



Cancer Research and Disparities

Understanding and Addressing the Issues

May 2021



Background

Disparities exist throughout the continuum of cancer care from prevention and screening to survivorship. The types and causes of these disparities are complex and include interactions between social, behavioral, and biological factors that can lead some populations to experience higher burdens of cancer morbidity and mortality relative to other groups and relative to the overall population. Eliminating disparities so all individuals – regardless of age, race, ethnicity, socioeconomic status (SES), education, sexual orientation, insurance status, or zip code – have the same opportunities to prevent, detect, and treat cancer, requires understanding of the role research plays in potentially causing disparities, as well as how research can help identify and address root causes of disparities. While disparities have been described in various domains of research – including the makeup of the research workforce, what researchers are awarded grant funding, and participation in clinical trials – each of these issues exist separately and have a different relationship to understanding and addressing disparities in clinical outcomes (Figure 1). As an example, addressing disparities in clinical trial participation, by itself, will not address disparities in outcomes. The various domains of research disparities are addressed in this report.

Cancer Research and Disparities

DISPARITIES IN CANCER CLINICAL TRIAL PARTICIPATION

The makeup of cancer clinical trials does not represent the real-world population which limits the broader applicability of trial results, leading to social injustice.



RESEARCHING DISPARITIES IN CANCER OUTCOMES

Certain groups bear a disproportionate burden of cancer. Cancer disparities research investigates outcome differences between groups and the underlying factors driving the differences.

CANCER WORKFORCE DISPARITIES

The cancer care and research workforce does not represent the U.S. population demographically. A diverse workforce can help to reduce implicit biases and systemic disparities; however, structural barriers impede workforce diversity.




Figure 1: Cancer research and disparities can be described along various domains.



Disparities in Cancer Clinical Trial Participation

Clinical research involves the study of people, data, or samples of tissue to understand health and disease.¹ Clinical research can be broadly divided into observational studies or interventional studies. In observational studies, participants are observed, and outcomes are measured.² No intervention is made to affect participant outcomes. In contrast, interventional studies test the efficacy of new medical approaches in prevention, screening, diagnosis, or treatment.³ An intervention is made to affect participant outcomes and these outcomes are subsequently measured.

Clinical Trials – A Brief Background

A clinical trial is a type of clinical research that is vital to advancing new and improved standards of care. Clinical trials are carefully controlled studies to understand if interventions are safe and effective. (*Interventions can be in prevention, screening, diagnosis, or treatment. Throughout the rest of the paper the use of “clinical trial” will refer to therapeutic, interventional studies that test treatments for disease*). Some clinical trials are designed to provide the evidence for safety and efficacy of new drugs before they are approved and prescribed, while others test the safety and efficacy of different doses, combinations, etc. of drugs that are already approved.

Prior to the early to mid-20th century, clinical trials were less regulated and participation was often risky. The burden of participation frequently fell on groups who have been marginalized, including people with low incomes, prisoners, and racial and ethnic minority groups,⁴ often without their consent. There are several documented instances of harm and abuse inflicted upon research participants during this period. Public outrage from notable cases, like the Tuskegee Syphilis Study, led to the recognition of the need for basic protections for research participants so that abuses could be prevented, and risks minimized.

In the late 1970s, Congress formed the *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* to address the protection of research participants and to develop federal research guidelines. The commission produced the seminal *Belmont Report* which outlines three basic principles relevant to research involving humans (Figure 2).

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Respect for Persons
Individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.

Beneficence
Do no harm and maximize possible benefits and minimize possible harms.

Justice
The benefits and burdens of research should be fairly distributed across groups.

Figure 2: The Belmont report outlines three basic principles for human subjects research: respect for persons, beneficence, and justice. **Source:** The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979)⁴



The *Belmont Report* would later be codified in the *Federal Policy for the Protection of Human Subjects* (i.e. The Common Rule). With these protections in place today, research is more commonly seen as an opportunity to access the newest developments in treatment, and in contrast to the past, groups who have been marginalized are frequently underrepresented.

Cancer Clinical Trials and Enrollment

To successfully assess the safety and efficacy of treatments, clinical trials must enroll an adequate number of trial participants. Although most cancer patients offered a clinical trial participate,⁵ adequate enrollment in cancer clinical trials is an ongoing challenge. Approximately 20% of cancer clinical trials fail due to inadequate enrollment, and the average participation rate of cancer patients is approximately 8% across academic and community settings combined.⁶ Several structural, clinical, and attitudinal barriers to enrollment that vary along demographic and socioeconomic attributes, have been noted.⁶



There are additional challenges and considerations to achieving adequate enrollment in cancer clinical trials as opposed to non-cancer clinical trials. First, cancer is not a singular disease, but rather more than 200 unique diseases. Second, the yearly incidence rate for some cancers is much lower when compared to other more common cancers. Cancers that occur less frequently have fewer patients available to enroll in clinical trials. Even in cancers that occur more frequently there are often multiple subtypes and stages that can affect treatment and clinical trial approaches. These factors contribute to notable differences between cancer clinical trials versus non-cancer clinical trials. Compared to non-cancer clinical trials, cancer trials are significantly more likely to be nonrandomized, smaller, and have ongoing recruitment.⁷ Participants in cancer clinical trials collectively represent only a small proportion of a diverse population in the U.S. with cancer. For example, of 127 clinical trials that supported 92 novel cancer drugs approved by the U.S. Food and Drug Administration (FDA) between 2000 to 2016, the median number of trial participants was 191.⁸ Comparatively, FDA approved 35 new cardiometabolic drugs between 2008 to 2017 in which the median number of participants across 143 trials was 5,930, which is over thirty times larger than in cancer.⁹

Representativeness in Cancer Clinical Trials – Social Justice and Applicability of Clinical Trial Results

Representativeness in clinical trials advances both ethical and scientific goals of research (Figure 3). First, representativeness contributes toward the ethical principle of social justice by ensuring that no one group receives a disproportionate benefit or bears a disproportionate burden of clinical research.⁴ Second, representativeness helps to ensure that trial outcomes are more likely to be observed in the real-world population; however, **proportional representation alone cannot allow researchers to understand variations in treatment response between groups.**



Social Justice

Social justice in clinical trials is realized when the population from which trial participants are selected reflect the population that would benefit from the actual or projected results of the trial.¹⁰ Clinical trials are intended to benefit a population with a disease, therefore underrepresentation of demographic subgroups (e.g. age, race, ethnicity, low income) within that population in clinical trial enrollment can create inequity. Clinical trials give patients the opportunity to access the latest developments in treatment and access to care that is equivalent to treatment outside of a trial. Disproportionate representation can lead to new, and perpetuate existing cancer disparities in outcomes and in access to treatment.

Applicability of Results

Clinical trials are intentionally conducted with a relatively small portion of a population with a disease, but the intent is to apply the results from this small group of individuals to the larger population with disease. If the group in the clinical trial is clinically different than the broader population for which the intervention is intended (e.g. younger, sicker, more/fewer comorbidities), then the overall study results may not transfer to the broader population with the disease. Equitable representation among demographic subgroups in clinical trials is necessary to ensure the applicability of results and equal access to advances in treatment.¹¹

Why Representation Matters

Broad Applicability of Results

Representative clinical trials help to ensure trial outcomes transfer to the broader population with the disease.

Social Justice

The population from which trial participants are selected should reflect the population that would benefit from the actual or projected results of the trial.

Figure 3: Representation in clinical trials advances both ethical and scientific goals of research.

Disparities by Race and Ethnicity*

Racial and ethnic minority groups in the U.S. are commonly underrepresented in cancer clinical trials compared to their cancer burden.^{11,12,13,14} **Although mistrust of the medical system is frequently cited as a barrier to participation,¹⁵ racial and ethnic minority groups express an equal willingness to participate in clinical trials.^{5,16}** Broad health-system level barriers such as lack of insurance, lack of trials at sites serving minority populations, and clinical trial design (e.g. inclusion/exclusion criteria) are key drivers of underrepresentation¹⁷ which contribute to inequity in access to treatment and lessens trial result applicability to broader populations.

Representation of racial and ethnic minority groups in cancer clinical trials varies by trial sponsor. The majority of cancer clinical trials are either sponsored by the federal government through the National Cancer Institute (NCI) or by the pharmaceutical industry. NCI-sponsored trials often involve the use of therapies that are already approved. Industry-sponsored trials are usually conducted to collect data

* The broadly defined racial and ethnic groups discussed herein are heterogeneous with substantial variations in cancer burden within each group. Race and ethnicity terminology may change throughout the report, reflecting the terminology used in the underlying source for each citation.



to support FDA-approval of new drugs or new indications for approved drugs. Underrepresentation of racial and ethnic minority groups is more pronounced in industry trials that support new drug approvals compared to NCI-sponsored trials.^{6,18} One major contributing factor is that many industry trials are conducted outside of the U.S. where patient demographics differ significantly from the U.S. population. For example, from 2017 to 2020, only 24—41% of patients enrolled in trials leading to FDA cancer drug approvals were from sites in the U.S.^{19,20,21,22} Most pharmaceutical companies are pursuing approval for their drug simultaneously in multiple countries, therefore their clinical trial programs tend to be global. FDA accepts data from trials conducted anywhere in the world so long as they follow FDA regulations governing ethical treatment of subjects and data integrity.²³ In fact, drug sponsors can submit a drug to FDA for approval without any clinical trial participants coming from the U.S. NCI-sponsored trials, on the other hand, are almost exclusively conducted at U.S. institutions, many of which are community based sites.

In one example, from a study examining the representation of Black patients in industry-sponsored trials supporting new FDA cancer drug approvals from 2008 to 2018, the overall proportion of Black patients was less than 3% (85 total trials) as compared to NCI-sponsored trials (273 total trials) over the same time period at 9%.¹⁸ Notably, during this time Black individuals represented 12.1% of the U.S. cancer population.¹⁸ A similar study found, that compared to White patients, Black and Hispanic patients were underrepresented relative to their proportion of the U.S. cancer population (22% and 44% of expected, respectively) in globally recruiting trials leading to FDA drug approvals over a ten-year period.¹²

Over a 20-year period, NCI-sponsored trials nearly doubled in participation of patients from racial and ethnic minority groups, from 14% in 1999 to 25% in 2019 (Figure 4).²⁴ Black or African American, Hispanic, and Asian representation reached 11, 10, and 4%, respectively by 2019.²⁴ Additional studies have documented underrepresentation across U.S.-based and global cancer clinical trials among Black, Hispanic, Asian American, Native American, and Hawaiian/Pacific Islander individuals.^{11,12,14}

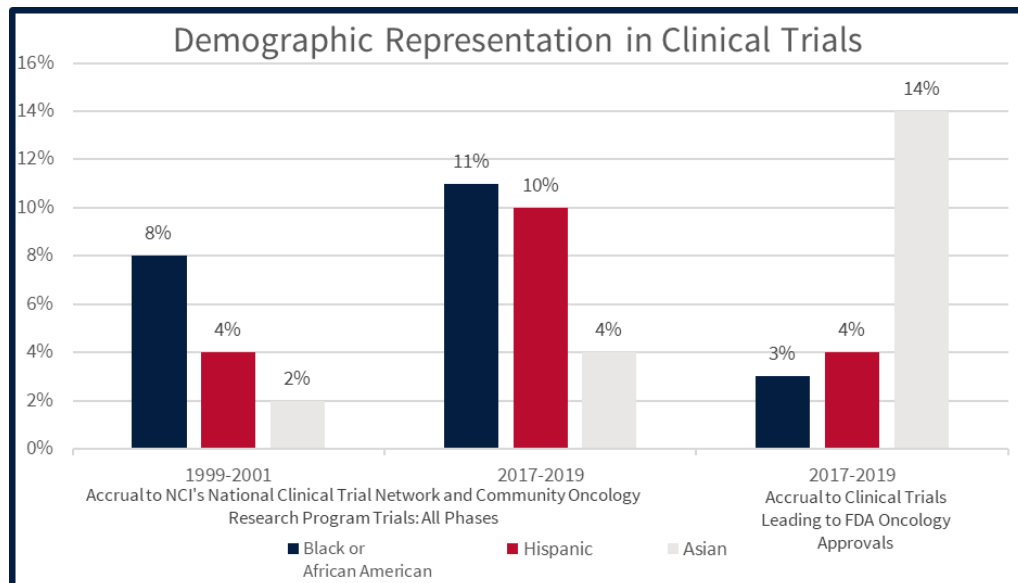


Figure 4: NCI-sponsored trials as compared to industry-sponsored trials tend to have better representation of U.S. racial and ethnic minority groups and over a 20-year period NCI-sponsored trials nearly doubled in participation of racial and ethnic minority patients. One major contributing factor is that many industry trials are conducted outside of the U.S. where patient demographics differ significantly from the U.S. population. **Source:** McCaskill Stevens, W. (2020),²⁴ FDA Drug Trial Snapshots for 2017 to 2019^{20,21,22}



Two examples that clearly illustrate the discrepancy between disease burden and clinical trial representation are multiple myeloma and prostate cancer. The incidence of multiple myeloma in Black individuals is two to three times higher than in White individuals.²⁵ An analysis of racial demographics in multiple myeloma trials found that the median percentage of Black patients enrolled across global multiple myeloma trials supporting FDA drug and biologic approvals between 2003 to 2017 was less than 5%.²⁵ During this time period, Black individuals represented 20% of U.S. patients with the disease while only accounting for approximately 13% of the U.S. population.²⁵ Even in global trials with high U.S. enrollment, Black patient enrollment did not represent the population affected by the disease.²⁵ Prostate cancer is another example of clear disparities in clinical trial participation. Black men in the U.S. and the Caribbean have the highest documented incidence of prostate cancer in the world,²⁶ yet the proportion of Black patients in global, industry-sponsored trials that supported FDA-approval of prostate cancer drugs from 2008 to 2018 was less than 4%, despite Black individuals representing nearly 15% of the U.S. prostate cancer population (Figure 5).¹⁸

While representation is usually thought of in terms of clinical trial participation, before drugs are tested in humans, they are typically tested on cells or tumors. Information gained from this kind of basic research is used in drug development and clinical trials. However, the tissue samples used in basic cancer research often have no record of race or ethnicity or an overrepresentation of samples from populations of European ancestry.^{27,28}

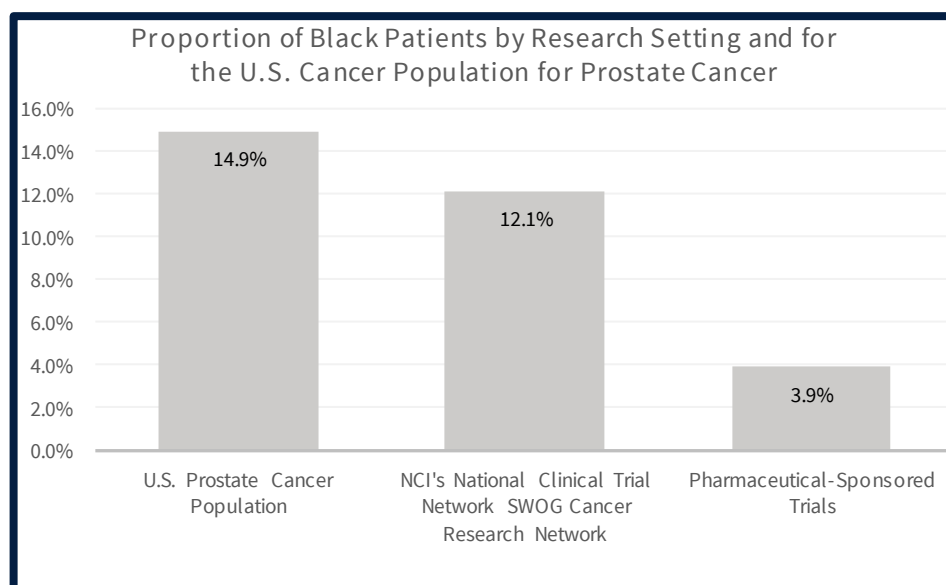


Figure 5: Despite having the highest incidence of prostate cancer in the world, Black men are underrepresented in both NCI- and industry-sponsored prostate cancer clinical trials. **Source:** Unger et al. (2020)¹⁸

Disparities by Age

Age disparities in clinical trial participation are among the largest noted disparities across all trial types, despite older adults being equally likely to consent to trials when compared to younger adults.²⁹ The risk of developing cancer increases with age. As life expectancy rises due to decreases in all-cause mortality, the proportion of the population living with cancer is projected to increase. Over two-thirds of all new cancers diagnosed in the U.S. are among adults 60 years or older³⁰ with cancer risk peaking in men and women in their eighties.³¹ **Despite higher incidence of disease, older adults – people 65 years and older – are underrepresented in cancer clinical trials** (Figure 6).³² Key contributors to underrepresentation of older adults are that fewer trials are available to them, often due to age-related comorbidities and fewer are asked to enroll.^{29,33}



Older adult participation in trials supporting drug approvals over the last decade has not kept pace with the incidence of disease in this population. From 2017 to 2020 the proportion of adults over 65 enrolled in trials leading to FDA cancer drug approvals ranged from 26—59%.^{19,20,21,22} Studies evaluating the age distribution of clinical trial participants in trials used for FDA -approval of cancer drugs have shown that underrepresentation of older adults has been an ongoing disparity^{34,35} and age related disparities are heightened among industry-sponsored trials as compared to non-industry sponsored trials.³⁶

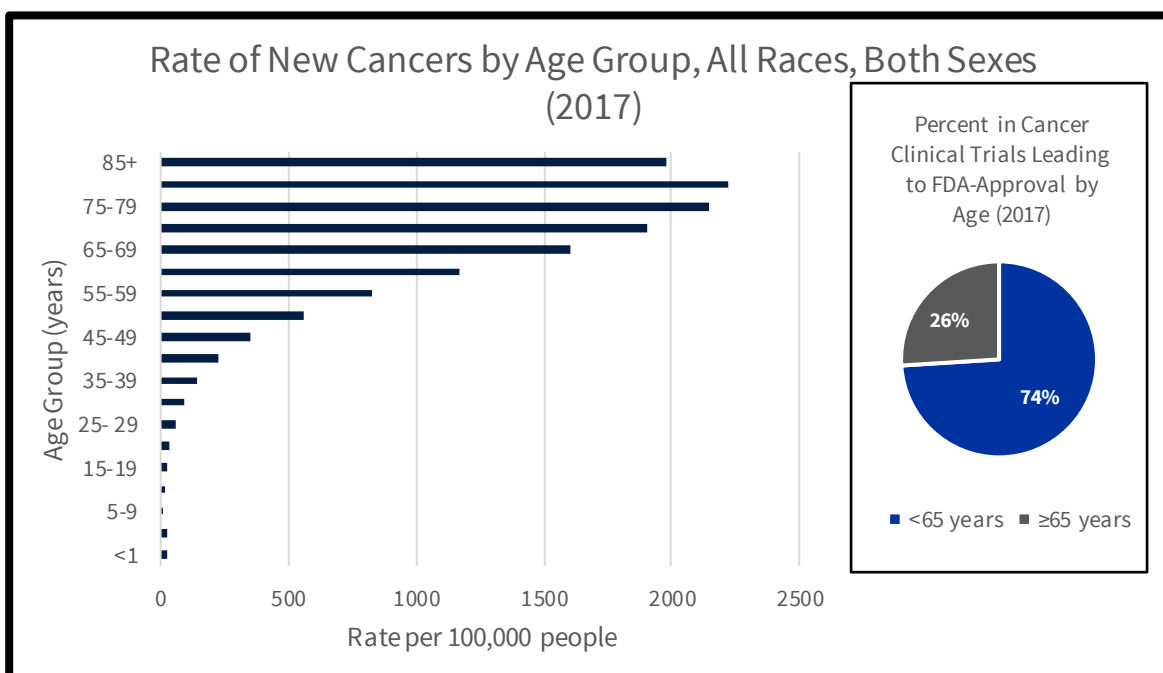


Figure 6: Cancer incidence is highest among those who are 65 years and older; however, in 2017 they represented only 26 percent of participants in cancer clinical trials leading to FDA drug approval. **Source:** U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool (2020)³²; FDA Drug Trials Snapshots 2017²²

Disparities by Socioeconomic Status

Socioeconomic (SES) status is frequently measured in terms of income level and educational attainment. Lower income and educational attainment have been associated with lower rates of cancer clinical trial participation. For example, in a survey study of patients questioned about their cancer care, both discussion of clinical trials and subsequent participation in trials was associated with having a higher education and income.³⁷ **People with lower SES were significantly less likely to participate in clinical trials and were more likely to show concern about how to pay for clinical trial participation.**³⁷ Those with incomes less than \$50,000 were 27% less likely to participate.³⁷ The disparity was more pronounced among people with incomes less than \$20,000 with 44% lower odds of participation.³⁷ Similar findings were found in another survey study of patients eligible to participate in clinical trials for breast, lung, and colorectal cancer at eight geographically diverse cancer clinics.³⁸ Although many insurers cover routine costs associated with clinical trials, people with lower incomes are more likely to be uninsured. Even when insured, non-medical costs



like travel, parking, and time off work, which are sometimes referred to as ancillary costs, can be significant and can be a barrier to patients with low income.

Disparities by Location

Although the majority of patients with cancer in the U.S. are treated in community settings, cancer clinical trials are typically located in metropolitan areas in academic medical centers that have specialized personnel, training, and resources necessary to conduct clinical trials.^{6,39} Length and frequency of travel to clinical trial sites is commonly cited a barrier to participation. **Logistical challenges can create barriers to participation in cancer clinical trials, particularly among rural adults, who may be required to travel significant distances to access clinical trials.** Studies have indicated that rural patients with cancer are underrepresented and underrecruited in clinical trials.^{39,40} While there are many contributing factors (e.g. age, comorbidities), long travel distances to trial sites can create disparities in access among rural cancer patients.

Toward Greater Diversity in Clinical Trials

Private stakeholders including patient advocacy organizations, clinical research organizations, and industry have long recognized the lack of representation of certain groups in clinical trials and the need to improve it. This has led to several attempts to further define and address the issue. Numerous reports, recommendations, and principles have been published by these organizations.

Federal agencies and Congress have also acknowledged and have taken steps to address representation in clinical trials (see *Appendix I*). Recent actions include FDA guidance for industry and legislation to address inclusion of underrepresented groups in clinical trials. In 2020, FDA released draft guidance for industry on the *Inclusion of Older Adults in Cancer Clinical Trials*⁴¹ and final guidance on *Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs*.⁴² Congress passed provisions of the ACS CAN-endorsed *Clinical Treatment Act*⁴³ which require state Medicaid Programs – which insure many Americans with lower income and from racial and ethnic minority groups – to cover routine clinical trial costs. Congress also enacted the ACS CAN-endorsed *Henrietta Lacks Enhancing Cancer Research Act*,⁴⁴ which requires the Government Accountability Office to study how federal agencies address barriers to participation in government-funded clinical trials by individuals from underrepresented populations, including racial and ethnic minority groups, older adults, rural residents, and lower income individuals. **Nonetheless, FDA still does not require proportional representation in clinical trials, nor can it absent of congressional action.**





ACS CAN Recommendations

Eliminating Disparities in Clinical Trial Participation

- 1. *Maintain and expand access to Medicaid:*** State Medicaid programs provide essential coverage for people with limited incomes including various populations likely to be underrepresented in clinical trials. States that have not already done so, should expand their Medicaid program pursuant to the provisions of the Patient Protection and Affordable Care Act.
 - **Disparities addressed:** Income, race, and ethnicity—Medicaid serves Americans with lower incomes. Some racial and ethnic minority groups are more likely to be insured through Medicaid due to higher rates of poverty.
 - **Barrier addressed:** The ability to access care and a financial mechanism to pay for routine care costs.
- 2. *Implement the Clinical Treatment Act:*** States that currently do not cover routine clinical trial care costs under their Medicaid program should implement federal requirements to ensure coverage is available by January 1, 2022.
 - **Disparities addressed:** Income, race, and ethnicity— Medicaid serves Americans with lower incomes. Some racial and ethnic minority groups are more likely to be insured through Medicaid due to higher rates of poverty.
 - **Barrier addressed:** The financial mechanism to pay for routine care costs.
- 3. *Shield patients from out-of-pocket ancillary costs of trial participation:*** The U.S. Department of Health and Human Services' Office of the Inspector General should clarify policies to ensure reimbursement of ancillary costs such as travel, parking, and housing by clinical trial sponsors is not seen as undue influence and ensure awareness of allowable reimbursements.
 - **Disparities addressed:** Income, race, ethnicity, and location
 - **Barrier addressed:** The financial mechanism to pay for ancillary costs of trial participation.
- 4. *Issue permanent guidance on the conduct of decentralized clinical trials:*** During the COVID-19 pandemic the U.S. Food and Drug Administration (FDA) significantly expanded opportunities for the use of decentralized trial practices like telemedicine, home delivery of medications and use of more local health care providers. These practices facilitated continuation of clinical trials while allowing patients to remain in their homes or travel less. These same practices hold promise outside of a pandemic setting to allow greater participation of underrepresented groups, yet these flexibilities are set to expire with the end of the public health emergency. FDA should issue permanent guidance on the conduct of decentralized trials. In addition to continuing these flexibilities, it will be critical to ensure new disparities are not created based on differential access to broadband or technology literacy.



- **Disparities addressed:** Income, race, ethnicity, age, and location
 - **Barrier addressed:** Broadens options for participation by reducing patient burden and ancillary costs.
5. **Modernize eligibility criteria:** Clinical trial inclusion and exclusion criteria determine which patients are eligible to participate in a clinical trial, therefore it is important to ensure these criteria do not preferentially exclude demographic groups. Overly restrictive eligibility criteria based on age or comorbidities can limit patient enrollment and applicability of clinical trial results to the broader population with disease.
- **Disparities addressed:** Age, race, and ethnicity
 - **Barrier addressed:** Trial eligibility



Researching Disparities in Cancer Outcomes

Even when a clinical trial's makeup is diverse and proportional to the broader population with a given cancer, clinical trials are not necessarily designed to identify, understand, or address disparities in outcomes. **Research to identify and address disparities in outcomes has to be deliberate and specifically designed.** This research is known as disparities research. Such research often requires significant over-representation of minority populations, and clinical trials informing disparities research are often much larger than trials intended to understand average responses across groups.

While there have been notable advancements in cancer prevention, screening, and treatment over the past decade, not all people benefit equally from these advancements – leading to cancer disparities. Disparities research is multi- and trans-disciplinary, spanning the fields of both clinical and social sciences which attests to the complex interaction of biological, structural, socioeconomic, and behavioral factors that influence disparities. Data informing this research are collected from a variety of sources (e.g. biospecimens, insurance claims, electronic health records, cancer registries, surveys, population- and patient-level data, etc.) and allow researchers to detect differences among populations. Depending on the source and type of data collected, researchers can employ a multitude of approaches to uncover underlying disparities and their associated causes. **Conclusions drawn from this research can inform evidence-based solutions aimed at alleviating disparities.** The following section is an overview of some of the primary domains of cancer disparities research, types of data/methods used in each domain, and how each has shaped an understanding of key factors contributing to cancer disparities.

Access to Cancer Care

Access to care is a significant driver of cancer disparities. When an individual receives timely, high-quality cancer care it puts them in the best position to prevent, find, treat, and survive cancer. While the structure and costs of plans vary, health insurance coverage is an important factor that influences an individual's ability to access cancer care by making care more affordable. Individuals without insurance are more likely to be diagnosed with advanced cancers, less likely to receive definitive treatment, and more likely to have a poorer prognosis.⁴⁵



Racial and ethnic minority groups and people with lower SES are more likely to be uninsured compared to non-Hispanic Whites and people with higher SES, respectively.⁴⁶

NCI's Surveillance, Epidemiology, and End Results (SEER) Program is a well-established resource that has been used to highlight disparities in insurance coverage. The SEER Program collects population-based data from cancer registries and provides information on cancer incidence and survival.⁴⁷ Notably, SEER Program data cover about 35% of the U.S. population and account for diverse racial and ethnic populations across the U.S.⁴⁷ As an example, a study using SEER Program data, evaluating



factors associated with race and ethnicity and cervical cancer survival, found that nearly 20% of the excess mortality observed in cervical cancer in non-Hispanic Black women compared to non-Hispanic White women was mediated by insurance status.⁴⁸ A similar study looking at differences in colorectal cancer outcomes by race and insurance status found that lack of health insurance is associated with an increase in colorectal cancer-related deaths.⁴⁹

Additional research has shown that expanding the insured population is associated with a reduction in cancer mortality, mediated by earlier detection of cancers, when survival odds are the greatest.

The Patient Protection and Affordable Care Act (ACA) contained several health insurance expansion provisions, including expanding Medicaid eligibility to

adults at or below 138% of the federal poverty level. Expansion increased insurance coverage among adults aged 18 to 64.⁵² However, not all states have expanded eligibility for their programs. This has yielded a body of research comparing non-expansion with expansion states. One such study found that between 2012 to 2015 expansion states experienced significantly decreased mortality in newly diagnosed breast, lung, and colorectal cancers.⁵³ The authors concluded that decreased mortality may be due to Medicaid expansion allowing for improved early-stage diagnosis associated with greater access to screening.⁵³ This study used data from the National Cancer Database (NCDB), another commonly used database for cancer disparities research that is sourced from over 1,500 health care facilities and represents over 70% of newly diagnosed cancer cases in the U.S.⁵⁴ Additional studies have confirmed that Medicaid expansion under the ACA diminished or eliminated disparities in the percentage of uninsured patients by race and ethnicity, census tract-level poverty, and rurality in expansion states but remained high in non-expansion states.⁵⁵

Socioeconomic Status

Socioeconomic differences in cancer outcomes are related to differences in risk factors and access to care between individuals with low SES compared to those with high SES.⁵⁶ Low SES is associated with reduced access to care, lower rates of screening, delays in treatment after diagnosis,⁵⁶ and heightened cancer risk factors like smoking, obesity, and lower levels of physical activity which contribute to

NCI Community Oncology Research Program (NCORP) **Increasing Representation and Understanding Disparities**

NCORP is a national network that brings together cancer clinical trials and care delivery studies to people in their own communities through trials and studies related to cancer prevention, screening, supportive care and symptom management, surveillance, health-related quality of life, and cancer care delivery. NCORP maintains community sites that are designated as Minority/Underserved Community sites that have a patient population comprised of at least 30% racial or ethnic minorities or rural residents. They are directed toward several goals including increasing the participation of minority populations in cancer clinical trials and understanding cancer disparities. NCORP supported research has revealed findings such as Black or African American patients appear to be undertreated compared to White patients for gastric cancers [50] and cultural and ethnic data may add important information to models identifying U.S. individuals at risk for gastric cancers [51].

Figure 7: NCORP has dual goals of increasing representation from underrepresented groups and understanding the disparities they encounter.



poorer outcomes.⁵⁷ **Over the last three decades, socioeconomic inequalities in cancer mortality have widened, with the biggest gaps for the most preventable cancers.**⁵⁶

Socioeconomic patterns in cancer disparities have been detected through studies comparing county-level SES indicators obtained from national surveys with trends in cancer mortality. One recent study estimated that U.S. counties that experience persistent poverty – counties with 20% or more of the population living below the federal poverty level since 1980 – had a 12% greater all-cancer mortality rate from 2007 to 2011 compared to counties not experiencing persistent poverty.⁵⁸ Compared to non-persistent poverty counties, persistent poverty counties had a higher percentage of Black and Hispanic residents, less education, and were more likely to be located in the rural south.⁵⁸ The authors indicated that higher rates of cancer risk factor behaviors, lower rates of cancer screening, and infrastructural issues may have contributed to elevated mortality rates in persistent poverty counties.⁵⁸

In addition to poverty, educational attainment is associated with a higher risk of cancer death – regardless of race or geographic location – for several cancers, most notably in cancers that are the most preventable.⁵⁹ Similar to those who live in poverty, this disparity is related to a higher prevalence of cancer risk factors.⁵⁹ One study, highlighting the association of educational attainment with cancer mortality estimated that, for 2018, more than one-fourth of all projected cancer deaths in the U.S. would be averted if all Americans had the same levels of exposure to risk factors and received the same quality of care as college graduates.⁵⁹

Biology

Disparities in cancer outcomes among U.S. racial and ethnic minority groups are well documented and are mostly explained by presentation at more advanced stages.⁶⁰ However, when stage at diagnosis is controlled, disparities remain.⁶⁰ While all humans are nearly identical genetically, small variations within the human genome are common among individuals of the same racial or ethnic ancestry.[†] A variety of research methods including clinical research involving biospecimens, data obtained from registries, and large population-based studies have been used to help understand how genetic differences contribute to disparities. **Using clinical methods, studies have discovered genes that play a role in disease. These genes can be found disproportionately in specific subgroups of different ancestries.** As an example, African American men have the highest incidence of prostate cancer in the U.S. One pivotal study identified a specific genetic variant common in men with African ancestry that may contribute to the increased incidence of prostate cancer in African Americans compared to European Americans.⁶¹

Breast cancer is another leading area where ongoing research has pointed to underlying genetic factors involved in observed differences between racial and ethnic groups. For example, Hispanic

[†] Race and ethnicity are social constructs that encompass ancestry and culture and are largely rooted in a person's self-identification that do not conform to any biological, anthropological, or genetic criteria. However, when controlling for lifestyle and environmental factors, they can be used as a proxy for genetic inheritance to determine genetic or biological differences in cancer outcomes.



women diagnosed with breast cancer present differently than non-Hispanic White women including, earlier age and later stage at diagnosis⁶² and tumor characteristics associated with poor prognosis.⁶³ In one study, differences between Hispanic and non-Hispanic White women persisted even when access to care was controlled, suggesting biologic or genetic bases for differences.⁶⁴ Similarly, Black women are more likely to die and be diagnosed with more aggressive forms of breast cancer as compared to non-Hispanic White women.⁶⁵ In 2016, NCI launched the Breast Cancer Genetic Study in African-Ancestry Populations, which includes a study population of 20,000 Black women with breast cancer to investigate biological and genetic factors contributing to this disparity.⁶⁵ Genetic variations can also affect a drug's absorption, distribution, metabolism, and excretion. These genetic variations can contribute to differences in cancer drug response and can lead some racial and ethnic groups to experience a more positive or negative response to a drug (Figure 8).

Detecting Racial/Ethnic Disparities in Safety and Efficacy of Cancer Treatment

Research to identify any racial/ethnic disparities in the safety and efficacy of treatments has to be deliberate and specifically designed. For example, docetaxel, an anti-cancer drug, is approved for the treatment of prostate cancer. This indication was based on the experience of 1006 patients in a clinical trial [66]. The demographic makeup of this trial was 93% White (936) and 7% (70) Black, Hispanic, Asian, and other groups combined [67]. Drug labeling does not indicate any disparities in safety or efficacy between races/ethnicities. However, the clinical trial was not intended to detect these disparities and the small proportion of non-White patients in the study would have made them difficult to detect.

A later study [68] was conducted specifically to compare overall survival of Black and White men with prostate cancer treated with docetaxel required pooling results across nine phase III clinical trials involving docetaxel in order to have enough patients to detect outcome differences by race/ethnicity. This analysis of 8,820 men found statistically significant differences in overall survival in Black versus White men. The demographic makeup was 85 percent White (7,528), 6% Black (500), 5% Asian (424), and 4% of unknown race (368). Notably, the number of Black patients used to make this conclusion was more than seven the times entire non-White patient population on which docetaxel's approval for prostate cancer was based.

Figure 8: Genetic variations can affect the way drugs are metabolized in the body resulting in differential outcomes among racial/ethnic groups. Research must be designed to detect these differences and groups must be represented in proportions sufficient to detect differences should they exist.

Funding Cancer Disparities Research

The National Institutes of Health (NIH) is the world's largest funder of biomedical research and leads several programs to reduce health disparities and to promote and support a diverse research workforce. The National Cancer Institute – one of several Institutes under NIH – leads the nation's cancer research efforts, trains, and supports cancer researchers, and coordinates and supports cancer clinical trials. NCI's Center to Reduce Cancer Health Disparities (CRCHD) aims to help reduce the unequal burden of cancer through several efforts in cancer disparity research and workforce diversity. CRCHD has several targeted programs and collaborations with other divisions, offices, and centers within NCI and NIH and also non-federal partnerships with research organizations and patient advocacy groups (see Appendix II).



ACS CAN Recommendations

Understanding Disparities in Cancer Outcomes

1. ***Invest in biomedical and public health research at the National Institutes of Health (NIH), the National Cancer Institute (NCI), and the Centers for Disease Control and Prevention (CDC):*** Not all people benefit equally from advancements in cancer prevention, screening, detection, and treatment which leads to disparities in cancer outcomes. Steady, significant funding increases to advance cancer disparities research at NIH, NCI, and CDC will help to identify, understand, and address the complex biological, structural, socioeconomic, and behavioral factors that prevent all people from benefitting from advancements in cancer care.
2. ***Address genetic variation leading to disparate responses to cancer therapeutics:*** Ancestry and genetic inheritance can have a direct effect on how a drug is metabolized, thus affecting the safety and efficacy of the treatment. These inherent genetic differences are not always considered when a new drug is being tested in clinical trials and, as a result, different groups may experience disparate outcomes not properly measured in pre-market clinical trials. The U.S. Food and Drug Administration (FDA) should facilitate the synthesis of evidence regarding differential safety and efficacy of therapies based on ancestry and develop guidance as needed to ensure drug labeling accurately reflects known causes and cases of disparities by ancestry. Congress should also consider giving FDA the authority to create requirements for sponsors to design clinical trials with appropriate demographic representation when prior evidence points to likely ancestral disparities in safety or efficacy. The use of post-market real-world-data is a key tool in understanding disparities in safety and efficacy.
3. ***Address disparities in data collection:*** Federal agencies, as well as state and local agencies should modernize and standardize data collection methods and reporting to include race, ethnicity, socioeconomic status, and other demographic data (sex, age, tribal affiliation, gender, sexual orientation, and disability status). Proper demographic data collection is necessary to inform policy and help lawmakers at all levels, health care providers, and hospitals invest in and direct resources to groups facing disparities.



Disparities in the Cancer Care and Research Workforce

The cancer care and cancer research workforce does not represent the U.S. population demographically, and many racial and ethnic minority groups – who often bear a disproportionate burden of cancer – are underrepresented. **The presence of a diverse workforce can help to reduce implicit biases and systematic disparities and can contribute towards culturally competent care.**⁶⁹

Cancer Care Workforce

Structural racism in health care has been well-documented and persists as a driver of health disparities in the U.S. An important consideration in health disparities is that patients from racial and ethnic minority groups may have negative encounters with providers related to bias, discrimination, and lack of cultural competence. This has led to research on whether patient-provider concordance (i.e. patient and provider are of the same racial/ethnic group) influences patient outcomes and health disparities. Evidence on whether patient-provider concordance alone will reduce health disparities is mixed,⁷⁰ but a diverse workforce can increase the likelihood of better care for patients from racial and ethnic minority groups through improved patient-provider communication, culturally competent care, treatment adherence, and patient trust and satisfaction.⁶⁹ In one example, Black or African American patients were better able to estimate their lung cancer risk when given information by concordant providers in contrast to non-concordant providers.⁷¹ Additionally, physicians from racial and ethnic minority groups are more likely to practice and serve patients in underserved communities,^{72,73} further emphasizing the benefits of a diverse cancer care workforce in reducing health disparities.

Despite increases between 2002 to 2017, Hispanic, Black or African American, and American Indian or Alaska Native individuals are underrepresented among medical students relative to their corresponding proportions in the population.⁷⁴ In 2019, Black or African American applicants and Hispanics, Latino, or Spanish origin applicants made up only 8.4 and 6.2% of U.S. medical school applicants, respectively, compared to 46.8% of White applicants.⁷⁵ **Issues contributing to lack of physician diversity are complex and include structural racism which has led to differences in achievement and opportunity for underrepresented students.**⁷⁶

In oncology, Black or African American and Hispanic individuals represent 4 and 5% of medical oncology fellows, respectively.⁷⁷ Moreover, only 3% of practicing oncologists identify as Black or African American, 4.7% identify as Hispanic or Latino, and 0.1% identify as American Indian or Alaska Native.⁷⁸





Cancer Research Workforce

The number of biomedical scientists in the U.S. increased over 150% from 1990 to 2014.⁷⁹ The rate of growth varied significantly by race and ethnicity. For example, the percentage of Asian biomedical scientists increased 12 to 34% while the percentage of Black scientist increased 1 to 2%.⁷⁹ A diverse research workforce broadens scientific inquiry and knowledge and can enhance the ability to solve population specific health problems.⁸⁰ Many scientists from racial and ethnic minority groups focus their efforts, including disparities research, in their own communities.⁸⁰ **As racial and ethnic minority groups in the U.S. grow and increasingly make up a larger share of the population, addressing cancer disparities in these groups can be enhanced by increasing diversity within the cancer research workforce.** Although there are several ongoing federal programs to increase diversity in research (see *Appendix II*), racial and ethnic minorities often lack the same access to educational and research opportunities to advance their research.



In general, biomedical researchers rely on grant funding to conduct research and NIH is a major source of such funding. However, studies have shown that researchers from racial and ethnic minority groups receive research awards at a lower rate compared to researchers from non-minority groups. One of the first studies to document this was a 2011 NIH-commissioned report on race, ethnicity, and NIH research awards. It showed that from 2000 to 2006 Asian and Black or African American R01

applicants (the most common type of NIH grant) were 4 and 13% , respectively, less likely to receive NIH investigator funding compared to White applicants.⁸¹ Black or African American applicants remained 10% less likely to be awarded NIH funding even when controlling for an applicant's educational background, country of origin, training, previous research awards, publication record, and employer characteristics.⁸¹ The probability of awards for Black or African American applicants was about 55% of that for White applicants.⁸¹ This probability remained unchanged from 2014 – 2016.⁸² A similar study on race and ethnicity and NIH research awards noted a persistent 7.5% lower funding rate for applicants from minority groups compared to non-minority group applicants in 2016.⁸³ Notably, in an analysis of research topic included in R01 applications, African American or Black scientists were more likely to describe research on health disparities compared to White scientists.⁸⁴

Funding disparities can potentially lead to gaps in knowledge in addressing health disparities in minority populations. Since the 2011 NIH-commissioned report, NIH has issued recommendations and created programs to improve diversity in its workforce. Most recently, NIH launched the UNITE initiative⁸⁵ to identify and address structural racism in the NIH-supported community.



ACS CAN Recommendations

Eliminating Cancer Care and Research Workforce Disparities

1. **Invest in a diverse cancer care and research workforce:** The National Institutes of Health (NIH), the National Institute on Minority Health and Health Disparities (NIMHD), and the National Cancer Institute (NCI) should expand existing opportunities and programs that support career development for scientists and researchers from underrepresented minority groups. Congress should allocate funds to Historically Black Colleges and Universities (HBCUs), tribal colleges, and other minority serving institutions (MSIs), for the purpose of increasing racial and ethnic minority representation across cancer research and care disciplines. Historically these institutions have succeeded in preparing students from underrepresented minority groups in these professions.⁸⁶
 - **Disparities addressed:** Representation of racial and ethnic minority groups in the cancer care and research workforce.
 - **Barrier addressed:** Structural racism has led to differences in achievement and opportunity for underrepresented students.


Summary











Various domains of research play a role in both contributing toward and addressing the root causes of disparities observed in cancer. Disparities exist in clinical trial participation which limits the applicability of trial results and prevents equitable access to treatment and care to some groups. Due to health system-related, socioeconomic, and biological factors certain groups bear a disproportionate burden of cancer compared to other groups. Understanding these factors and their underlying causes requires a deliberate effort and is the goal of disparities research. Finally, there are disparities within the cancer care and research workforce driven by complex structural, historical, and institutional factors which have limited the representation of professionals from racial and ethnic minority groups.






Appendix I

Select Federal Efforts to Improve Clinical Trial Diversity

 Applies to federally-funded research

 Applies to industry-funded research

<p>1993</p> 	<p>The National Institutes of Health Revitalization Act⁸⁷</p> <ul style="list-style-type: none"> Directed NIH to establish guidelines for inclusion of women and minorities in clinical research
<p>2001</p> 	<p>NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research⁸⁸</p> <ul style="list-style-type: none"> As directed by the NIH Revitalization Act <i>“If the data from prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on sex/gender, racial/ethnic, and relevant subpopulation comparisons, the primary question(s) to be addressed by the proposed NIH-defined Phase III clinical trial and the design of that trial must specifically accommodate this. For example, if men and women are thought to respond differently to an intervention, then the Phase III clinical trial must be designed to answer two separate primary questions, one for men and the other for women, with adequate sample size for each.”</i>
<p>2007</p>  	<p>Food and Drug Administration Amendments Act of 2007 (FDAAA)⁸⁹</p> <ul style="list-style-type: none"> Established clinical trial registration and results information submission requirements to promote the transparency of clinical trial information to the public
<p>2012</p> 	<p>Food and Drug Administration Safety and Innovation Act (FDASIA)⁹⁰</p> <ul style="list-style-type: none"> Directed FDA to publish a report to Congress on how and to what extent information is available on the safety and effectiveness of drugs in different demographic subgroups Required FDA to produce an action plan with recommendations on improving the analysis of data on demographic subgroups, on the inclusion or lack of demographic data on product labeling, and improving the availability of such data to patients, health care providers, and researchers
<p>2014</p> 	<p>FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data⁹¹</p> <ul style="list-style-type: none"> Published as directed by FDASIA Included priority areas on the quality of demographic subgroup data, barriers to participation of demographic subgroups, and transparency of demographic subgroup data
<p>2016</p>   	<p>The 21st Century Cures Act⁹²</p> <ul style="list-style-type: none"> Required the NIH to address issues related to the inclusion of all ages in NIH-funded clinical trials. <p>Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11)⁹³</p> <ul style="list-style-type: none"> Clarifies and expands the requirements for submitting clinical trial registration and results information to ClinicalTrials.gov in accordance with FDAAA Requires trial sponsors and investigators to report participants race and ethnicity if the information is collected when trial results are submitted to <i>ClinicalTrials.gov</i> <p>NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information⁹⁴</p> <ul style="list-style-type: none"> Complementary to the statutory and regulatory reporting requirements established by FDAAA
<p>2017</p> 	<p>Amendment: NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research⁹⁵</p> <ul style="list-style-type: none"> Amended to include a requirement that recipients conducting applicable NIH-defined Phase III clinical trials ensure results of valid analyses by sex/gender, race, and/or ethnicity are submitted to ClinicalTrials.gov (<i>if prior studies strongly support the existence of significant differences of clinical or public health importance in intervention effect based on race or ethnicity</i>)

 	<p>NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects⁹⁶</p> <ul style="list-style-type: none"> • As directed by the 21st Century Cures Act • <i>“The purpose of the Inclusion Across the Lifespan Policy is to ensure individuals are included in clinical research in a manner appropriate to the scientific question under study so that the knowledge gained from NIH-funded research is applicable to all those affected by the researched diseases/conditions.”</i> <p>The FDA Reauthorization Act of 2017 (FDARA)⁹⁷</p> <ul style="list-style-type: none"> • Directed FDA to publish guidance related to broadening trial eligibility criteria to better reflect populations most likely to benefit if the drug is approved
<p>2020</p>   	<p>Inclusion of Older Adults in Cancer Clinical Trials: Draft Guidance for Industry⁴²</p> <ul style="list-style-type: none"> • Provides recommendations regarding the inclusion of older adult patients (>65 years) in clinical trials of drugs for the treatment of cancer <p>Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry⁴³</p> <ul style="list-style-type: none"> • As directed by FDARA • Recommends approaches that sponsors of clinical trials intended to support a new drug application or a biologics license application can take to increase enrollment of underrepresented populations in their clinical trials <p>Henrietta Lacks Enhancing Cancer Research Act⁴⁴</p> <ul style="list-style-type: none"> • Requires the Government Accountability Office to study how federal agencies address barriers to participation in government-funded clinical trials by individuals from underrepresented populations and to provide recommendations for addressing such barriers

Appendix II

NCI Center to Reduce Cancer Health Disparities (CRCHD) Programs Dedicated to Diversity Research and Training

Continuing Umbrella of Research Experiences (CURE)⁹⁸

The CURE program is a research training program which aims to create a diverse workforce of cancer investigators through training opportunities, starting at middle school and continuing to the independent researcher level. As of 2020, the CURE program had trained more than 4,000 students, trainees, and investigators from underrepresented backgrounds.⁹⁹ Evaluations of the program have shown that investigators who received career development awards through CURE had greater success at obtaining subsequent NIH research grants than those who did not receive such awards.⁹⁹ In 2017, NCI extended the CURE program to focus on improving workforce diversity within NCI through the Intramural CURE (iCURE) program. As of 2020, iCURE had recruited 24 researchers – 63% of whom are Black or African American and 25% of who are Hispanic or Latino.⁹⁹

Partnerships to Advance Cancer Health Equity (PACHE)¹⁰⁰

The PACHE program provides awards to institutions to develop partnerships between institutions serving underserved populations and underrepresented students with NCI-designated Cancer Centers. Partnering institutions conduct research on cancer and cancer health disparities, cultivate research experiences, and disseminate advances to underserved communities.

Geographical Management of Cancer Health Disparities Program (GMap)¹⁰¹

The GMap program was created to support and enhance teams conducting cancer disparities research, training, and outreach through 7 regionally-based “hubs” that share information, resources, and tools and improve access to underrepresented investigators, trainees, and students. GMap provides access to career development resources such as networking opportunities, mentoring, and grant writing workshops. One focus of GMap has been the development of biorepositories that include specimens from underrepresented populations.

National Outreach Network (NON)¹⁰²

The NON program supports culturally-appropriate education and outreach between underserved communities and NCI-designated Cancer Centers through the use of community health educators.

Basic Cancer Research Program¹⁰³

CRCHD supports basic cancer biology research by providing funding opportunities to investigate biological differences across racially and ethnically diverse populations that may contribute to cancer disparities and opportunities for investigators from underrepresented groups to study cancer biology. CRCHD also supports translational research that moves research into the clinical setting including the pre-clinical testing of cancer models derived from racial and ethnic minority populations.

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