—organizations or individual experts—through literature on clinical trials, as well as through our interviews. We identified those that had a history of focusing on both cancer and clinical trials and conducted interviews with the following:

- **Patient advocates:** American Cancer Society Cancer Action Network; Friends of Cancer Research; National Minority Quality Forum; and a long-time health advocate.
- **Clinical research organizations:** American Society of Clinical Oncology; Association of Community Cancer Centers; the Patient-Centered Outcomes Research Institute, an independent, non-profit, non-federal organization authorized by the Patient Protection and Affordable Care Act; and the Society of Gynecologic Oncology.
- **Clinical researchers:** A Bloomberg Distinguished Professor at the John Hopkins University who is an expert in cancer prevention and control; and an Associate Professor in the Cancer Prevention Program at the Fred Hutchinson Cancer Center and Assistant Professor at the University of Washington School of Public Health, with a background in health services research who focuses on cancer outcomes and disparities.

- **Pharmaceutical industry representatives:** Eli Lilly and Company, Genentech, and the Pharmaceutical Research and Manufacturers of America, which represents pharmaceutical and biotechnology companies.

Review of Federal Actions, Policies and Guidance, and Practices

To describe the actions federal agencies have taken to include diverse representation in cancer clinical trial participation, we analyzed interviews we conducted with federal officials from the agencies named above as well as additional information about the actions as reported on agency websites. We also reviewed and analyzed documents from the federal agencies that outline relevant agency policies (including guidance) and practices related to clinical trial participation. A complete list of federal guidance we reviewed is in app. II.

Identification of Selected Cancer Centers and Their Practices

To describe practices that facilitate diverse representation in cancer clinical trial participation, we identified non-federal cancer centers that enrolled a larger than average proportion of patients from diverse backgrounds in cancer clinical trials or were recognized in academic journals for doing so. We then fielded a questionnaire to these centers to learn more about the practices that they have implemented.

Identification of Selected Cancer Centers

To identify those cancer centers that enrolled patients from diverse backgrounds, we asked federal officials and stakeholders to identify such centers directly or for articles that described such centers. For example, one article described eight cancer centers that had sustained participation of ethnic minorities between 10 percent and 50 percent per trial.¹

We also conducted a literature search to identify cancer centers. We searched SCOPUS, PubMed, and all available collections in ProQuest, EBSCO, and Dialog databases for materials published since 2017 that identified or described cancer centers that enroll underrepresented

¹J. M. Regnante, et al., "US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials." *Journal of Oncology Practice*, vol. 15, no. 4 (2019).

populations.² From this search, we identified 38 unique and potentially relevant articles. We reviewed each article to determine if it focused on diverse representation in cancer clinical trials, versus clinical trials more broadly, and the inclusion of the underrepresented groups cited above.³ For each article that met this criteria, we further reviewed the article to determine if it described activities that were in operation during the prior 5 years. We also looked for evidence of effectiveness in enrolling patients of diverse backgrounds. One way to demonstrate this was through data showing that the center enrolled high numbers of underrepresented groups or has increased the participation of underrepresented groups since implementing practices to increase diverse representation. Another way was external recognition of the center as enrolling diverse populations. Of the 38 articles, four met this criteria.⁴

Based on these combined efforts, we identified 17 cancer centers for our review. Because our selection methodology was not exhaustive, there may be other centers we did not identify that also enrolled diverse populations into cancer clinical trials. The selected cancer centers we identified were the following:

²The search terms we used were cancer clinical trials; oncology clinical trials; exemplary programs, promising programs, notable programs, programs of excellence (and programs can be “programs”, “practices” or “centers”); enrollment, accrual, recruitment, retention; minorities; racial diversity; representation, underrepresentation; community outreach, community engagement, community partnership; community advisory board; peer support, patient navigators, lay navigators, community ambassadors; provider education and training; cultural competence, cultural awareness; culturally sensitive recruitment; mobile clinics; and telehealth.

³The centers may serve other populations not in the scope of how we define diversity for purposes of this report.

⁴J. M. Regnante et al., “Abstract PO-096: A Guide for Development of a Successful and Inclusive Lung Cancer Research Strategy Based on U.S. Best Practices.” *Cancer Epidemiology Biomarkers Prevention*, vol. 29, no. 12 (2020); J. M. Regnante, et al., “Operational Strategies in US Cancer Centers of Excellence that Support the Successful Accrual of Racial and Ethnic Minorities in Clinical Trials.” *Contemporary Clinical Trials Communications*, vol. 17 (2020); A. Trant et al., “Increasing Accrual of Minority Patients in Breast Cancer Clinical Trials.” *Breast Cancer Research and Treatment*, vol. 184 (2020); N. Mittal et al., “A Tri-Institutional Approach to Address Disparities in Children’s Oncology Group Clinical Trial Accrual for Adolescents and Young Adults and Underrepresented Minorities.”, *Journal of Adolescent and Young Adult Oncology*, vol. 8, no. 3 (2019).

- Abramson Cancer Center
- Avera Health
- Benefis Sletten Cancer Institute
- Children’s Oncology Group – University of Illinois at Chicago, Rush University Medical Center, and John H. Stroger Hospital
- Duke Cancer Institute
- Fox Chase Cancer Center
- Harold C. Simmons Comprehensive Cancer Center
- Henry Ford Cancer Institute
- Hollings Cancer Center
- Mary Bird Perkins Cancer Center
- Meharry Medical College, Vanderbilt-Ingram Cancer Center, and Tennessee State University Cancer Partnership
- University of California at Davis Comprehensive Cancer Center
- University of New Mexico Cancer Research and Treatment Center
- University of Texas MD Anderson Cancer Center
- Winship Cancer Institute
- Yale Cancer Center and Yale Center for Clinical Investigation
- Yuma Regional Medical Center Cancer Center

Identification of Practices

To identify examples of practices—the activities each of these cancer centers uses to facilitate enrollment of patients from diverse backgrounds in cancer clinical trials—we asked representatives from each of the selected cancer centers to complete a written questionnaire we developed. We sent the questionnaire via email in March and April 2022. The first part of the questionnaire asked about the specific activities the center has used or uses to facilitate the recruitment and retention of patients from diverse backgrounds in cancer trials. We prefilled the questionnaire with the activities we were already aware of from the literature and asked the center to make corrections or add any we may have missed. For each of the activities, the questionnaire asked the center officials to provide supporting documentation where available. The second part of the questionnaire asked more general questions about the center as a whole, such as examples of notable practices, populations of interest, and how the center’s activities function together.

Of the 17 centers we asked to complete our questionnaire, 13 (76 percent) returned completed questionnaires by May 2022. We then analyzed the responses to develop categories of activities that the cancer centers described.⁵ We included examples of these activities in the report. For those four cancer centers that did not return the questionnaire, we used publicly available information to describe their activities. We provided representatives of the 13 centers that completed the questionnaire the opportunity to review the parts of the draft report relevant to their center and incorporated technical comments, as appropriate. We did not independently verify the information reported by the centers in their response to the questionnaires we sent them or from published sources.

⁵We did not evaluate the effectiveness of the specific categories of activities that the cancer centers described.

Appendix II: Federal Agency Guidance and Policy Related to Diversity in Clinical Trials

Below is a list of guidance and policy documents from the Food and Drug Administration (FDA) and National Institutes of Health (NIH) related to improving diversity in clinical trials, and issued since 2014. Those that are not specific to cancer clinical trials are still relevant to them.

U. S. Department of Health and Human Services, Food and Drug Administration. *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials – Guidance for Industry* (Draft Guidance). Silver Spring, MD: Apr. 2022.

U. S. Department of Health and Human Services, Food and Drug Administration. *Inclusion of Older Adults in Cancer Clinical Trials – Guidance for Industry*. Silver Spring, MD: Mar. 2022.

U. S. Department of Health and Human Services, Food and Drug Administration. *Digital Health Technologies for Remote Data Acquisition in Clinical Investigation* (Draft Guidance for Industry, Investigators, and Other Stakeholders). Silver Spring, MD: Jan. 2022.

U. S. Department of Health and Human Services, Food and Drug Administration. *Enhancing the Diversity of Clinical Trial Populations—Eligibility Criteria, Enrollment Practices, and Trial Designs – Guidance for Industry*. Silver Spring, MD: Nov. 2020.

U. S. Department of Health and Human Services, Food and Drug Administration. *Conduct of Clinical Trials of Medical Products during the COVID-19 Public Health Emergency — Guidance for Industry, Investigators, and Institutional Review Boards*. Silver Spring, MD: Mar. 2020, updated Aug. 2021.

U. S. Department of Defense, Department of the Army, *The CDMRP Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*. Fort Detrick, MD: July 2020.

U. S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. *Interim Guidance for Patients on Clinical Trials Supported by the NCI Cancer Therapy Evaluation Program and the NCI Community Oncology Research Program (NCORP)*. Bethesda, MD: Mar. 2020.

U. S. Department of Health and Human Services, Food and Drug Administration. *Payment and Reimbursement to Research Subjects -*

Guidance for Institutional Review Boards and Clinical Investigators (Information Sheet). Silver Spring, MD: Jan. 2018.

U. S. Department of Health and Human Services, National Institutes of Health. *Revision: NIH Policy and Guidelines on the Inclusion of Individuals across the Lifespan as Participants in Research Involving Human Subjects*, NOT-OD-18-116. Bethesda, MD: Dec. 2017.

U. S. Department of Health and Human Services, National Institutes of Health. *Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*, NOT-OD-18-014. Bethesda, MD: Nov. 2017.

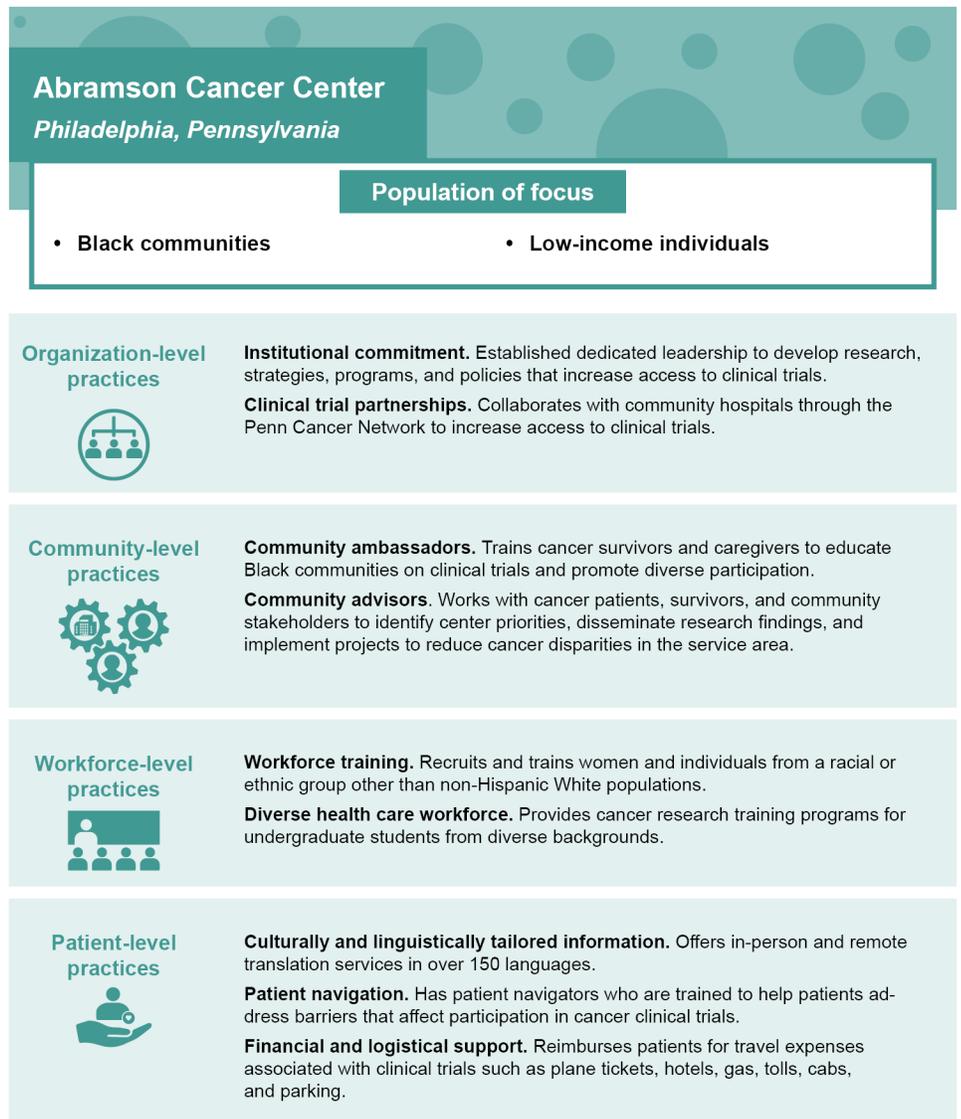
U. S. Department of Health and Human Services, Food and Drug Administration. *Collection of Race and Ethnicity Data in Clinical Trials – Guidance for Industry and Food and Drug Administration Staff*. Silver Spring, MD: Oct. 2016.

U. S. Department of Health and Human Services, Food and Drug Administration. *Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data*. Silver Spring, MD: Aug. 2014.

Appendix III: Selected Cancer Center Practices Related to Diversity in Clinical Trials

The 17 selected cancer centers have implemented various practices to help facilitate the enrollment of patients from diverse backgrounds in cancer clinical trials. Figures 5 through 17 include descriptions of some of the relevant practices from the 13 cancer centers that responded to the questionnaire we sent.

Figure 5: Selected Abramson Cancer Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



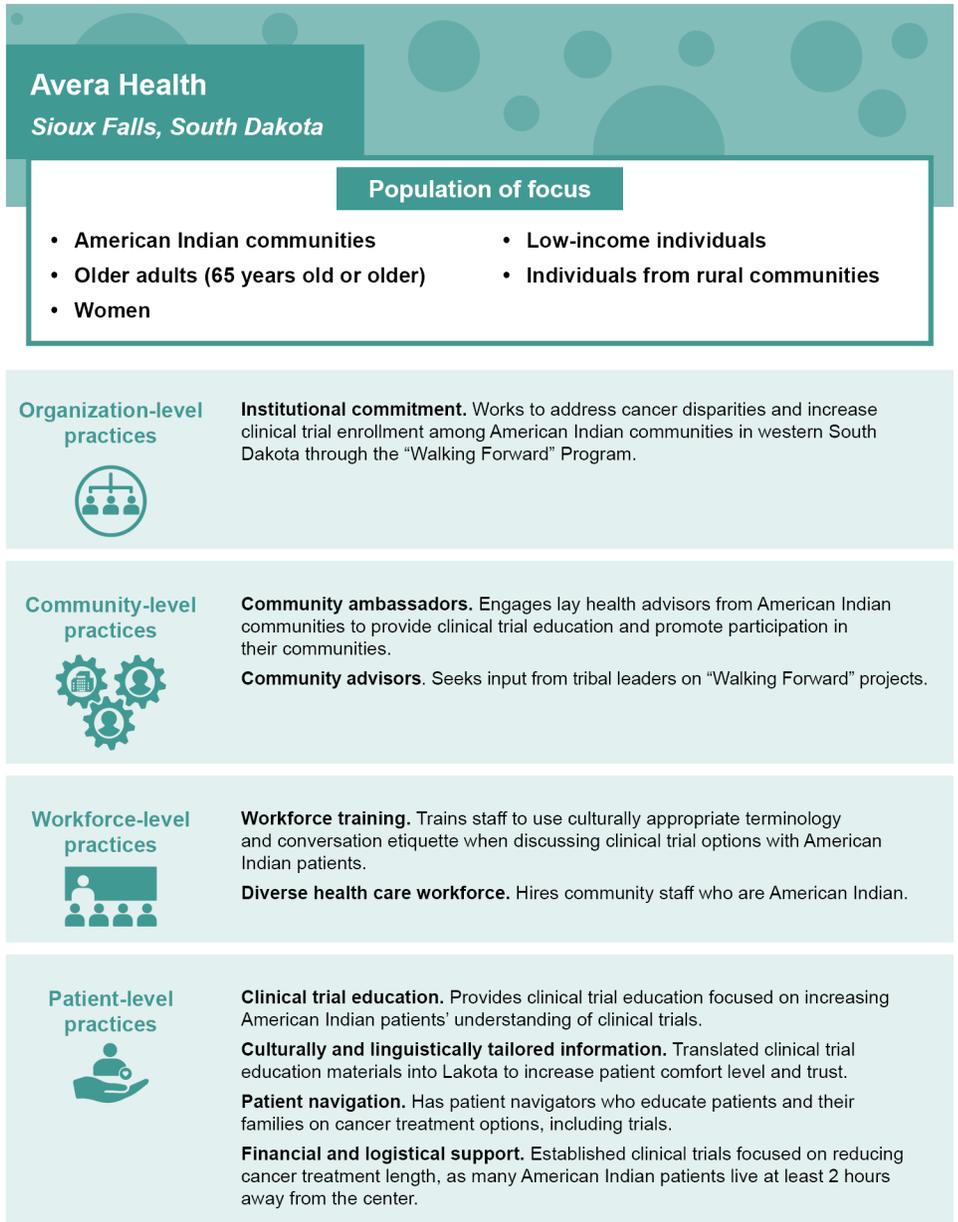
Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Initiative to enroll Black patients into cancer clinical trials

In 2014, Abramson Cancer Center implemented an initiative to increase the enrollment of Black patients into cancer clinical trials. As part of the initiative, the Center promoted clinical trials addressing cancers that affected Black residents and required that each trial have a plan to recruit Black patients. The initiative also included: culturally tailored marketing strategies, community education by faith-based organizations serving Black communities, transportation through ride-sharing companies to and from appointments, and patient education by nurse navigators.

These efforts have reached more than 10,000 individuals and doubled the percentage of Black patients enrolled in the Center's cancer clinical trials. From 2014 through 2018, the percentage of Black patients enrolled in cancer treatment trials increased from 12.2 percent to 23.9 percent.

Figure 6: Selected Avera Health Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

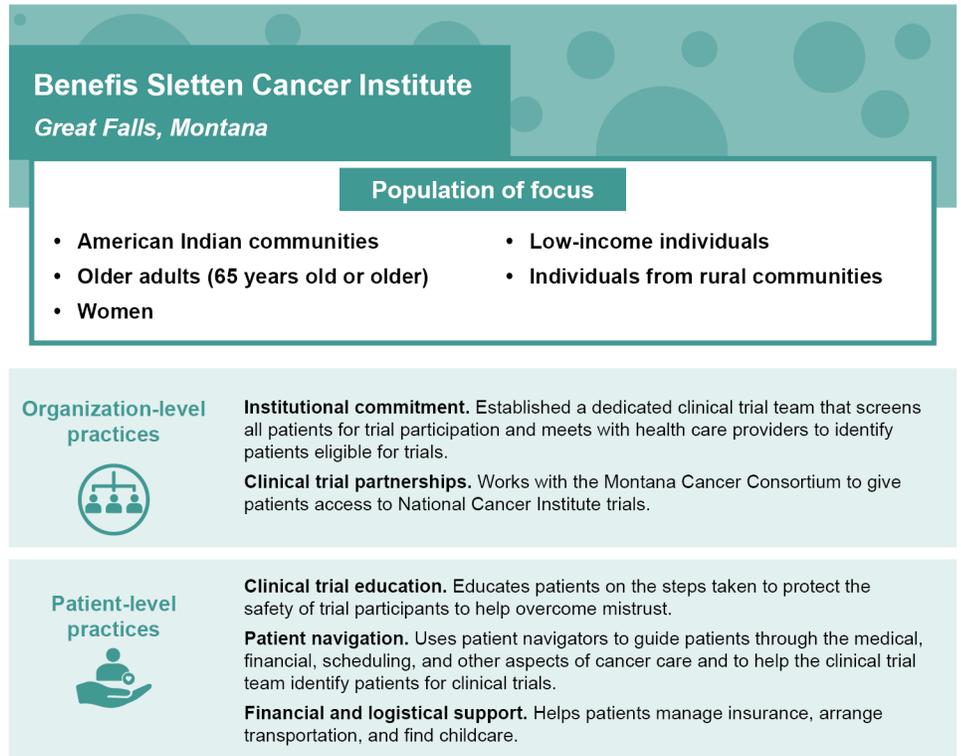
Case example: Program to enroll American Indian patients in cancer clinical trials

Avera Health’s “Walking Forward” program is focused on enrolling American Indians in cancer clinical trials to help decrease the high cancer mortality rates among American Indian populations living in western South Dakota—specifically, communities living in Rapid City, South Dakota, and on the Pine Ridge, Rosebud, and Cheyenne River reservations. To increase participation, “Walking Forward” has done the following:

- Implemented community surveys to evaluate barriers to accessing care.
- Created culturally tailored education on cancer screening and clinical trial opportunities.
- Engaged American Indian patient navigators and community research representatives to increase community trust, improve access to early diagnosis and treatment, and support the needs patients.

Since it was established in 2002, “Walking Forward” has enrolled 4,500 American Indian patients—the highest in the nation, according to program officials.

Figure 7: Selected Benefis Sletten Cancer Institute Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Efforts to engage rural and American Indian communities

Benefis Sletten Cancer Institute provides care to a 13-county region in central Montana. The Center’s service area includes rural communities and approximately 20 percent of patients live more than 100 miles from the Center. There are also three reservations and one federally recognized but landless tribe within the Center’s service area. About 7 percent of patients are American Indian. To help provide diverse communities access to care and clinical trials, Center offers the following:

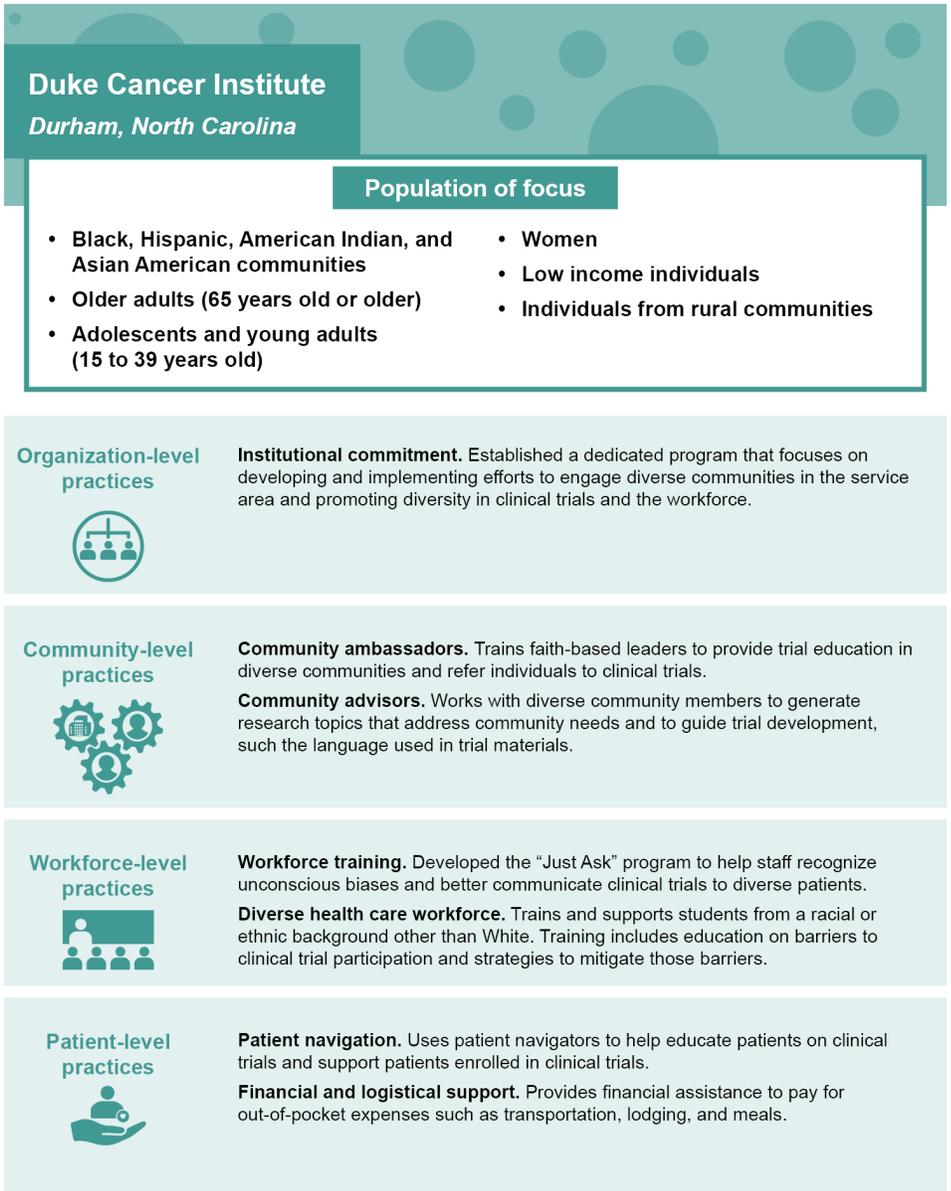
- Complementary housing for patients who live farther from the center to relieve some of the financial burden of traveling to and from the cancer center.
- Telehealth services so that patients can receive care when travel to the Center is not possible, for instance due to weather.

**Appendix III: Selected Cancer Center Practices
Related to Diversity in Clinical Trials**

- A Welcoming Center that provides culturally sensitive care and support for American Indian patients and their families, including a cultural room for smudging ceremonies and a quiet area for meditation or traditional prayer. This helps build trust and allows for continued practice of spiritual and cultural beliefs, according to Center officials.

The Center has between 80 and 120 trials open for enrollment, and about 4 percent of its patients are enrolled in clinical trials annually.

Figure 8: Selected Duke Cancer Institute Practices to Facilitate Diverse Patient Representation in Clinical Trials



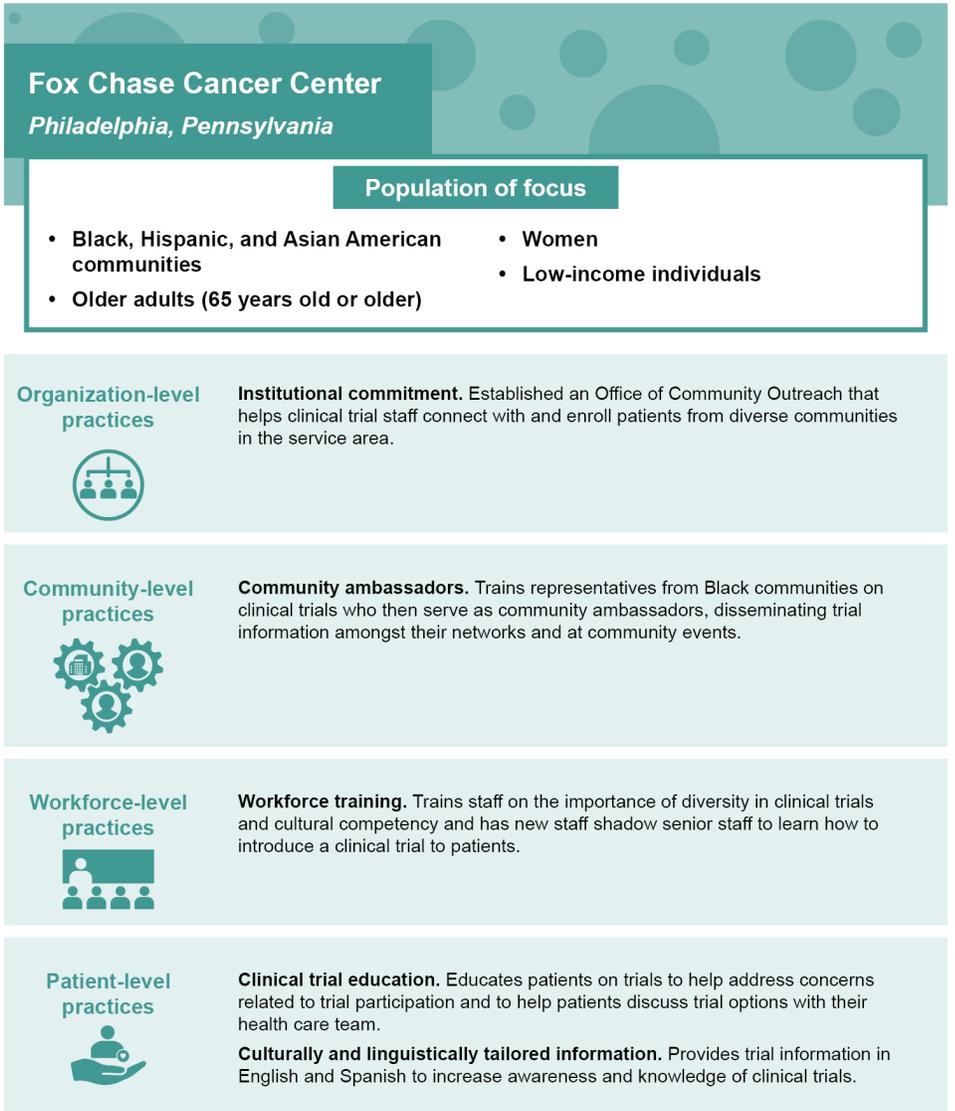
Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Training the health care workforce

The Duke Cancer Institute provides training on diversity and inclusion in the workforce and clinical trials for staff and for students from diverse backgrounds to increase retention in the academic pipeline. For example, the Institute has implemented the following programs:

- The “Just Ask” training program helps staff recognize unconscious biases and teaches them strategies to mitigate the effect of unconscious biases on the participation of patients from diverse backgrounds in clinical trials.
- The “Cancer Research Education Program” trains students from diverse backgrounds at Duke and North Carolina Central University, a historically black university, to improve their skills in recognizing biases and addressing issues of equity and inclusion within professional settings. The program also includes training on community engagement, barriers to enrolling diverse patients in clinical trials, and strategies to help address enrollment barriers.
- According to Center officials, the “Diversifying Research and Experiential Learning in Cancer Training Fellowship” program promotes cancer research equity among trainees from diverse backgrounds through mentorship, professional development, and science communication.
- A five-part training program educates and mobilizes health care workers and scientists on strategies for community engagement, according to Center officials.

Figure 9: Selected Fox Chase Cancer Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



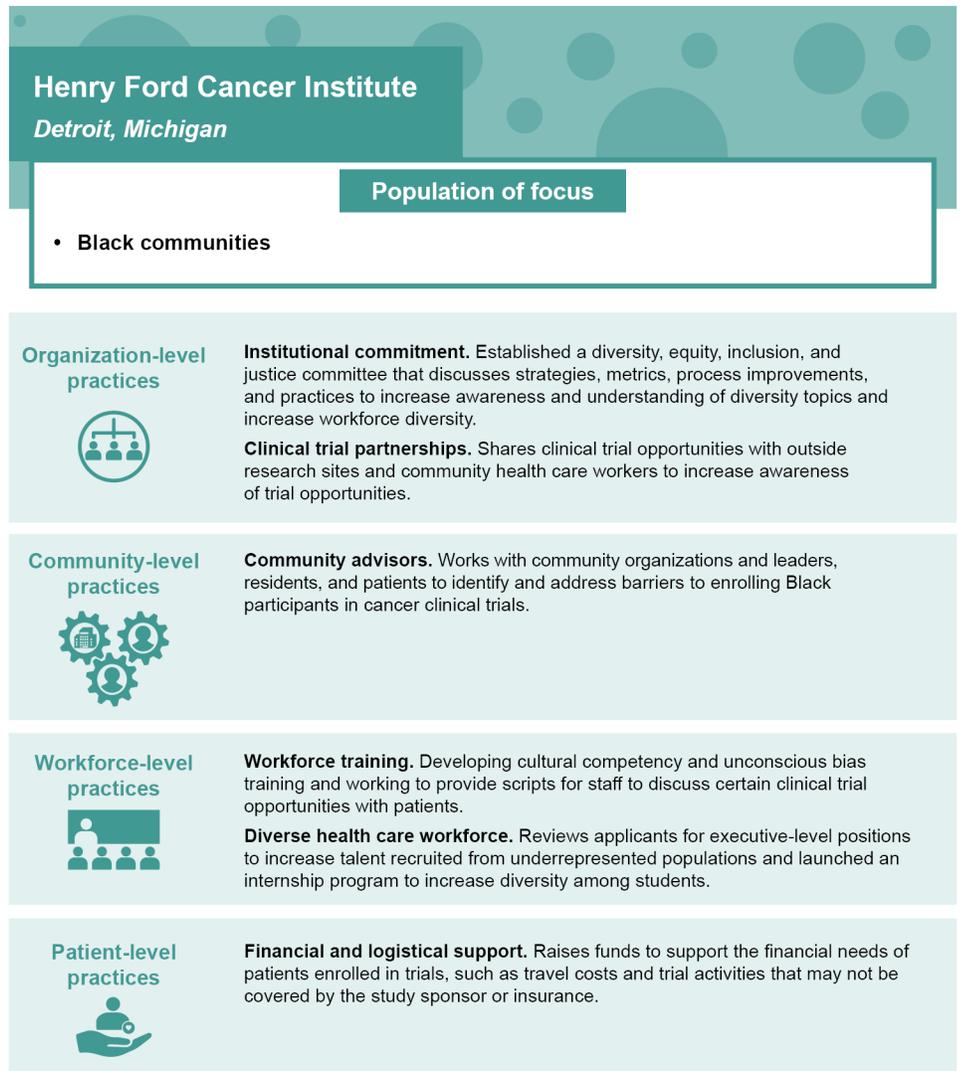
Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Efforts to educate patients on clinical trials

The Fox Chase Cancer Center is focused on increasing clinical trial awareness and knowledge among diverse communities and patients from diverse backgrounds to help enrollment in clinical trials. The Center has worked to develop several efforts to support this goal:

- The “Be the Breakthrough” campaign provides patients with clinical trial information in English and Spanish to encourage patients to discuss clinical trial options with their health care provider.
- The Preparatory Education About Clinical Trials education program provides general information about clinical trials to help patients better understand what trials are and how they work. Information is provided through a series of short videos.
- *Mychoice* is a web-based education tool that was designed to address concerns related to clinical trial participation and to help patients facilitate conversations about clinical trials with their health care providers. The tool has been adapted to reflect multi-cultural audiences and, according to Center officials, will be available in multiple languages.
- The Community Bilingual Speakers Bureau provides cancer education on a variety of cancer topics including: breast, cervical, colorectal, liver, lung, ovarian, prostate and skin. All topics provide an overview of what cancer is, risk factors, symptoms, screening guidelines, and treatment option including clinical trials.

Figure 10: Selected Henry Ford Cancer Institute Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Project to the enrollment of Black patients in cancer clinical trials

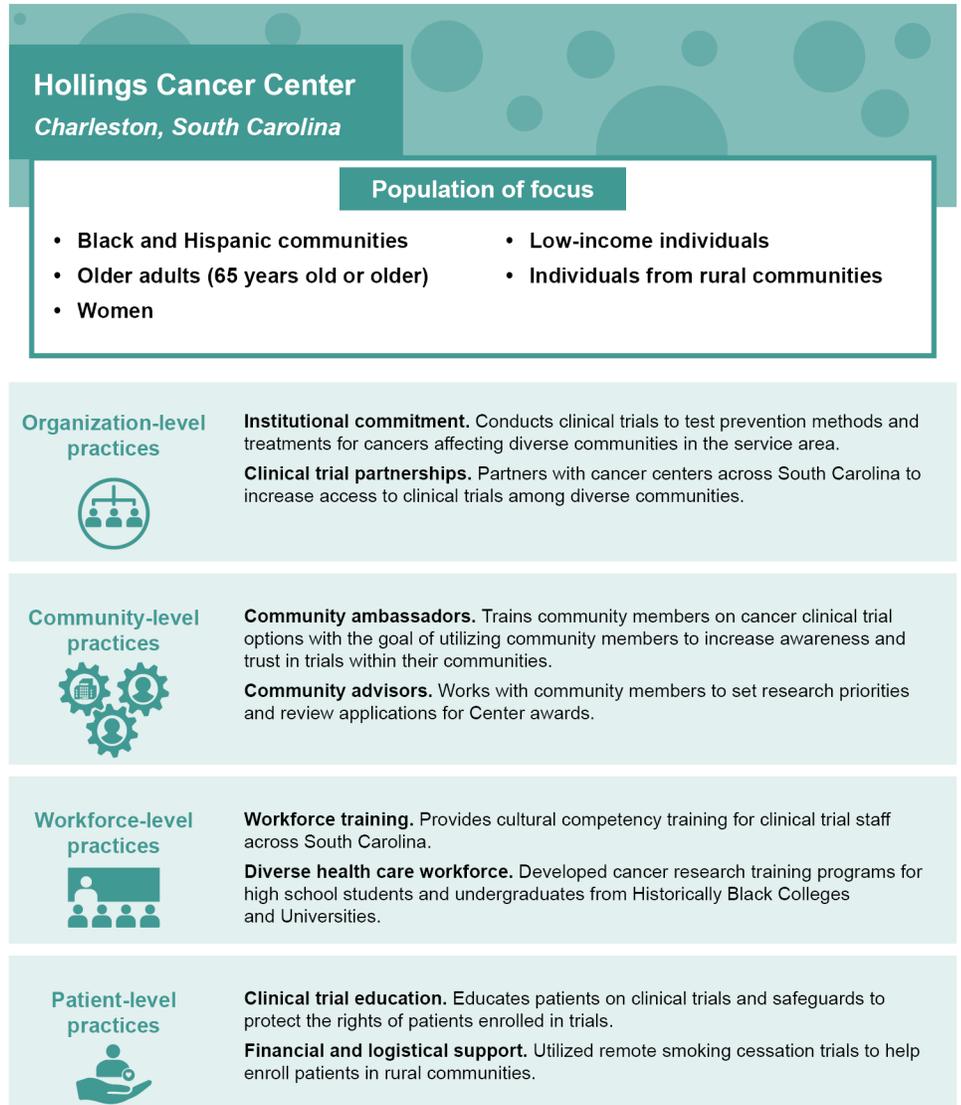
In 2021, the Henry Ford Cancer Institute initiated the Participatory Action for Access to Clinical Trials project with the goal of improving the representation of Black individuals in cancer clinical trials. The Institute conducted focus groups and interviews with patients and survivors,

**Appendix III: Selected Cancer Center Practices
Related to Diversity in Clinical Trials**

community members, and providers and research staff to better understand barriers to clinical trial participation and Black individuals' attitudes about research. The goal is to use this information to understand whether there are opportunities to better engage Black patients in clinical trials and to develop and test interventions to overcome identified barriers.

The project is being implemented in collaboration with community organizations and leaders and will focus on clinical trials involving breast, colorectal, lung, and prostate cancers, which are more likely to result in death for Black individuals when compared to other racial and ethnic groups.

Figure 11: Selected Hollings Cancer Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

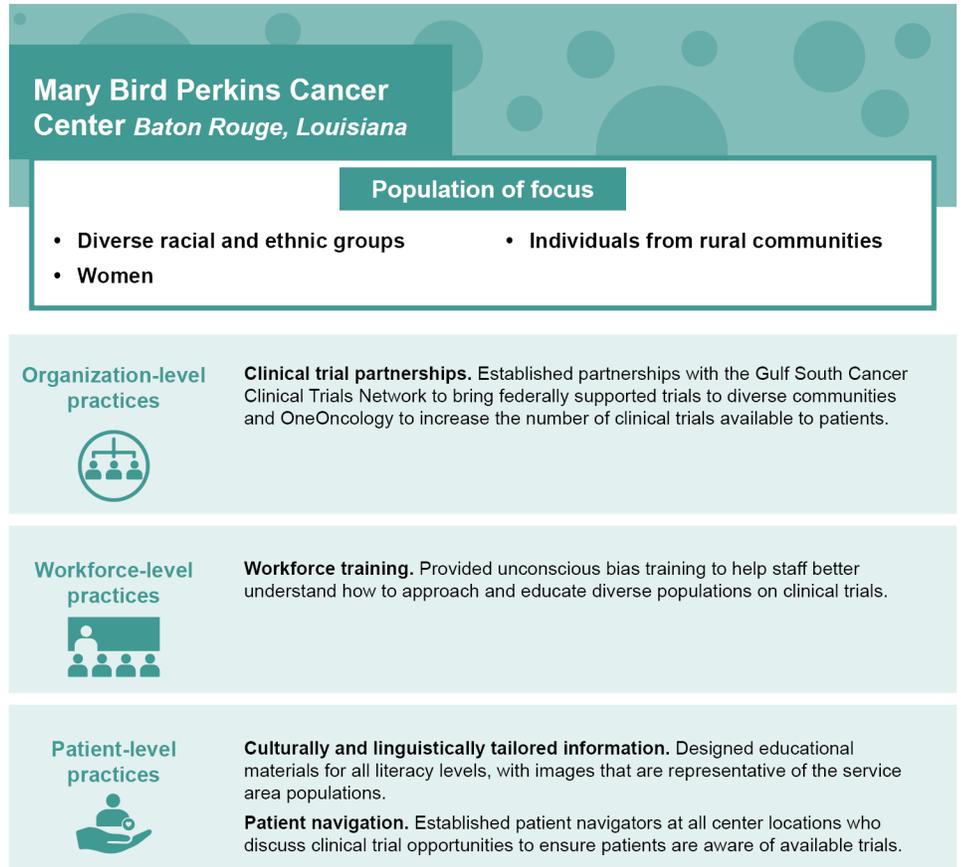
Case example: Program to address prostate cancer disparities

In September 2021, Hollings Cancer Center initiated a 3-year program to reduce prostate cancer disparities in its service area by increasing prostate cancer screening rates among Black men aged 40 to 69 in South Carolina. Prostate cancer is the second leading cause of cancer death

among Black men in South Carolina, and the mortality rate among Black men with prostate cancer is 2.5 times higher than among White men. To increase screening, Hollings will deliver monthly prostate cancer education sessions and provide navigation services for those who attend education sessions to address barriers they may face in getting prostate cancer screening.

As of November 2022, Center officials report that 156 Black men had enrolled in the trial and 93 percent of the men enrolled were navigated to prostate cancer screening or had made an appointment to get screened for prostate cancer. Center officials said they expect the effort will help guide the development and implementation of future trials focused on cancer prevention, control, and treatment strategies for Black men.

Figure 12: Selected Mary Bird Perkins Cancer Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

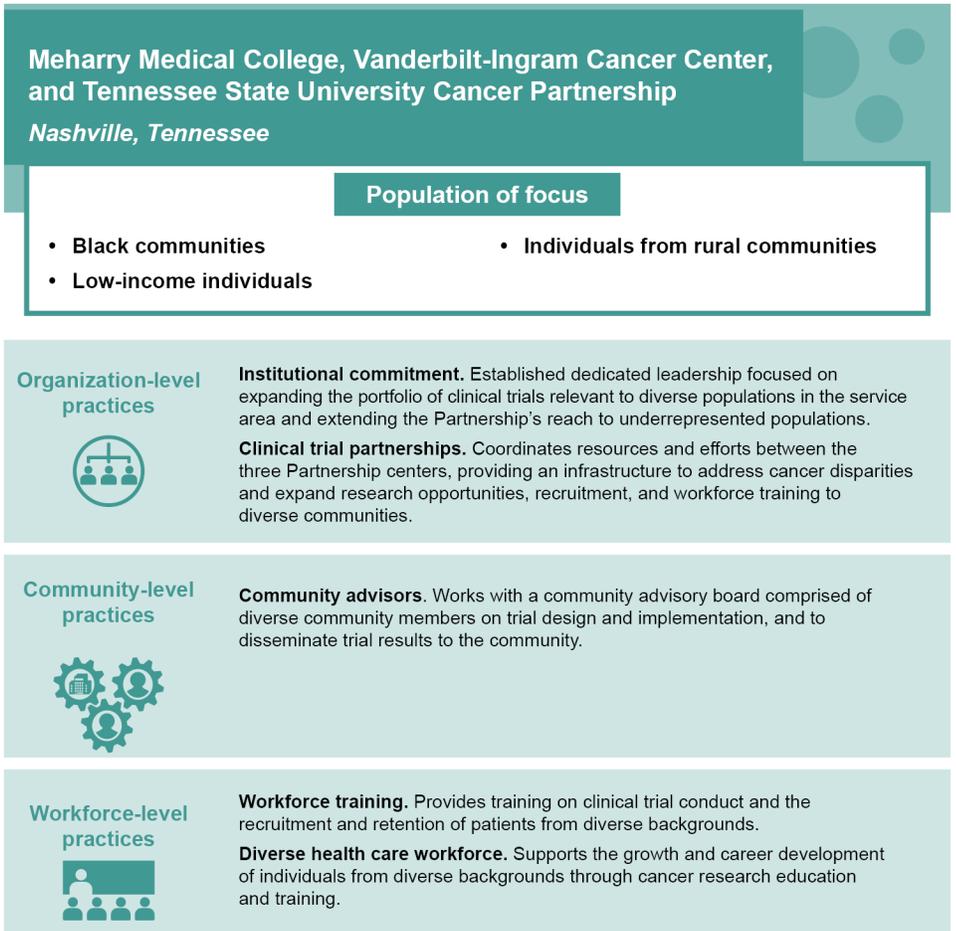
Case example: Clinical trial partnerships to expand clinical trial availability

The Mary Bird Cancer Center is an independent, community-owned, nonprofit cancer center that serves diverse communities throughout southeast Louisiana and southwest Mississippi. Four of the six areas in which the Center has a facility have a Black majority population. The Center partners with the Gulf South Minority Underserved NCI Community Oncology Research Program Cancer Clinical Trials Network and OneOncology, which helps the Center meet its goal of offering a number of trial opportunities to patients.

**Appendix III: Selected Cancer Center Practices
Related to Diversity in Clinical Trials**

- Participating in the Gulf South Minority Underserved NCI Community Oncology Research Program Cancer Clinical Trials Network enables the Center to offer NCI supported cancer clinical trials to its patients. The network consists of cancer centers and health care providers in Louisiana and Mississippi that work together to improve patient outcomes by expanding access to cancer prevention and treatment trials as well by providing community based outreach and education programs. Collectively, the network offers cancer trials at more than 40 locations.
- In January 2022, the Center established a partnership with OneOncology, a national platform that provides operational, regulatory, and research services for independent cancer practices. The partnership will enable the Center's patients to access clinical trials OneOncology is participating in, offering additional opportunities for them to participate in a study that may enhance their treatment.

Figure 13: Selected Meharry Medical College, Vanderbilt-Ingram Cancer Center, and Tennessee State University Cancer Partnership Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Community engagement and workforce training efforts

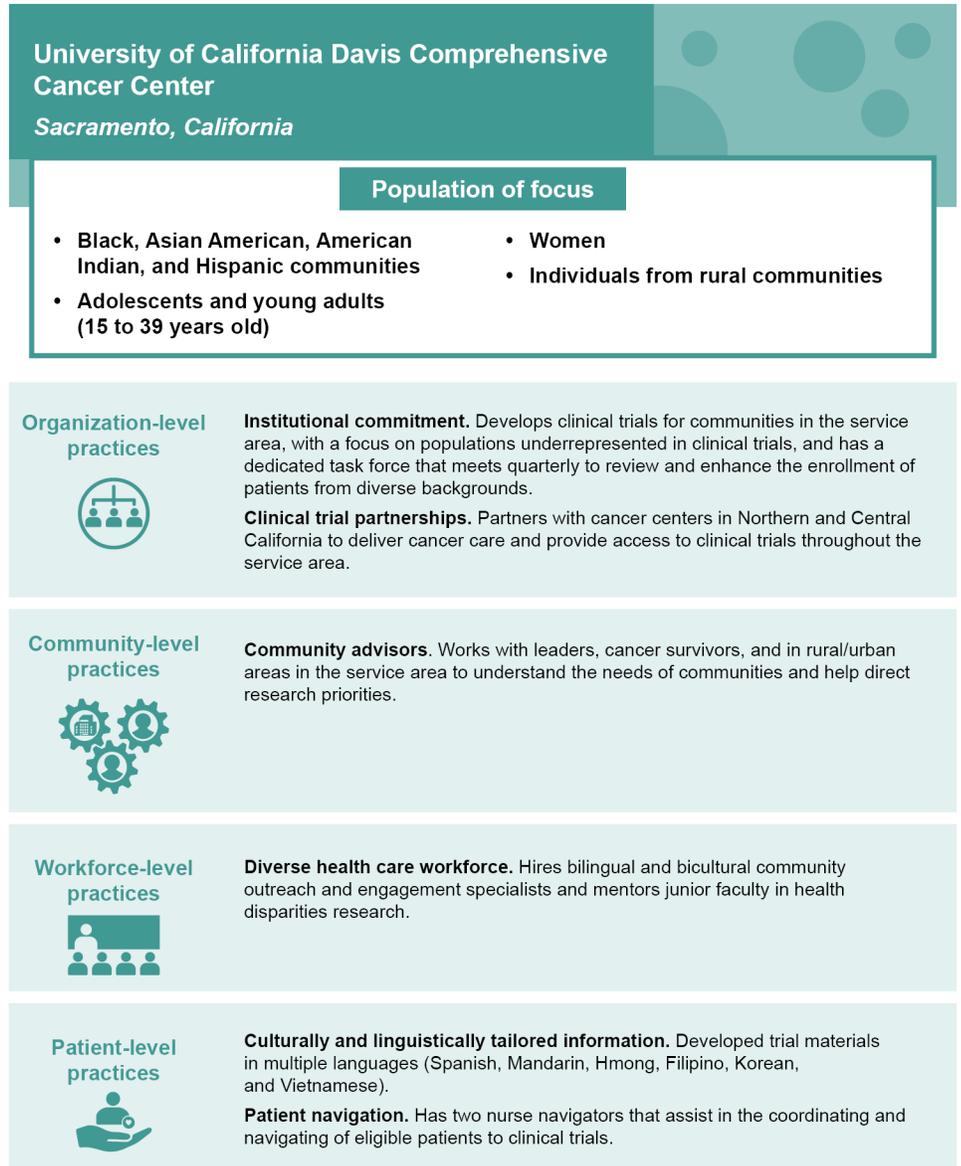
The Meharry Medical College, Vanderbilt-Ingram Cancer Center, and Tennessee State Cancer Partnership is a collaboration between three programs in Nashville, Tennessee, focused on increasing the diversity of the health care workforce and the enrollment of patients from diverse backgrounds in cancer clinical trials. The Partnership has developed the dedicated programs to support community outreach and workforce training.

**Appendix III: Selected Cancer Center Practices
Related to Diversity in Clinical Trials**

- The cancer outreach program works with community partners to help ensure that the Partnership’s activities reflect the needs and concerns of diverse communities in the service area and to provide community-based education. The program also conducts events focused on recruiting and referring Black and Hispanic patients to cancer clinical trials.
- The “Pathway to Discovery” program provides cancer research education for high school students from diverse backgrounds to increase their awareness of careers in cancer research. The program also supports students from Meharry Medical College and Tennessee State University.

From 2011 through 2018, the Partnership enrolled 862 patients in clinical trials of which approximately 76 percent (653 patients) were Black patients.

Figure 14: Selected University of California at Davis Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

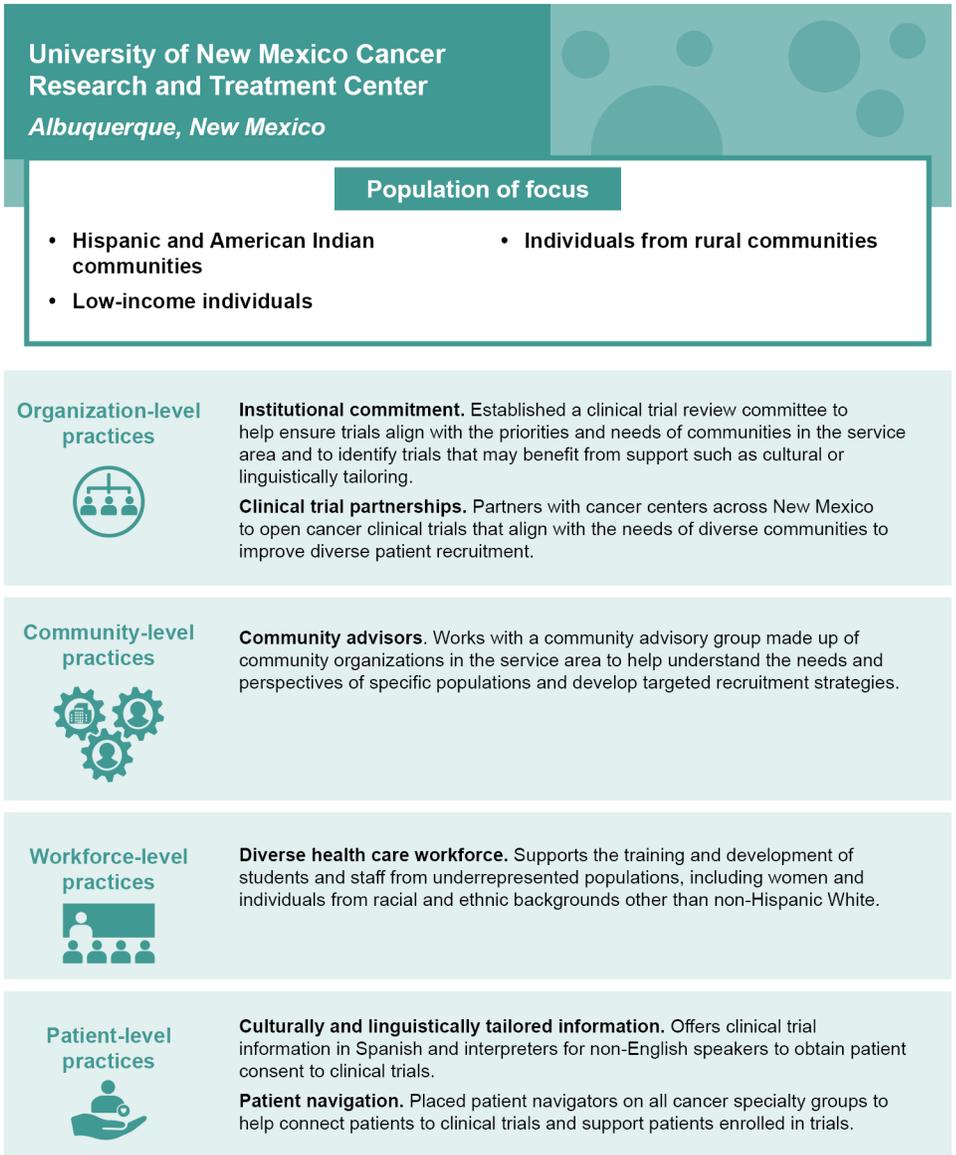
Case example: Projects informed by service area demographics

The University of California Davis Comprehensive Cancer Center has developed programs to identify and address cancer disparities and

increase clinical trial enrollment among Hispanic and Asian communities within its service area, including the following:

- The Latinos United for Cancer Health Advancement project, which is focused on reducing cancer disparities by identifying community needs and increasing participation in early detection screenings and clinical trials, conducted a population assessment to better understand cancer within Hispanic communities and conducted outreach in the community by participating in local health fairs, church and other community events. According to Center officials, by forming partnerships with local community organizations, the center was able to build trust with patients and better ensure they completed the population assessment which, in turn, increased the Center's ability to identify disparities and develop interventions to address needs.
- The Asian-American Network for Cancer Awareness, Research and Training initiative—which is focused on reducing cancer disparities through community education, workforce and training, and research—developed clinical trial information in Mandarin, Hmong, Filipino, Korean, and Vietnamese to increase access and knowledge of clinical trials and the use of procedures to reduce cancer disparities and related comorbid conditions among Asian Americans. According to Center officials, having materials in a patient's native language helps to increase trust and education among individuals with limited English proficiency and a better understanding of clinical trial information increases trial participation.

Figure 15: Selected University of New Mexico Cancer Research and Treatment Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



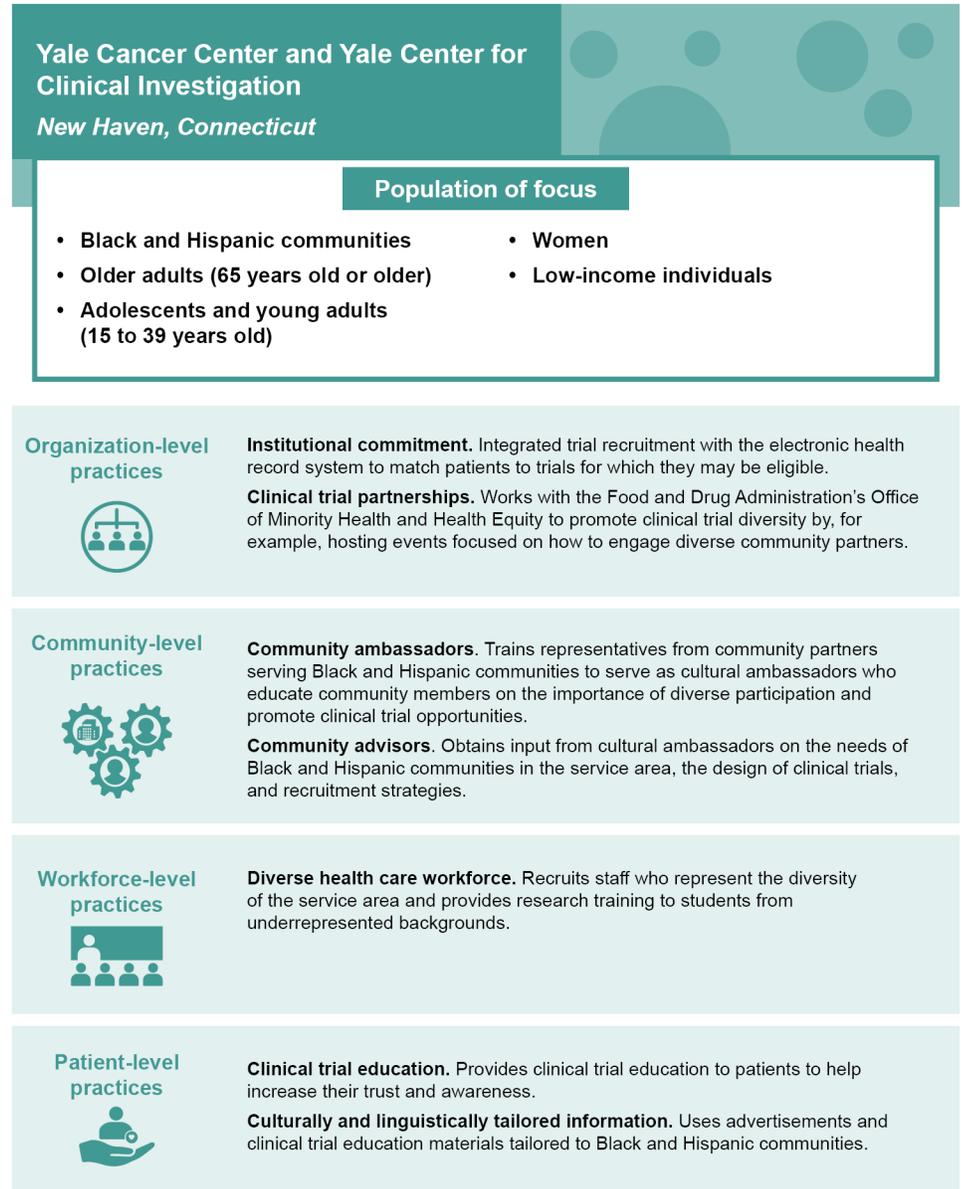
Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Partnerships to help address cancer disparities through clinical trials

The University of New Mexico Cancer Research and Treatment Center partners with the New Mexico Cancer Research Alliance—a statewide collaboration of clinical trial sites—to address cancer disparities through increased cancer clinical trial awareness, access, and participation among diverse communities across New Mexico. To support and monitor the performance of trials conducted at the Center and at partner sites, the Center established a centralized

Clinical Research Office. Additionally, the Center implemented a Community Oncology Work Group that includes representatives from partner sites and meets monthly to review trial options to ensure trials opened are aligned with the needs of diverse communities.

Figure 16: Selected Yale Cancer Center and Yale Center for Clinical Investigation Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

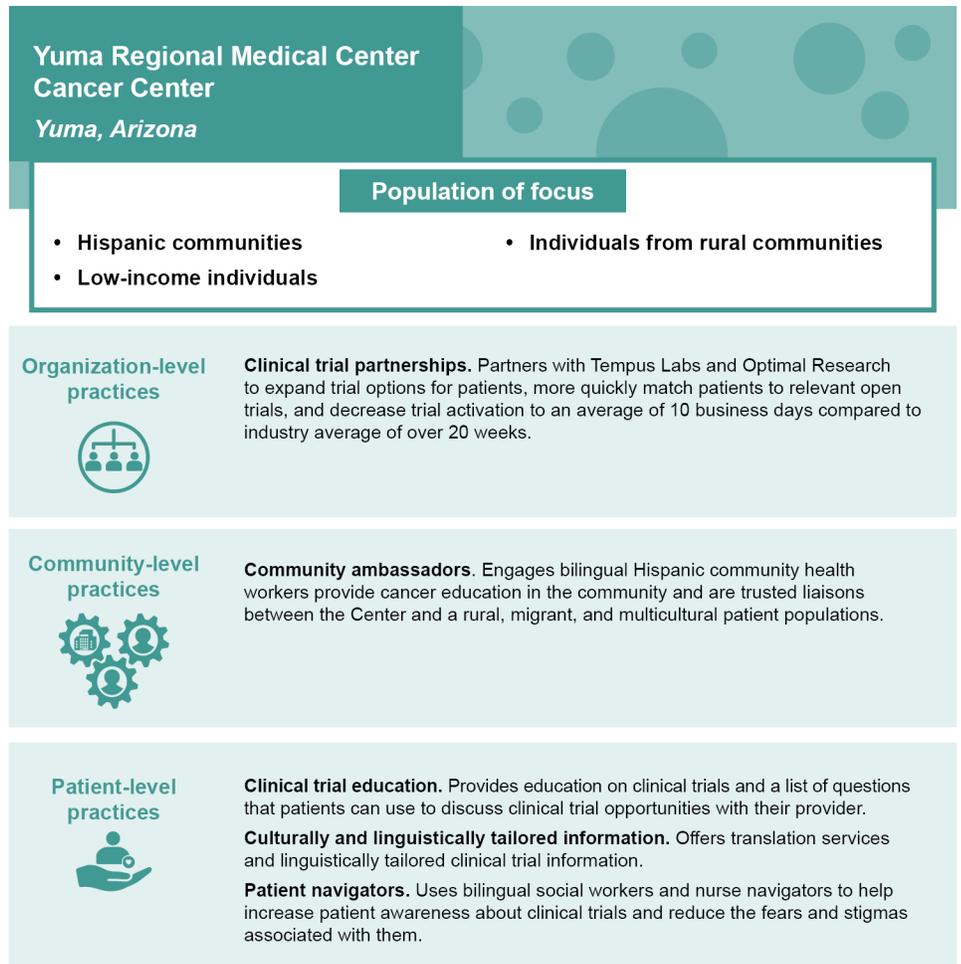
Case example: Cultural Ambassador Program

Established in 2010, the Yale Center for Clinical Investigation Cultural Ambassador Program is a partnership with the Connecticut African Methodist Episcopal Zion Churches and Junta, organization that serves Hispanic communities in New Haven. Ambassadors are selected by community partners and assist in the development of protocols and recruitment plans for clinical trials and translate information into Spanish. Additionally, ambassadors:

- Promote and increase participation in clinical trials. For example, cultural ambassadors and Yale staff discuss health care issues and how to access clinical trials on two local television shows.
- Support workforce diversity initiatives. For example, Yale staff and cultural ambassadors co-developed a new internship program for high school and undergraduate students to expose and prepare individuals from diverse backgrounds for careers in clinical research.

Center officials reported that, between 2016 and 2021, approximately 61 percent of patients enrolled in trials that involved cultural ambassadors were from racial and ethnic groups other than non-Hispanic White.

Figure 17: Selected Yuma Regional Medical Center Cancer Center Practices to Facilitate Diverse Patient Representation in Clinical Trials



Source: GAO analysis of cancer center questionnaire responses and other public information. | GAO-23-105245

Case example: Engaging Hispanic patients in cancer clinical trials

Yuma Regional Medical Center Cancer Center is located in southwest Arizona and serves a majority Hispanic population. To help ensure Hispanic patients are represented in cancer clinical trials, the Center has taken the following steps:

- Engaged bilingual clinical research staff, social workers, and nurse navigators into patient care and clinical trial outreach to increase

awareness of clinical trials and reduce the fears and stigmas associated with them.

- Provided culturally and linguistically tailored clinical trial education for both patients and their caregivers to help increase their understanding of trials.
- Provided patient consent forms are available in multiple languages and formats at the beginning of clinical trial enrollment.
- Employed certified translators so that family members do not have to serve a patient's sole translator and to help enable shared decision-making between patients and their health care providers.

Center officials reported that 39.2 percent of patients enrolled in cancer clinical trials are Hispanic, compared to an average of 3 percent to 6 percent across cancer therapeutic trials more broadly.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contacts

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Staff Acknowledgments

In addition to the contacts named above, Jill Center (Assistant Director); Carolyn Feis Korman (Analyst-in-Charge), Derry Henrick and Timothy Kinoshita made key contributions to this report. Also contributing were Ashley Dixon, Keith Haddock, Ruby Samim, Laurie Pachter, Vikki Porter; Emily Wilson Schwark, Cathleen Hamann Whitmore, and Nicole Willis.

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