

Barriers to Black patient participation in cancer clinical trials

Executive Summary

Prepared by Kristine De La Torre, October 2020

The American Society for Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) began a collaboration aimed at identification of strategies to increase participation in cancer clinical trials by under-represented populations, including Blacks. Healio, which began in 2013, is a website that publishes news and research for medical professionals in the health care system. As an initial step in this collaboration, Healio identified 29 articles* that describe the statistics and challenges of accruing diverse patients to clinical trials for all cancers. These articles were linked to the information ASCO members received about submitting ideas for this project to raise clinical trial participation among racial and ethnic groups. These articles along with five additional studies, which were posted or published between 2018 and 2020, consisted of both studies published in peer-reviewed medical journals and articles posted on the websites of Healio and other organizations. After disregarding four articles that were out of scope, 30 articles in total were summarized and reviewed.

Below are the key findings from these articles:

Known participation levels (of African-American Women in breast cancer associated clinical trials)

Although Blacks[†] represent approximately 15% of cancer patients in the US, only 4-6% of clinical trial participants are Black. To understand participation further, a participation-to-prevalence ratio (PPR) was calculated in which the percentage of African Americans among trial patients was divided by the percentage of African Americans with a given disease. A PPR of 1 means identical representation of African Americans in the trial population and the population with the disease. For breast cancer, the PPR was 0.29, indicating under-representation in trials.

Reported barriers to access by patients (as related to breast cancer clinical trials)

Barriers to Black patient participation in clinical trials can be categorized into several categories. Barriers are present at institutional, community, provider, and patient levels. Institutional barriers include those that are system-wide and involve how trials are designed. For example, trial eligibility criteria may result in exclusion of certain populations. Community barriers are those that are present at local geographic levels. An example is the location of a trial and the need to travel to it. Provider-level barriers include preexisting attitudes or negative biases by health care providers that may disproportionately affect minority populations. Finally, patient-level barriers are those that pertain to the characteristics of the patient and include factors such as socioeconomic status that may make trial consideration or participation more difficult. These barriers are complex and may interact with one another.

* These articles were provided to Kris De La Torre by Shirley Mertz. Thus, no exclusion/inclusion criteria were used, and no search of the literature using keywords was performed.

[†] Note that terms such as “Black”, “African American”, etc. are used according to the term used by the authors in the original article.

Legacy of unethical treatment of African-Americans by the medical system and mistrust

One important barrier to Black patient participation in clinical trials involves mistrust due to historic mistreatment of Black people. One well-known example is the Tuskegee syphilis study, which began in the 1930s and continued for 40 years, in which Black men with syphilis were purposefully left untreated to determine the natural history of the disease. The men in the study were misled, misinformed, and did not provide informed consent. Another example is that of Henrietta Lacks, a Black woman whose cervical cancer cells were taken in 1951 and used to establish the widely used cell line known as “HeLa” cells. Her cells were used for research without her knowledge or consent.

Recruitment and retention strategies of researchers engaged in cancer research to involve African-American women

Similar to the barriers to Black patient participation, progress and current efforts to increase trial participation can be classified into four categories: institutional-, community-, provider-, and patient-level impacts. Institutional-level impacts include various efforts by the NIH, FDA, other government entities, the National Clinical Trials Network, and pharmaceutical companies. Including more Black volunteers in clinical trial roles is also expected to increase diversity. At the community level, community engagement, trials run by diverse investigators, and local outreach efforts are expected to positively impact enrollment by diverse populations. Churches and other places of support in the community may be useful to increase education and recruitment of Black cancer patients. At the provider level, health care providers should mention trials to patients, acknowledge their biases, and undergo training to increase sensitivity. Efforts to involve more Black scientists and clinicians in clinical trials are also important. At the patient level, Black patients can discuss trials with family members, friends, their care team, and other trusted sources to help in the decision-making process. Social media use by Black patients may increase awareness about clinical trials.

Barriers to Black patient participation in cancer clinical trials

Background

Among ethnic/racial groups, African Americans* have the highest death rate and shortest survival for many cancers including breast cancer [1, 2][†]. African Americans have a higher incidence of hormone receptor-negative breast cancer and triple negative breast cancer [3].

Although Blacks represent approximately 15% of cancer patients in the US, only 4-6% of clinical trial participants are Black [4, 5]. Black patients are less well represented in clinical trials sponsored by pharmaceutical companies compared to trials sponsored by the National Cancer Institute (NCI), the former of which sponsor the majority of trials; about 2.9% of the population enrolled in pharmaceutical company-sponsored trials are Black [6]. The reasons for under-enrollment of Black patients by pharmaceutical companies are unclear but may involve where these trials are conducted. Trials may not frequently be conducted in community oncology sites and other geographic areas where many Black patients reside [6]. In contrast, National Clinical Trials Network (NCTN) trials included in the Southwest Oncology Group (SWOG) Cancer Research Network enrolled 8.3% Black patients [6].

The safety and effectiveness of new treatments may vary according to multiple factors including race [5]. Thus, adequate representation of Blacks in clinical trials improves the likelihood that trial results will apply to these individuals [4]. Under-enrollment of Black patients may explain why approved drugs are sometimes less effective in this population [6]. Treating African American patients with a drug approved by trials that primarily enrolled whites may result in suboptimal responses to the drug by African American patients [2]. Physicians may have low confidence in the effectiveness of study drugs in under-represented patients [7]. Only when trial participants reflect the diversity of the general population can physicians understand how a drug will work in different racial/ethnic groups [8]. African Americans who participate in clinical trials may help improve the health of everyone and increase understanding of health disparities [9].

Patients who participate in clinical trials have better outcomes and live longer than those who do not [10, 11]. However, whether this is related to therapy, bias, more frequent visits, closer monitoring of patients, comorbidities, or socioeconomic factors is unclear [10]. A previous study showed that trial participation removed differences in survival outcomes between patients living in rural vs. urban areas [10]. Overall survival benefits were the same according to age, sex, and race/ethnicity but not insurance status [10]. In a study of clinical trials conducted before implementation of the Affordable Care Act, uninsured cancer patients or those with Medicaid in clinical trials received no added survival benefits from investigational medications compared with standard of care medications and compared with insured patients. Supportive and post-treatment care may be suboptimal in these patients, possibly due to limited financial resources. Trials are typically designed to test the benefit of a treatment across the entire patient group in the study and may not explain benefits or lack of benefits in subpopulations according to demographics or insurance status [10, 12].

In some European countries, up to 30% of patients with cancer enroll in trials [11]. In the US, most cancer trial participants are young, healthy, white, insured patients with metastatic disease who are

* Note that in this document, terms such as “Black”, “African American”, etc. are used according to the term used by the author in the original article cited.

[†] The numbers in brackets correspond to the individual article summaries that begin on page 8.

treated at an academic medical center [11]. Whites are more likely to enroll in cancer clinical trials than African Americans [13]. The percentage of Black participants in cancer trials has decreased since 2011 [13]. Researchers calculated a participation-to-prevalence ratio (PPR) in which the percentage of African Americans among trial patients was divided by the percentage of African Americans with a given disease. A PPR of 1 means identical representation of African Americans in the trial population and the population with the disease. For breast cancer, the PPR was 0.29, indicating under-representation in trials [2].

Barriers to clinical trial participation by Blacks

Factors impacting clinical trial participation are variable, complex, and may interact with one another [4]. Barriers to diversity in patients enrolled in clinical trials can be due to institutional, community, provider, or patient factors [14-21] as summarized below:

Institutional barriers. The following institution-level barriers may negatively impact diversity in clinical trials.

- Restrictive trial eligibility criteria [14, 19].
- Prior therapy [14].
- Long washout periods and treatment delays [18].
- Required number of visits [14].
- Patients often need to find trials on their own [18], and finding trials can be complex [20].

Community barriers. The following community-level barriers may negatively impact diversity in clinical trials.

- Distance to the trial site and the need to travel to the study site [4, 5, 8, 14].
- Population size is the main determining factor in the number of spaces in a trial for patients in urban areas. The low representation of minorities in cancer clinical trials may be due in part to an unequal distribution of trial sites relative to the population [16].

Provider barriers. The following barriers related to physicians or other health care providers may negatively impact diversity in clinical trials.

- Negative perceptions may lead a physician or trial coordinator to not mention trial opportunities or to not provide a referral about a trial [2, 8, 14, 15, 19].
- The provider may have a preexisting bias, attitude, presumption, and/or stereotype about a patient's likelihood of observing the trial requirements. The provider may assume that minorities have a lower understanding of cancer research, and that minorities are less likely to have an altruistic attitude [2, 4, 14, 15].
- Minority participants may be perceived by providers to be unsuitable study participants [15].
- Language barriers may impede communication [14, 15].
- Some investigators consider race to be irrelevant when screening potential enrollees [15].
- Physicians may worry that they will lose their patient if the patient enrolls in a trial [20].

Minority patient barriers. The following patient characteristics may negatively impact diversity in clinical trials.

- Comorbidities such as high blood pressure, diabetes, or stroke, which are more common in Blacks, contribute to the low trial enrollment of Blacks [1, 8, 14, 18]. Biological variations may play a role [10].

- Legal status [14].
- Low health literacy [4, 14], limited education [7, 20], lack of information [2, 4, 7, 16], limited access to trial information [10, 20], and low awareness of trials [4, 7]. The percentage of African American/Blacks who were aware of trials was lower than that of whites (67.1% vs. 77.5%) [19, 20].
- Language barriers [4, 18].
- Less use of the internet [14].
- No phone [14].
- Skepticism about the benefits of participating [10, 14].
- Lack of acceptance or appreciation of trials. Blacks may see themselves as outsiders in medical research or have negative attitudes about research [7, 8, 14, 19].
- Distrust of the medical system due to past mistreatment of African Americans and fear of exploitation [1, 2, 4, 5, 7, 8, 18]. A high number (29%) of African Americans were included in trials in which informed consent was waived because the trial tested emergency procedures and/or enrolled patients who were incapacitated and unable to provide consent. This could lead to distrust [1, 5].
- Perception that a trial is a last resort rather than providing access to innovative treatments [20].
- Ambivalence (i.e., mixed feelings) may impact trust and may be due to previous experiences with health care, lack of access to health care, lack of transportation to receive care, prior discrimination regarding health care, self-reported health status, low income, and low education [21].
- Concerns about randomization, receiving a placebo, harm, risk, and discomfort [2, 11, 14, 19].
- Fear [14, 18, 19].
- Loss of control [14].
- Emotional struggles regarding the cancer diagnosis [20].
- Fatalism/reliance on God [7, 14].
- Cultural factors [4, 7]
- Lack of childcare [8, 14].
- Lack of time and lack of time off work [4, 8, 16, 20].
- Lack of transportation [16, 18, 20].
- Low income, uninsured, or underinsured [1, 4, 10, 18, 20].
- Logistical problems [1, 19].

Possible strategies and current efforts to increase clinical trial participation by Black cancer patients

System-wide and institutional-level impacts

The American Society for Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) has begun a collaboration aimed at identification of strategies to increase participation in clinical trials by under-represented populations, including Blacks. The groups issued a request for ideas, which closed in August 2020. Review and selection of ideas will be completed by the end of 2020, and implementation will begin in 2021. A one-size-fits-all approach is unlikely to be successful. The group ultimately hopes to provide a toolkit to improve assessment, training, education, and communication regarding strategies to break down barriers to trial participation. Implementation may need to happen at the patient, provider, program, and/or community level [4].

A 1993 law requires that NIH-funded trials prioritize inclusion of minorities. Researchers funded by NIH are required to seek diversity in their studies. NCI-designated comprehensive cancer centers are required to perform outreach and identify the needs of under-represented populations to increase diversity [14]. Recent efforts to increase trial awareness include a website launched in 2012 by the NIH to educate the general public about clinical trials; the Center for Information and Study on Clinical Research Participation, which established large-scale efforts to increase clinical trial awareness targeted at the same group; the Clinical Trial Education Program; and the Education Network to Advance Cancer Clinical Trials (ENACCT), which is particularly aimed at increasing trial awareness and accrual in minorities [19].

In 2014, the FDA established an action plan for improving diversity in trials. The FDA also publishes a “Drug Trial Snapshot” that shows demographics including race for trials for every new drug approved. The FDA is also working on strategies to increase enrollment of Black patients in FDA-registered trials by encouraging trial sponsors to design clinical trials with broader eligibility requirements [6, 17, 23]. FDA guidance requires collection of race and ethnicity data from clinical trials and the use of standardized terminology. The FDA also sponsors a Minorities in Clinical Trials Initiative that provides information in the form of videos and other platforms. The FDA works with patients in initiatives like these [17]. Accountability regarding plans to enroll diverse populations is important but difficult to achieve [23].

The Affordable Care Act and some states require insurance coverage of standard of care treatment costs associated with a trial [14]. Federal guidelines, ethical codes, institutional review boards, and the informed consent process are in place to prevent abuse, affirm safety, and protect the rights of patients [9].

The NCTN specifically recruits patients from community oncology sites where most patients receive care. Studies have shown that Black patients are willing to participate in trials if they are eligible [6].

Pharmaceutical companies should also adopt strategies to expand access and design equitable inclusion criteria, which will increase diversity [6]. Leveraging industry competition to encourage pharmaceutical companies to promote enrolling diverse patients and create stronger requirements for reporting of diversity may increase enrollment of diverse patients [18].

Including more Blacks as volunteers, in clinical research roles, and in trial design and interpretation may help increase diversity [8]. Patient advisory panels and expert consultants should include representatives from diverse populations to provide input about what diverse patients care most about [23]. Access to trials is not the only factor that will level the playing field for disparate populations. Trial design, interpretation, informed consent, and policies may need to be changed [10].

The COVID-19 pandemic has changed oncology care in ways that will benefit all clinical trial participants, including minorities. Changes include the ability to provide more efficient, safer, and more convenient care; register patients online; and reduce the number of laboratory visits and in-person visits. Telehealth has facilitated many of these changes. Clinical trial design may be more flexible in the future [23].

Trial investigators need to conduct self-assessments and understand differences [7]. Education materials should be developed for patients based on known gaps [14]. Additional strategies to increase trial enrollment include reducing inconvenience and being flexible.

Real-world evidence, which is information collected outside clinical trials and then analyzed, and improved methods of recruiting diverse patients to trials are needed [7]. Innovative trial designs, inclusion of real-world evidence, and the use of big data analytics are becoming more popular. Real-world data (data collected outside clinical trials) are being considered as surrogate control data for trials.

However, the utility of real-world data is unclear, as this information is obtained from electronic health records or insurance claims data. Robust methods to collect, abstract, and verify these data are in their infancy [10].

Community-level impacts

Community members should be engaged to increase education, improve enrollment, and publicize study results [14]. Those conducting trials must work to engage with and build trust with African Americans by including trial sites in areas of community outreach [5, 14]. Decentralization and new technology may aid in this effort [5]. Community engagement and trials run by diverse investigators will also work to build trust about the important role and advantages of clinical trials [23].

The COVID-19 pandemic will have community-level impacts on how clinical trials are conducted, including allowing patients to visit community physicians rather than the trial site, mailing prescription medications, and increased use of telemedicine. However, some medications with toxicity need to be administered by carefully trained personnel, and not all adverse events can be captured via a telemedicine visit. Long-term implementation of these strategies may help remove geographic barriers, increase trial participation for more patients, and increase diversity in trial participants [25].

Another community-level impact involves churches. Project CHURCH (Creating a Higher Understanding of Cancer Research and Community Health) is a collaboration between The University of Texas MD Anderson Cancer Center and African American churches in the Houston region. This project goes to where the people are with a “boots on the ground” approach and seeks to understand and address cancer prevention disparities and to engage African Americans as research partners. Researchers engaged with three large churches to build trust, establish credibility, and recognize the strengths of churches as partners. They developed a cohort study of church members to understand risk factors for disparities in cancer prevention. They established an advisory board, recruited participants to the study cohort through various communications at the church, and hosted a health fair to kick off enrollment of the cohort. After trust had been established, participants were asked for saliva samples for biobanking. Results were disseminated to the entire church community through newsletters and an annual report. Patient navigation services were provided, and prevention programs were implemented. The program has also trained racial/ethnic minority researchers. The group reported rapid and high recruitment and retention in their study cohort [26]. Although this approach was not specifically geared toward increasing trial participation by African Americans, the results demonstrate the effectiveness of a boots on the ground approach in African American churches, places where many African Americans receive support [27].

Provider-level impacts

Positive impacts on increasing trial participation can be made when physicians simply mention trials to patients [28]. Clinical trial discussion should be a physician’s best practice, even if no trial is available at the time of discussion. Prior to a patient’s visit, the physician should review the patient’s medical records, cancer type, and demographic characteristics to identify trials, determine if trials had been previously discussed, and the outcome of the discussion [14].

Providers must also work on relationships with patients, actively listen, and be respectful [7]. Acknowledging biases and addressing misunderstandings about research may help build trust [15]. Potential bias must be considered when developing strategies to increase enrollment of minorities in clinical trials [15]. Training should be initiated that addresses cultural sensitivity, implicit bias, and education with online training segments and seminars [14, 15]. Clinical trialists should not assume that patients who are under-represented in trials do not enroll because of low education or low income.

Rather, all possible reasons for the lack of diversity should be considered [18]. Telehealth can be used for appointment reminders and communication between the study coordinator and patient [7, 23].

Physicians also identified positive impacts of social media on trial recruitment, visibility, patient engagement, and better communication. Disadvantages of the use of social media included administrative load, the possibility of providing incorrect information, lack of regulatory oversight, and limited outreach. Guidance is needed on how to best use social media for this purpose. Social media users may tell others, leading to a snowball effect. Barriers include the time involved to develop content and the lack of evidence showing that this strategy actually increases enrollment. Physicians who practiced at community-based settings had similar attitudes about social media as those who practiced in academic medical facilities. ASCO provides ways for physicians to learn how to effectively use social media [28].

The funding rates for African American scientists are below those of others. Efforts are underway to bring more Black investigators into research institutes [23]. A program of the National Medical Association called Increasing Minority Participation and Awareness in Clinical Trials (IMPACT) encourages minority doctors to become clinical investigators and discuss clinical trial participation, especially in African American/Blacks [19].

Support centers may offer clinical trial navigation and streamline the process of searching for trials. A model of such an effort is The Leukemia & Lymphoma's Clinical Trial Support Center. This service is being made available to health care providers to facilitate trial searches. Nurse navigators help patients identify potential trials; help with enrollment; collect health information, travel abilities, and insurance information; and provide support to the patient [20].

Motivational interviewing is a technique that may dispel ambivalence, to which minorities may be especially susceptible, and facilitate decision making. In motivational interviewing, the health care provider addresses the patient with a collaborative spirit. Features of motivational interviewing are active listening, open-ended questions, affirmations, reflections, and summaries. The use of motivational interviewing may increase trust, decrease ambivalence, and contribute to increased clinical trial participation [21].

Patient-level impacts

Doctors, family members, friends, and clergy members may help someone decide whether or not to participate in a trial [9]. Patients for possible trial enrollment can be identified through health professional societies, churches and other house of worship, talk radio shows, historically black colleges and universities, and Medicaid. Howard University's Cancer Center and Driver is aimed at culturally targeted strategies to connect Black patients to trials (Howard University is a historically Black university) [8]. Culturally appropriate strategies are needed to engage Black patients. A faith-based group called the National Black Church Initiative, which is made up of 34,000 churches and nearly 16 million African Americans, asked the FDA to demand diversity. The FDA responded that they do not have the authority to do so [8].

Participants should remain engaged and informed before and during a trial [7]. Some patients may consult social media or the internet before talking to their doctor about trials. These platforms are likely to be more useful than phone calls or print media [18]. Between 2008 and 2012, awareness about clinical trials increased among African American/Blacks (by 10.6%), and use of the internet also increased in this group (by 14.2%). A causal relationship between internet use and awareness could not be determined by this study [19]. Social media, high-speed internet, and smartphone apps have

increased awareness. Although trial awareness is increasing in African American/Blacks, this group remains less well informed than whites [19].

A study tested the effect of an educational video on knowledge and education about clinical trials in a group of oncology patients, one-third of whom were Black. The video intervention did not increase knowledge about trials or enrollment. Too few minority participants were enrolled to assess the impact on this population. Refining this method by personalizing the message or using means other than a video may be useful for addressing the negative attitudes about clinical trials and providing more information to minority populations. Previous studies have shown that African Americans prefer to receive health-based information from faith-based groups, community groups, and their peers, and these may be more effective than providing information in a video [29].

Other considerations

Between 2004 and 2015, few newly diagnosed patients with cancer, only 0.1%, enrolled in trials for first-line treatment. Most trials are not designed to enroll patients to receive first-line treatment on the trial. More emphasis needs to be placed on the goal of enrolling newly diagnosed patients in a trial [11].

Only about 62% of published studies of clinical trial results reported health-related quality of life (HRQOL) outcomes. Although HRQOL information was collected in the trials, it was not analyzed and/or published. Breast cancer trials did fairly well, with 8/11 (72%) trials reporting HRQOL. Treatment results and HRQOL results are often published separately, making HRQOL results more difficult to find [22].

A person who has or who had cancer has a cancer-specific identity that may determine treatment choices and disease outcomes. Cultural differences may impact the cancer experience and coping strategies. Social network analysis can be used to understand these factors. Social factors that play a role in cancer identity include family factors, support groups, health care providers, friends and others in social settings, and online social networks. Members of various ethnic groups may look to family, friends, faith-based leaders, and community leaders when deciding to undergo cancer screening. Lack of trust in the health care community may impact decision making. African American women with breast cancer accepted a greater amount of sympathy and found more support at church than their white counterparts [27].

Project Data Sphere (PDS) provides access to oncology clinical trial data. For confidentiality reasons, PDS data are deidentified including deletion of demographic information. A study was conducted to describe a way to connect deidentified patient-level clinical trial data with nationally representative health-related data on cancer survivors collected from the national Medical Expenditure Panel Survey, which addresses social, economic, and health-related factors. The authors of this study used statistical linkage and model-based techniques to enhance the data, thus permitting assessment of socioeconomic factors in the data. This increased insight is expected to improve trial design. The enhanced database allows probabilistic assessments of the representation of the patients in the clinical trials relative to the characteristics of cancer patients in the general population. A more extensive range of research questions about characteristics that may impact patient outcomes can be investigated and may inform studies on identifying disparities [30].

Summaries of individual articles

[1] [African Americans are largely excluded from cancer clinical trials.](https://www.cancerhealth.com/article/african-americans-largely-excluded-cancer-clinical-trials)

<https://www.cancerhealth.com/article/african-americans-largely-excluded-cancer-clinical-trials>

Among ethnic/racial groups, African Americans have the highest death rate and shortest survival for many cancers including breast cancer. Financial issues, distrust, and logistical challenges are some of the reasons that African Americans do not enroll as frequently in clinical trials. Exclusion of patients with comorbidities such as high blood pressure or diabetes, which are more common in Blacks, contributes to the low trial enrollment of Blacks. A higher number of African Americans are enrolled in trials in which informed consent is waived because the trial tested emergency procedures. This could lead to distrust.

[2] [African Americans are under-represented in clinical trials for all cancers that have led to FDA approval of drugs.](https://www.healio.com/news/hematology-oncology/20200623/african-americans-underrepresented-in-cancer-trials-that-led-to-fda-approvals) <https://www.healio.com/news/hematology-oncology/20200623/african-americans-underrepresented-in-cancer-trials-that-led-to-fda-approvals>

Socioeconomic factors and distrust of the medical community based on prior mistreatment of African Americans are factors involved in under-enrollment. Other factors may include insufficient information about trials, concerns about patient randomization in trials, and problems with the attitudes of their health care teams. Another possibility is that African Americans may be less often offered a clinical trial due to the belief that they may be less compliant with study requirements. Among ethnic groups, African Americans have the highest death rate from cancer in the US. Researchers calculated a participation-to-prevalence ratio (PPR) in which the percentage of African Americans among trial patients was divided by the percentage of African Americans with a given disease. A PPR of 1 means identical representation of African Americans in the trial population and the population with the disease. For breast cancer, the PPR was 0.29, indicating under-representation in trials. Treating African American patients with a drug approved by trials that primarily enrolled whites may result in suboptimal response to the drug by African American patients. [This article mentions a paper by Hadidi in *Annals of Internal Medicine*, link/full citation not provided]

[3] [Health Behaviors and Lifestyle Interventions in African American Breast Cancer Survivors: A Review.](https://www.frontiersin.org/articles/10.3389/fonc.2019.00003/full) Paxton et al. <https://www.frontiersin.org/articles/10.3389/fonc.2019.00003/full>

African Americans have a higher incidence of HR- breast cancer and TNBC. Reasons for health disparities may include: access to equitable health care, late disease stage at diagnosis, biology, and sociodemographic factors such as lifestyle factors (i.e., inactivity, obesity, and poor diet). This review of multiple studies involving breast cancer survivors identified low physical activity, poor diet, and obesity/weight problems as important factors. The interventions studied in this paper were generally successful at improving weight, exercise, and diet.

[4] <https://www.healio.com/news/hematology-oncology/20200731/asco-accc-collaboration-aims-to-make-clinical-trial-diversity-part-of-our-dna>

Although Blacks represent approximately 15% of cancer patients in the US, only 4-6% of clinical trial participants are Black. Adequate representation of Blacks in clinical trials improves the likelihood that trial results will apply to these individuals. The American Society for Clinical Oncology (ASCO) and the Association of Community Cancer Centers (ACCC) has begun a collaboration aimed at identification of strategies to increase participation in clinical trials by under-represented populations, including Blacks. The groups issued a request for ideas, which closed in August 2020. Review and selection of ideas will be completed by the end of 2020, and implementation will begin in 2021. A one-size-fits-all approach is unlikely to be successful. The group ultimately hopes to provide a toolkit to improve assessment, training, education, and communication regarding strategies to break down barriers to trial participation. Implementation may need to happen at the patient, provider, program, and/or

community level. Many factors are involved in this under-representation, and thus, solving the problem will be complex. Interrelated barriers to trial participation include socioeconomic status, education and literacy, geography, cost, insurance, healthcare provider bias, lack of awareness of trials, lack of trust of the health care system, language barriers, and cultural factors.

[5] [Diversifying Clinical Trials. file:///C:/Users/baerw/Downloads/s41591-018-0303-4.pdf](file:///C:/Users/baerw/Downloads/s41591-018-0303-4.pdf)

The safety and effectiveness of new treatments may vary according to multiple factors including race. A 1993 law requires that NIH-funded trials prioritize inclusion of minorities in these trials. In 2014, the FDA established an action plan for improving diversity in trials. The FDA also publishes a “Drug Trial Snapshot” that shows demographics including race for trials for every new drug approved. An analysis by ProPublica, a nonprofit news organization, of the Snapshot information showed that for 24 of 31 new cancer drugs approved, only 5% of trial participants were African American although they make up 13.4% of the US population. Distrust and fear of exploitation in medical research are some of the main reasons for this disparity. Some African Americans may not receive sufficient information about the benefits and safety procedures of trials. The need to travel and the inability to take time off work may also impede trial participation. A high percentage (29%) of African Americans were included in clinical trials over the last 20 years in which informed consent was not required (i.e., patients were incapacitated and unable to provide consent). This may undermine attempts to enroll African Americans in trials requiring consent. Those conducting trials must work to engage with and build trust with African Americans by including trial sites in areas of community outreach. Decentralization and new technology may aid in this effort.

[6] <https://www.healio.com/news/hematology-oncology/20200625/black-patients-less-represented-in-pharmaceuticalled-vs-ncisponsored-cancer-trials>

Under-enrollment of Black patients may explain why approved drugs are sometimes less effective in this population. Black patients are less well represented in clinical trials sponsored by pharmaceutical companies compared to trials sponsored by the NCI, the former of which sponsor the majority of trials. The NCI is determined to enroll and provide access to trials for under-represented populations. Blacks make up about 12.1% of cancer patients in the US, and about 2.9% of the population enrolled in pharmaceutical company-sponsored trials. In contrast, National Clinical Trials Network (NCTN) trials included in the SWOG Cancer Research Network enrolled 8.3% Black patients. The reasons for under-enrollment by pharmaceutical companies are unclear but may involve where these trials are conducted. Trials may not frequently be conducted in community oncology sites and other geographic areas where many Black patients reside. One possible solution is proactive and strategic recruitment of diverse patients. The NCTN specifically recruits patients from community oncology sites where most patients receive care. Studies have shown that Black patients are willing to participate in trials if they are eligible. Thus, pharmaceutical companies should adopt strategies to expand access and design equitable inclusion criteria, which will increase diversity. Differences in access to care, socioeconomic factors, and molecular genetic profiles may lead to disparities in cancer risk and prognosis, and under-enrollment of minority patients in clinical trials may worsen these disparities. The FDA is also working on strategies to increase enrollment of Black patients in FDA-registered trials.

[7] <https://www.healio.com/news/endocrinology/20200612/an-urgent-need-steps-to-increase-black-participation-in-diabetes-clinical-trials>

[this article is about enrollment in diabetes trials, but contains some relevant information] Under-enrollment of Blacks in clinical trials means that physicians may have low confidence in the effectiveness of study drugs in these under-represented patients. Many factors affect trial enrollment including the patient’s awareness, appreciation for the study, education, expectations, study environment, and

communication. Perceptions of danger and distrust need to be addressed. Effective communication between the patient and trial investigator may be reduced if cultural barriers are present. African Americans sometimes distrust the healthcare system because of past bad experiences, and culturally may view a devastating diagnosis as fatalistic and as God's intention. Trial investigators need to conduct self-assessments and understand differences. Real-world evidence, which is information collected outside clinical trials and analyzed, and improved methods of recruiting diverse patients to trials are needed. Patients for possible trial enrollment should be sought through health professional societies, churches and other house of worship, talk radio shows, historically black colleges and universities, and Medicaid. Additional strategies include reducing inconvenience, being flexible, being respectful, working on relationships, and actively listening. Participants should remain engaged and informed during the trial. Telehealth can be used for appointment reminders and communication between the study coordinator and patient.

[8] Black Participants Are Sorely Absent from Medical Research. <https://leapsmag.com/black-participants-are-sorely-absent-from-medical-research/>

Only when trial participants reflect the diversity of the general population can physicians understand how a drug will work in different racial/ethnic groups. Although mistrust is a major barrier, often Black patients are simply not asked by their doctors to participate. Culturally appropriate strategies are needed to engage Black patients. A faith-based group called the National Black Church Initiative, which is made up of 34,000 churches and nearly 16 million African Americans, asked the FDA to demand diversity. The FDA responded that they do not have the authority to do so. Blacks often see themselves as outsiders in medical research. Trial exclusion criteria such as people with high blood pressure or stroke may preferentially exclude Blacks who have a higher prevalence of these conditions. Including more Blacks as volunteers, in clinical research roles, and in trial design and interpretation may help increase diversity. Howard University's Cancer Center and Driver is aimed at culturally targeted strategies to connect Black patients to trials (Howard University is a historically Black university). Transportation, time off from work, and childcare are barriers that need to be addressed by government and pharmaceutical entities.

[9] African Americans and Clinical Research. <https://www.cisrhp.org/african-americans-and-clinical-research/>

African Americans who participate in clinical trials may help improve the health of everyone and increase understanding of health disparities. Federal guidelines, ethical codes, institutional review boards, and the informed consent process are in place to prevent abuse, affirm safety, and protect the rights of patients. Benefits of trial participation include the possibility of receiving a new treatment before it is widely available, expert care of the patient's medical condition, and helping other patients. Risks may include not selecting your treatment, being given a treatment that does not work, and side effects. Doctors, family members, friends, and clergy members may help someone decide whether or not to participate in a trial.

[10] <https://www.healio.com/news/hematology-oncology/20191002/access-to-cancer-clinical-trials-may-not-entirely-level-the-playing-field>

Patients who participate in clinical trials have better outcomes than those who do not. However, whether this is related to therapy, bias, more frequent visits, closer monitoring of patients, comorbidities, or socioeconomic factors is unclear. Significant therapeutic effects (positive or negative) in small subpopulations of trial participants can be lost in the background noise of large trials. The notion that one size fits all has become less popular due to the emergence of targeted therapies. Innovative trial designs, inclusion of real-world evidence, and the use of big data analytics are becoming

more popular. Real-world data (data collected outside clinical trials) are being considered as surrogate control data for trials. However, the utility of real-world data is unclear, as this information is obtained from electronic health records or insurance claims data. Robust methods to collect, abstract, and verify these data are in their infancy. Trial participation may help reduce disparities because all patients in a trial are treated the same way. Biological variations and trial access remain unsolved issues. J Unger and colleagues performed a Southwest Oncology Group (SWOG) study of patients with various cancers enrolled in trials and showed that trial participation removed differences in survival outcomes between patients living in rural vs. urban areas. In another SWOG study also by Unger and colleagues, overall survival benefits were the same according to age, sex, and race/ethnicity but not insurance status. Patients with Medicaid or no insurance received no benefit from the study drug, but those with private insurance did. Possible causes include low access to supportive services and financial reasons for non-compliance with study protocols. The financial burden for trial participation is higher for patients with low incomes. Trial design, interpretation, informed consent, and policies may need to be changed. Thus, access to trials is not the only factor that will level the playing field for disparate populations. [Unger JM, et al. *JAMA Netw Open*. 2018; doi:10.1001/jamanetworkopen.2018.1235 <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2696871>]

[11] <https://www.healio.com/news/hematology-oncology/20200131/few-patients-enroll-in-cancer-clinical-trials-as-first-line-of-treatment>

Compared to other countries, clinical trial accrual in the US is very low. Around 5% of patients with cancer in the US enroll in clinical trials, whereas in some European countries, up to 30% of patients with cancer enroll in trials. In the US, most cancer trial participants are young, healthy, white, insured patients with metastatic disease who are treated at an academic medical center. Patients who participate in a trial live longer than those who do not. Between 2004 and 2015, few newly diagnosed patients with cancer, only 0.1%, enrolled in trials for first-line treatment. Most trials are not designed to enroll patients to receive first-line treatment on the trial. More emphasis needs to be placed on the goal of enrolling newly diagnosed patients in a trial. Patients who do not enroll may prefer other treatments or live too far away. Patients often ask what the benefit is for them and have misunderstandings about receiving a placebo. This is the article that was cited:

<https://jncn.org/view/journals/jncn/17/11/article-p1309.xml>

[12] <https://www.healio.com/news/hematology-oncology/20200611/insurance-status-linked-to-survival-benefit-in-cancer-treatment-trials>

In a study of clinical trials conducted before implementation of the Affordable Care Act, uninsured cancer patients or those with Medicaid in clinical trials received no added survival benefits from investigational medications compared with standard of care medications and compared with insured patients. Supportive and post-treatment care may be suboptimal in these patients, possibly due to limited financial resources. Trials are typically designed to test the benefit of a treatment across the entire patient group in the study and may not explain benefits or lack of benefits in subpopulations according to demographics or insurance status. [Paper by JM Unger et al. in *JAMA Network Open*. Link/full citation not provided.]

[13] [Duma N, et al. *J Oncol Pract*. 2018;doi: 10.1200/JOP.2017.025288](#). (cited in the above article [1]) Whites were more likely to enroll in cancer clinical trials than African Americans. The percentage of Black participants in cancer trials has decreased since 2011.

[14] [Problem Solving to Enhance Clinical Trial Participation Utilizing a Framework-Driven Approach](#). Lansey et al. <https://www.hematologyandoncology.net/files/2020/07/ho0820Lansey-1.pdf>

Researchers funded by NIH are required to seek diversity in their studies. NCI-designated comprehensive cancer centers are required to perform outreach and identify the needs of under-represented populations to increase diversity. Interventions to increase trial participation can occur at institutional, community, provider, or patient levels. Making trials available in community settings will help increase enrollment. Barriers can be due to institutional, community, provider, or patient factors and may include time; physicians' decisions, bias, attitudes, lack of provider referral, and provider presumptions about a patient's likelihood of observing trial requirements; eligibility criteria; prior therapy; poor communication; comorbidities; distance to trial site; legal status; low health literacy; less use of the internet; no phone; skepticism of the benefits of participating; negative attitudes about research; fatalism/reliance on God; loss of control; fear; concern about harm; discomfort; required number of visits; and lack of childcare. Clinical trial discussion should be a physician's best practice, even if no trial is available at the time of discussion. The Affordable Care Act and some states require insurance coverage of standard of care treatment costs associated with a trial. Possible solutions include: ahead of a visit, physicians should review the patient's medical records, cancer type and demographic characteristics to identify trials, determine if trials had been previously discussed, and the outcome of the discussion. Training should be initiated that addresses cultural sensitivity, implicit bias, and education with online training segments and seminars. Education materials should be developed for patients based on known gaps. Community members should be engaged to increase education, improve enrollment, and publicize study results.

[15] <https://www.healio.com/news/hematology-oncology/20200309/bias-stereotypes-may-play-role-in-cancer-clinical-trial-enrollment>

Bias by medical professionals may explain persistent under-enrollment of racial minorities in clinical trials. These professionals may have negative stereotypes of minorities including the tendency to not follow study instructions. Other stereotypes about African Americans include assumptions that this group has a lower understanding of cancer research and that this group is less likely to have an altruistic attitude. Acknowledging these biases is the first step in removing disparities in clinical trial enrollment. Some themes that emerged from this study: communication with minorities about recruitment was challenging due to language barriers; minority participants were perceived to be unsuitable study participants; negative perceptions led trial coordinators to not mention trial opportunities to minorities; and a successful strategy is to address misunderstandings about research to build trust. Some investigators considered race to be irrelevant when screening potential enrollees. Potential bias must be considered when developing strategies to increase enrollment of minorities in clinical trials. Training is needed to reduce bias. [Study by SJ Niranjana et al. *Cancer*, no link/full citation provided]

[16] [Disparities in Clinical Trial Access Across US Urban Areas](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2762014#240086501). Feyman et al.

<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2762014#240086501>

Population size is the main determining factor in the number of spaces in a trial for patients in urban areas. Racial and socioeconomic disparities in trial enrollment and participation may also be due to factors affecting recruitment and retention. The low representation of minorities in cancer clinical trials may be due in part to an unequal distribution of trial sites relative to the population.

[17] [FDA to Eliminate Health Disparities in Clinical Trials, Research](https://healthitanalytics.com/news/fda-to-eliminate-health-disparities-in-clinical-trials-research)

<https://healthitanalytics.com/news/fda-to-eliminate-health-disparities-in-clinical-trials-research>

The FDA is working to eliminate disparities and promote diversity in clinical trials. Minorities may lack transportation, time, or information about clinical trials. FDA guidance requires collection of race and ethnicity data from clinical trials and the use of standardized terminology. The FDA also sponsors a

Minorities in Clinical Trials Initiative that provides information in the form of videos and other platforms. The FDA works with patients in initiatives like these.

[18] Another Health Disparity: Clinical Trials <https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2020/02/28/another-health-disparity-clinical-trials>

Barriers to clinical trial participation may include transportation problems, comorbidities, fear, distrust of the medical system, lower income, language barriers, and the need for patients to find trials on their own. Long washout periods and treatment delays that are often part of the trial design can also be barriers to recruitment. Some patients may consult social media or the internet before talking to their doctor about trials. These platforms are likely to be more useful than phone calls or print media. As reported by Dana Dornsife, chairman of the [Lazarex Cancer Foundation](#), leveraging industry competition to encourage pharmaceutical companies to promote enrolling diverse patients and create stronger requirements for reporting of diversity may increase enrollment of diverse patients. Clinical trialists should not assume that patients who are under-represented in trials do not enroll because of low education or low income. Rather, all possible reasons for the lack of diversity should be considered.

[19] Clinical trial awareness: Changes over time and sociodemographic disparities. Leiter et al. https://journals.sagepub.com/doi/10.1177/1740774515571917?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed&

Between 2008 and 2012, awareness about clinical trials increased among African American/Blacks (by 10.6%), and use of the internet also increased in this group (by 14.2%). A causal relationship between internet use and awareness cannot be determined by this study. The percentage of African American/Blacks who were aware of trials was lower than that of whites (67.1% vs. 77.5%). Other barriers to trial enrollment exist such as patients' not accepting trials, restrictive trial eligibility criteria, lack of health care providers referring patients to clinical trials, and logistical problems. Minorities are less aware of trials, and have issues with fear and concerns about risk. Recent efforts to increase trial awareness include a website launched in 2012 by the NIH to educate the general public about clinical trials; the Center for Information and Study on Clinical Research Participation, which established large-scale efforts to increase clinical trial awareness targeted at the same group; the Clinical Trial Education Program and the Education Network to Advance Cancer Clinical Trials (ENACCT), which is particularly aimed at increasing trial awareness and accrual in minorities; and Increasing Minority Participation and Awareness in Clinical Trials (IMPACT), which is a National Medical Association program to encourage minority doctors to become clinical investigators and discuss clinical trial participation, especially in African American/Blacks. Social media, high-speed internet, and smartphone apps have increased awareness. Thus, although trial awareness is increasing in African American/Blacks, this group remains less well informed than whites.

[20] <https://www.healio.com/news/hematology-oncology/20200123/collaboration-to-ease-clinical-trial-search-process-for-patients-with-blood-cancers>

Barriers to trial participation (all patients) include: limited ability to travel, limited schedules, financial and emotional struggles, perception that a trial is a last resort rather than providing access to innovative treatments, and limited education, awareness, and access to trials. Finding appropriate trials can be complex. Physicians may worry that they will lose their patient. Support centers may offer clinical trial navigation and streamline the process of searching for trials. The Leukemia & Lymphoma's Clinical Trial Support Center is a model of this capability. This service is being made available to health care providers to facilitate trial searches. The nurse navigators help patients identify potential trials; help with enrollment; collect health information, travel abilities, and insurance information; and provide support to the patient.

[21] [Ambivalence: A Key to Clinical Trial Participation?](https://www.frontiersin.org/articles/10.3389/fonc.2018.00300/full) Chilton et al.

<https://www.frontiersin.org/articles/10.3389/fonc.2018.00300/full>

Ambivalence (i.e., mixed feelings) may impact trust and distrust regarding clinical trial engagement and retention. This paper examined the role of trust and distrust in minorities regarding the trial process. Managing ambivalence may increase trial participation, especially among minorities, who may be especially susceptible to ambivalence. The relationship between the patient and the clinical trial team is important and mediates trust/distrust. Trust, distrust, and ambivalence are modifiable and can be managed. Ambivalence may be due to previous experiences with health care, lack of access to health care, lack of transportation to receive care, prior discrimination regarding health care, self-reported health status, income, and education. Motivational interviewing is a technique that may dispel ambivalence and facilitate decision making. In motivational interviewing, the health care provider addresses the patient with a collaborative spirit. Features of motivational interviewing are active listening, open-ended questions, affirmations, reflections, and summaries. The use of motivational interviewing may increase trust, decrease ambivalence, and contribute to increased clinical trial participation.

[22] <https://www.healio.com/news/hematology-oncology/20200523/despite-nci-support-some-cancer-trials-fail-to-publish-healthrelated-quality-of-life-data>

Only about 62% of published studies of clinical trial results reported health-related quality of life (HRQOL) outcomes. Although HRQOL information was collected in the trials, it was not analyzed and/or published. Breast cancer trials did fairly well, with 8/11 (72%) trials reporting HRQOL. Treatment results and HRQOL results are often published separately, making HRQOL results more difficult to find.

[23] <https://www.healio.com/news/hematology-oncology/20200721/aacr-forum-confronts-racism-inequality-in-research-we-have-kept-quiet-for-way-too-long>

Although the Black Lives Matter movement is about police brutality, Black lives should also matter in terms of health equity. To improve diversity in trials, clinical trials should be conducted in countries with a diverse population such as Central American nations and countries in sub-Saharan Africa, and patient advisory panels and expert consultants should include representatives from diverse populations to provide input about what diverse patients care most about. Community engagement and trials run by diverse investigators will also work to build trust about the important role and advantages of clinical trials. The funding rates for African American scientists are below those of others. Efforts are underway to bring more Black investigators into research institutes. The FDA is encouraging trial sponsors to design clinical trials with broader eligibility requirements. Accountability regarding plans to enroll diverse populations is important but difficult to achieve.

[24] <https://www.healio.com/news/hematology-oncology/20200507/covid19-response-may-lead-to-lasting-changes-in-cancer-care>

The COVID-19 pandemic has changed oncology care. Short-term changes include increasing the number of patients that can be seen in a given time. Long-term changes include providing more efficient, safer, and more convenient care. Registering patients online and reducing the number of laboratory visits were necessitated by COVID-19 but may be helpful to implement as permanent changes. Telehealth has also increased with the pandemic, providing opportunities not just for patients and physicians, but for all members of the care team. Clinical trial design will probably look the same but may be more flexible. Some in-person visits and frequent lab tests may be deemed not necessary.

[25] <https://www.healio.com/news/hematology-oncology/20200721/covid19-a-real-wakeup-call-in-how-cancer-clinical-trials-are-conducted>

The COVID-19 pandemic has led to changes in how clinical trials are conducted, including allowing patients to visit community physicians rather than the trial site, mailing prescription medications, and increased use of telemedicine. However, these changes are partial solutions, as some medications are toxic and need to be administered by carefully trained personnel, and not all adverse events can be captured via a telemedicine visit. Long-term implementation of these strategies may help remove geographic barriers, increase trial participation for more patients, and increase diversity in trial participants.

[26] [Engaging Black Churches to Address Cancer Health Disparities: Project CHURCH](https://www.frontiersin.org/articles/10.3389/fpubh.2018.00191/full). McNeill et al. <https://www.frontiersin.org/articles/10.3389/fpubh.2018.00191/full>

Project CHURCH (Creating a Higher Understanding of Cancer Research and Community Health) is a collaboration between The University of Texas MD Anderson Cancer Center and African American churches in the Houston region. This project goes to where the people are (“boots on the ground”) and seeks to understand and address cancer prevention disparities and to engage African Americans as research partners. This project worked with three large churches to build trust, establish credibility, and recognize the strengths of churches as partners. They developed a cohort study of church members to understand risk factors for disparities in cancer prevention, including intrapersonal, interpersonal, institutional, community, and public policy factors, and shared the results with the entire church community. They established an advisory board. Recruitment to the study cohort occurred through various communications at the church. They hosted a health fair to kick off enrollment of the cohort. The height and weight of enrolled participants was collected, and enrollees answered a questionnaire. After trust had been established, participants were asked for saliva samples for biobanking. Results were disseminated to the community through newsletters and an annual report. Patient navigation services were provided, and prevention programs were implemented. The program has also trained racial/ethnic minority researchers. The group reported rapid and high recruitment and retention in their study cohort.

[27] [How Social Networks May Influence Cancer Patients' Situated Identity and Illness-Related Behaviors](https://www.frontiersin.org/articles/10.3389/fpubh.2018.00240/full). Jones et al. <https://www.frontiersin.org/articles/10.3389/fpubh.2018.00240/full>

A person who has or who had cancer has a cancer-specific identity that may determine treatment choices and disease outcomes. Cultural differences may impact the cancer experience and coping strategies. Social network analysis can be used to understand these factors. Social factors that play a role in cancer identity include family factors, support groups, health care providers, friends and others in social settings, and online social networks. Members of various ethnic groups may look to family, friends, faith-based leaders, and community leaders when deciding to undergo cancer screening. Lack of trust in the health care community may impact decision making. African American women with breast cancer accepted a greater amount of sympathy and found more support at church than their white counterparts.

[28] <https://www.healio.com/news/hematology-oncology/20200117/physicians-weigh-risks-rewards-of-social-media-for-clinical-trial-recruitment>

Positive impacts on increasing trial participation can be made when physicians simply mention trials to patients and when physicians use social media to promote trials. Physicians do have concerns about using social media to promote trials. A qualitative study of breast oncologists at the City of Hope was conducted by MS Sedrak and colleagues. Physicians identified positive impacts of social media on trial recruitment, visibility, patient engagement, and better communication. Disadvantages included administrative load, the possibility of providing incorrect information, lack of regulatory oversight, and

limited outreach. Guidance is needed on how to best use social media for this purpose. Social media users may tell others, leading to a snowball effect. Barriers include the time involved to develop content and the lack of evidence showing that this strategy actually increases enrollment. Physicians who practiced at community-based settings had similar attitudes about social media as those who practiced in academic medical facilities. ASCO provides ways for physicians to learn how to effectively use social media.

[29] [The Impact of an Educational Video on Clinical Trial Enrollment and Knowledge in Ethnic Minorities: A Randomized Control Trial.](https://www.frontiersin.org/articles/10.3389/fpubh.2019.00104/full) Skinner et al.

<https://www.frontiersin.org/articles/10.3389/fpubh.2019.00104/full>

This study tested the effect of an educational video on knowledge and education about clinical trials in a group of oncology patients. Approximately one-third of participants were Black. The number of people enrolling in a trial among those who did or did not view the video was not significant, and the video intervention did not increase knowledge about trials. Too few minority participants were enrolled to assess the impact on this population. Refining this method by personalizing the message or using means other than a video may be useful for addressing the negative attitudes about clinical trials and providing more information to minority populations. Previous studies have shown that African Americans prefer to receive health-based information from faith-based groups, community groups, and their peers, and these may be more effective than providing information in a video.

[30] [Data Integration Innovations to Enhance Analytic Utility of Clinical Trial Content to Inform Health Disparities Research.](https://www.frontiersin.org/articles/10.3389/fonc.2018.00365/full) Cohen and Unangst

<https://www.frontiersin.org/articles/10.3389/fonc.2018.00365/full>

Project Data Sphere (PDS) provides access to oncology clinical trial data. For confidentiality reasons, PDS data are deidentified including deletion of demographic information. This study describes a way to connect deidentified patient-level clinical trial data with nationally representative health-related data on cancer survivors collected from the national Medical Expenditure Panel Survey (MEPS), which addresses social, economic, and health-related factors. The authors of this study used statistical linkage and model-based techniques to enhance the data, thus permitting assessment of socioeconomic factors in the data. This increased insight is expected to improve trial design. The enhanced database allows probabilistic assessments of the representation of the patients in the clinical trials relative to the characteristics of cancer patients in the general population. A more extensive range of research questions about characteristics that may impact patient outcomes can be investigated and may inform studies on identifying disparities.

[The below articles were not included in the synthesis report]

<https://www.healio.com/news/ophthalmology/20200824/details-matter-when-participating-in-clinical-trials>

When enrolling patients in clinical trials, the following areas need to be carefully addressed: obtaining informed consent, carefully enrolling patients who meet the inclusion/exclusion criteria, correct randomization of patients, and proper drug distribution and documentation.

<https://www.healio.com/news/cardiology/20200619/diverse-populations-underrepresented-in-clinical-trials>

[disregarded. This article is about enrollment in trials for atrial fibrillation.]

<https://www.healio.com/news/cardiology/20200612/acc-program-to-bolster-women-underrepresented-clinicians-in-clinical-trial-research>

[disregarded. This article is about enrolling more women and minorities in cardiac trials. The article mentions providing mentoring and training toward this goal, but no details are provided.]

<https://www.healio.com/news/ophthalmology/20200313/what-common-mistakes-might-a-practice-owner-make-when-starting-to-host-clinical-trials>

[disregarded. This article is about the correct staff to have in place when conducting a trial]