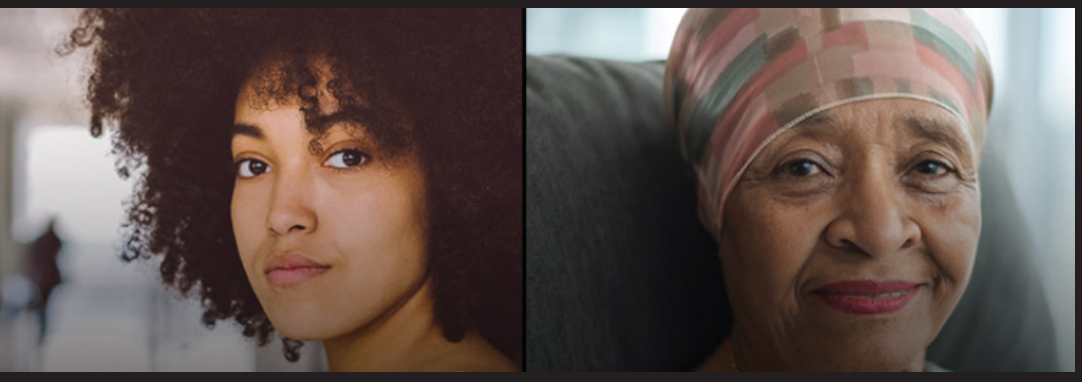
BECOME

(Black Experience of Clinical Trials and Opportunities for Meaningful Engagement)

RESEARCH REPORT



OCTOBER 2022

Metastatic Breast Cancer MBCalliance

Metastatic Breast Cancer Alliance, New York, NY; Breast Cancer Research Foundation, New York, NY

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1.
Executive Summary: Background/ Key Learnings

1.1 Situation analysis/goals

The facts are starkly disturbing:

- Among U.S. racial/ethnic groups, Black women and men have the highest death rate and shortest survival for many cancers including breast cancer [1,2].
- Clinical trials help improve outcomes and survival for people living with cancer, but Black women and men represent only 4% to 6% of patients in all cancer clinical trials – although about 15% of cancer patients in the U.S. are Black [3-9].
- Only when clinical trial participants reflect the diversity of the general population can oncologists understand how a drug works across subpopulations [10].

The Black Experience of Clinical Trials and Opportunities for Meaningful Engagement (BECOME) project aims to drive change by **better understanding barriers** to clinical trial participation for Black patients with metastatic breast cancer (MBC) and **identifying actions** to increase participation.

> *"As a metastatic breast cancer patient, I don't want my daughter to go through what I've experienced. I want to understand barriers to clinical trials for the Black community, so we can find answers on why Black men and women with MBC are dying at a faster rate."*
>
> *-Stephanie Walker, BECOME project lead & patient advocate living with MBC*

1.2 BECOME project origins

The patient-led BECOME project grew out of a conversation at the 2019 San Antonio Breast Cancer Symposium between two patient advocates living with MBC – Stephanie Walker, RN, and Marina Kaplan, an epidemiologist – who connected via Living Beyond Breast Cancer's "Hear My Voice" program. Marina had presented her study about barriers to clinical trial participation and patient-driven solutions to increasing participation (Appendix A). Concerned that only 8.87% of the respondents in her survey were Black, she and Stephanie discussed conducting additional research in the Black community.

Marina passed away in 2020 before the groundwork could be laid, but Stephanie was determined to pursue their shared goal. That year, she launched the BECOME project in partnership with the Metastatic Breast Cancer Alliance (**MBCA**), a consortium of representatives from cancer nonprofits and pharmaceutical and biotech companies, as well as individual patient advocates – many of whom are living with MBC. The mission of the MBCA is to extend life, to enhance quality of life, and to end suffering and death from MBC by advancing MBC research, improving access to quality treatments and care, and empowering people through increased education and information about the disease, and access to available resources.

1.3 Overview of research phases

As BECOME project lead, Stephanie worked with a diverse team on the multi-phase research initiative. Researchers first conducted a literature review (Appendix B) of selected articles on Black patient participation in cancer clinical trials. Next, they conducted virtual interviews with 31 Key Informants (Appendix C) including Black women and men living with MBC, clinicians involved in breast cancer treatment, hospital and academic research administrators, breast cancer researchers, and administrators with insurance/payer organizations.

Based on the information learned from the literature review and Key Informant interviews, researchers developed a web-based survey (with a paper-based option) of U.S. adults living with MBC. The survey (Appendix D) explored attitudes toward and interest in clinical trials, and included some general questions about demographics and experience with the oncology care team. Survey participants were recruited through social media posts and emails—from the MBCA, MBCA members, subcommittee members, and ambassadors—to people connected with cancer communities.

Of the 424 survey respondents, 102 self-identified as Black. Respondents tended to be highly educated with high socioeconomic status, receive care through an academic medical system, and be well-insured, frequently with private insurance.

The analysis focused primarily on the responses from Black participants, consistent with BECOME's objectives. Black and non-Black respondents were compared, and the most meaningful differences are summarized below. **Additional details on survey responses can be found below in the Responses/ Detailed Findings sections.**

1.4 Key learnings from survey responses

The survey found that *8 out of 10 Black people living with MBC would consider participating in clinical trials.*

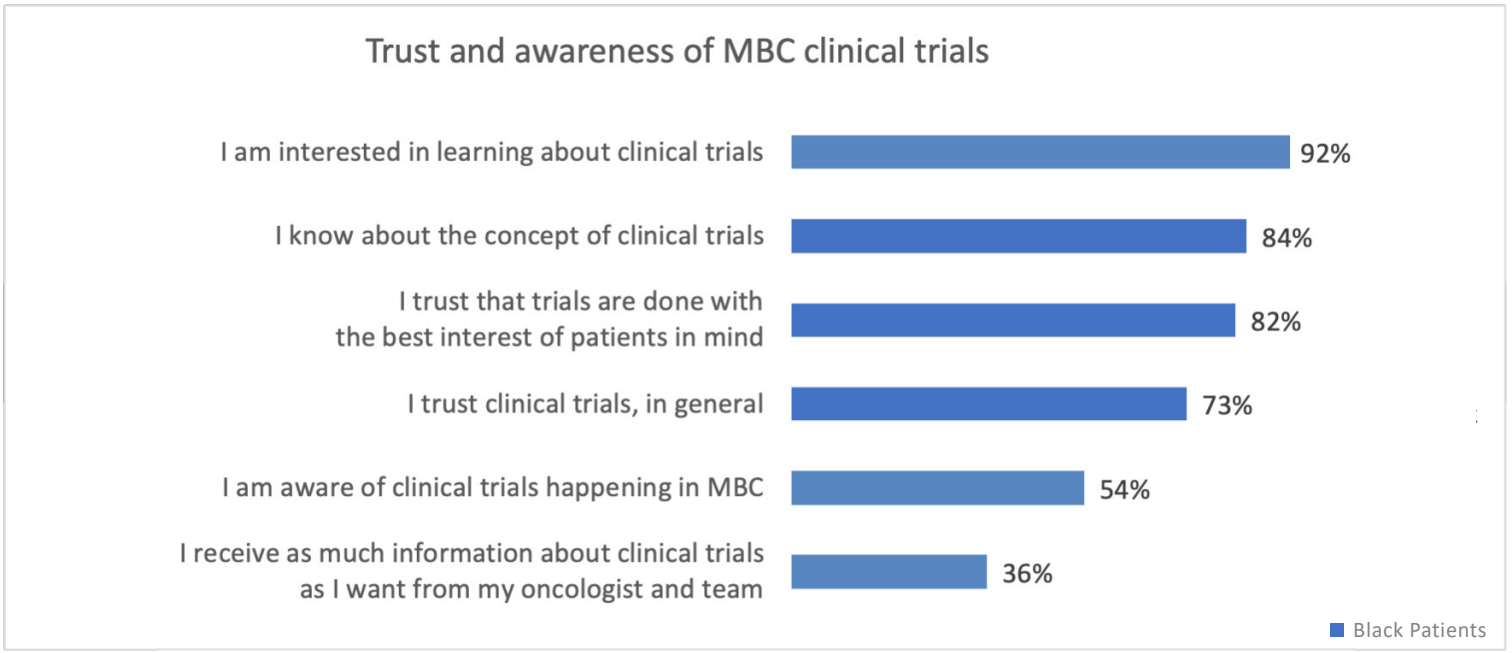
So why are participation numbers so low? The survey revealed a broad spectrum of barriers and concerns that prevent participation by Black patients, as well as motivations that drive willingness to participate. While many of these factors have been documented in other research, the BECOME project seeks to focus on understanding the most compelling ones and identifying actions stakeholders can take to propel change.

These actions include:

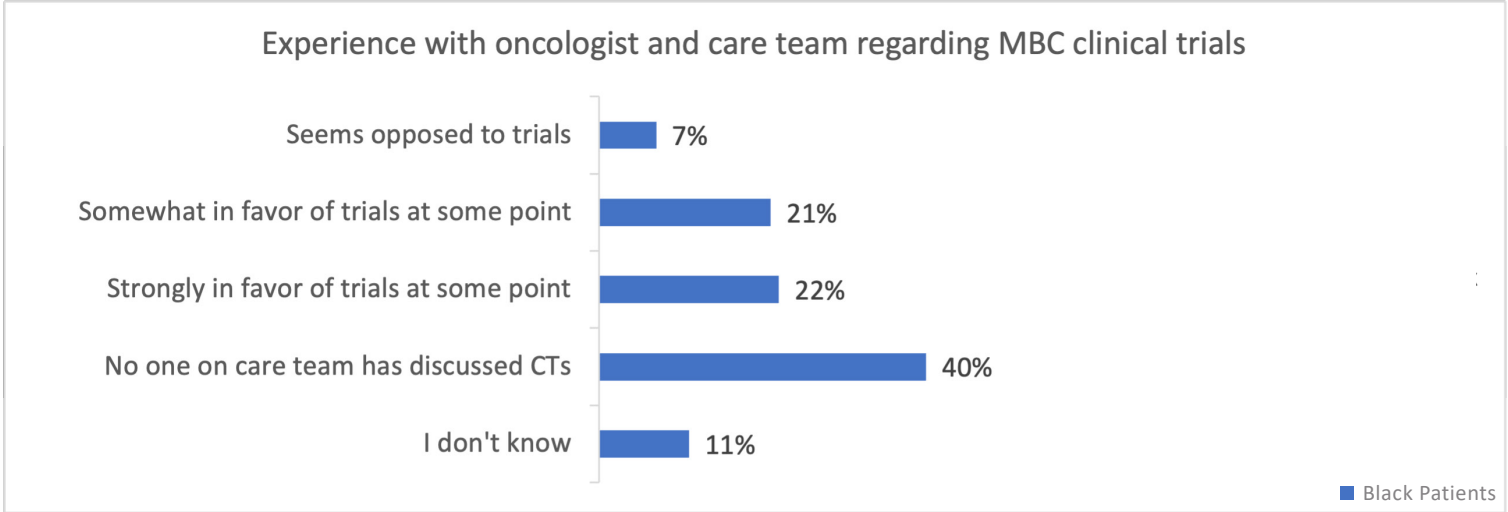
#1. Better Inform

The survey responses showed that Black patients (blue bars in the below graphs) want to know about and would consider participating in clinical trials, but they lack information.

More than 90% indicated they would be interested in learning about clinical trials, and 83% said they were somewhat or very likely to consider participating. However, only 54% were aware of clinical trials happening, and only 36% said they receive as much information as desired from their oncologist and care team.



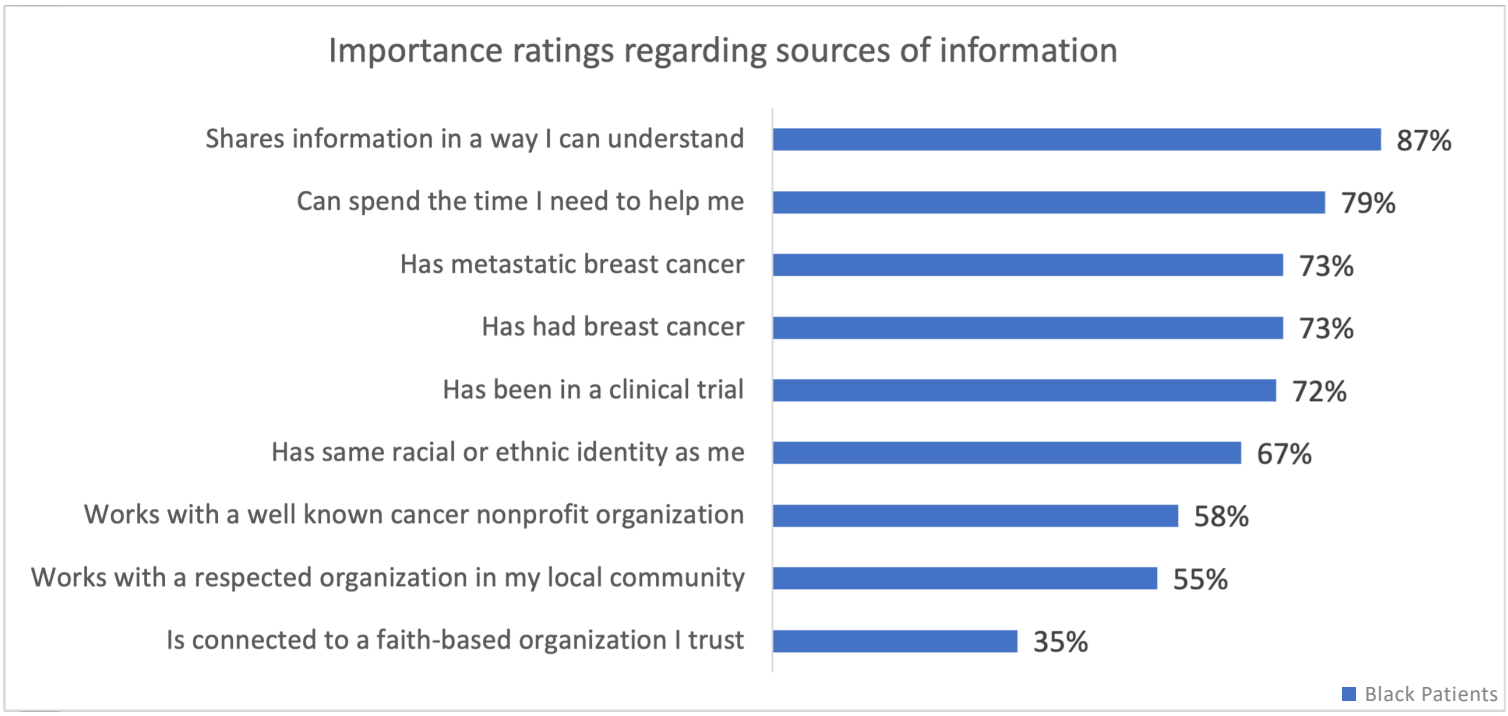
In addition, 40% of Black respondents reported that no one on their care team had discussed clinical trials for MBC.

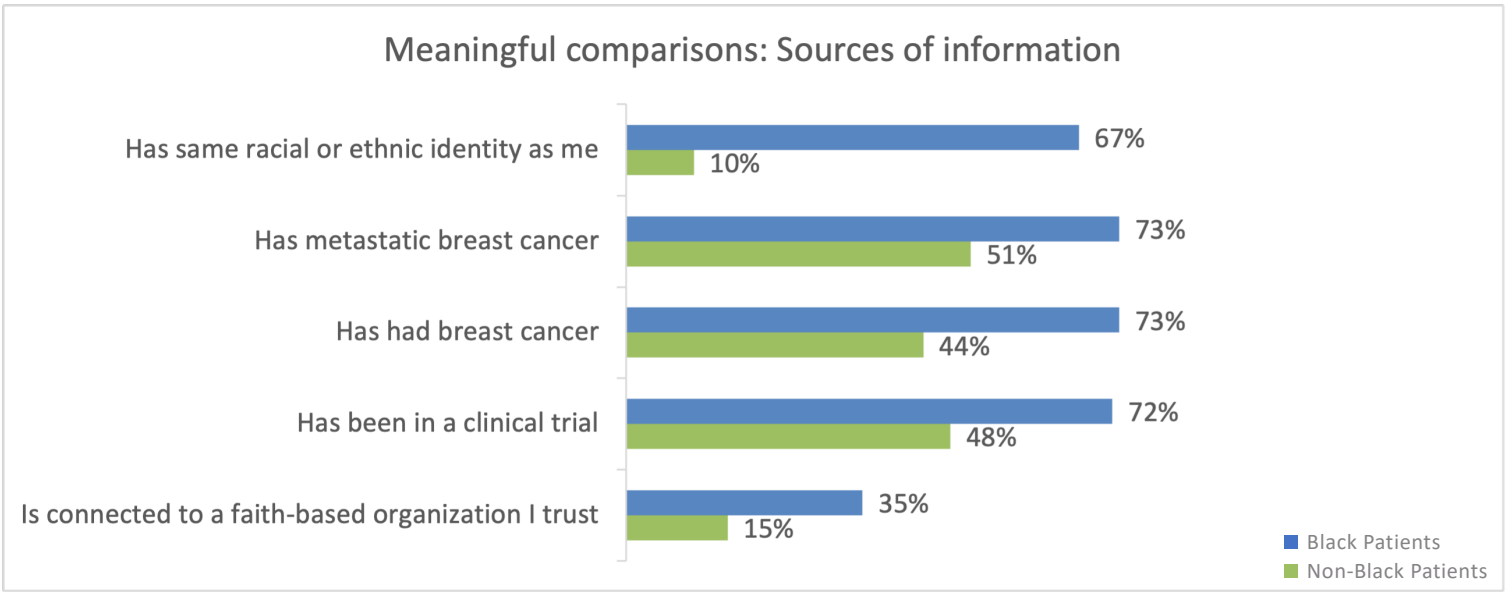


#2. Inspire Trust

A wide variety of sources provide information about clinical trials. Some people learn about them from their doctors, while others hear from patient advocates (also known as peer support), patient or nurse navigators who work in the hospital system, an oncology nurse, or a community health worker.

Whatever the source, Black patients were more likely than non-Black patients to want to learn about clinical trials from someone with the same racial or ethnic identity and shared health experience.


Importance ratings regarding sources of information
Shares information in a way I can understand
87%
Can spend the time I need to help me
79%
Has metastatic breast cancer
73%
Has had breast cancer
73%
Has been in a clinical trial
72%
Has same racial or ethnic identity as me
67%
Works with a well known cancer nonprofit organization
58%
Works with a respected organization in my local community
55%
Is connected to a faith-based organization I trust
35%
Black Patients


Meaningful comparisons: Sources of information
Has same racial or ethnic identity as me
67%
10%
Has metastatic breast cancer
73%
51%
Has had breast cancer
73%
44%
Has been in a clinical trial
72%
48%
Is connected to a faith-based organization I trust
35%
15%
Black Patients
Non-Black Patients

#3. Ensure Access

Gaining a deeper understanding of the barriers to Black patient participation in clinical trials was one of the key goals of the BECOME project. It is notable that these barriers persist even in this group of respondents with a high level of resources, access (i.e., care at academic medical institutions), education, and insurance.

The survey found that Black respondents considered the following to be important barriers to clinical trial participation:

Logistics

47% Requires a lot of travel time

40% Too many appointments and tests

Finding Trials

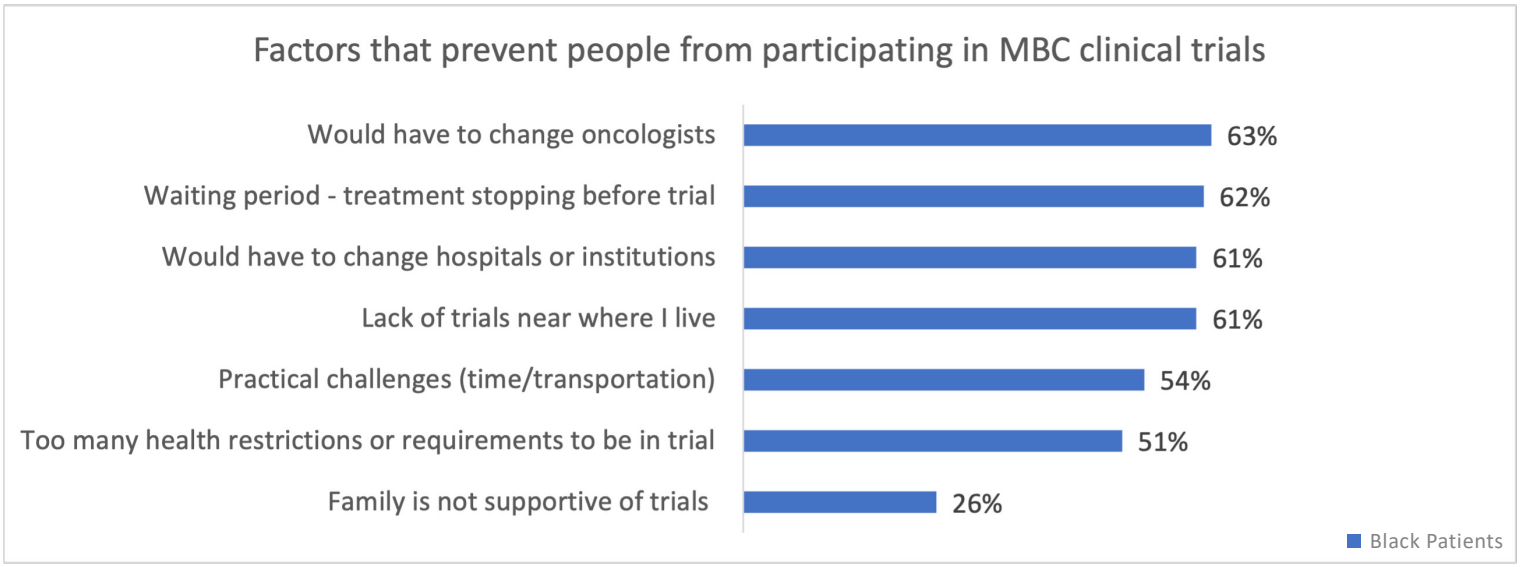
64% Difficulty finding trials

Expense

73% Centers that run trials don't take my insurance

56% Financial burden

51% I worry there may be extra medical costs

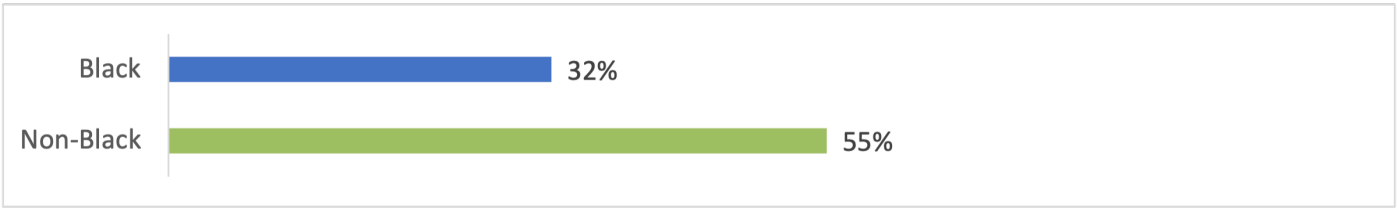


#4. Address Concerns and Reinforce Motivations

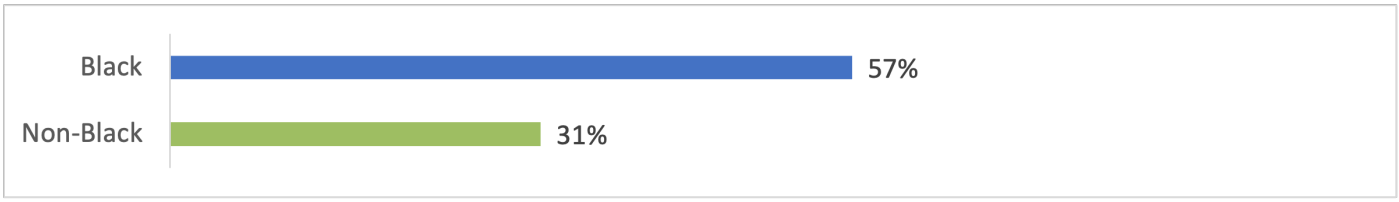
The survey identified numerous concerns about participation in clinical trials. Common worries, which were shared by Black and non-Black respondents, included side effects (73% Black, 66% non-Black) and effectiveness of trial drugs (63% Black, 62% non-Black).

However, some concerns were much more significant to Black patients:

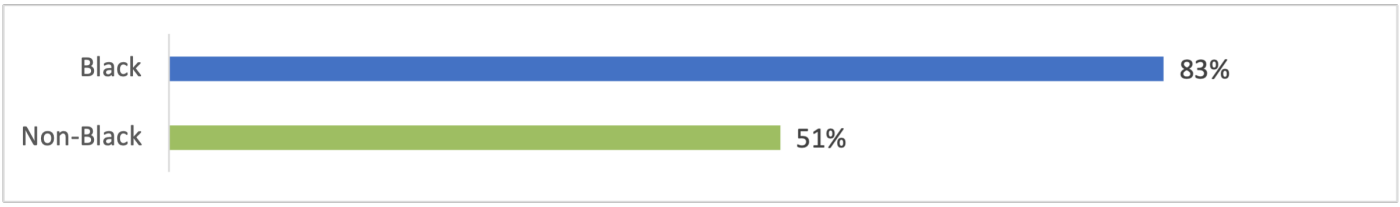
- Black patients were *less likely* than non-Black patients to trust that people of all races and ethnicities get fair and equal treatment in trials.

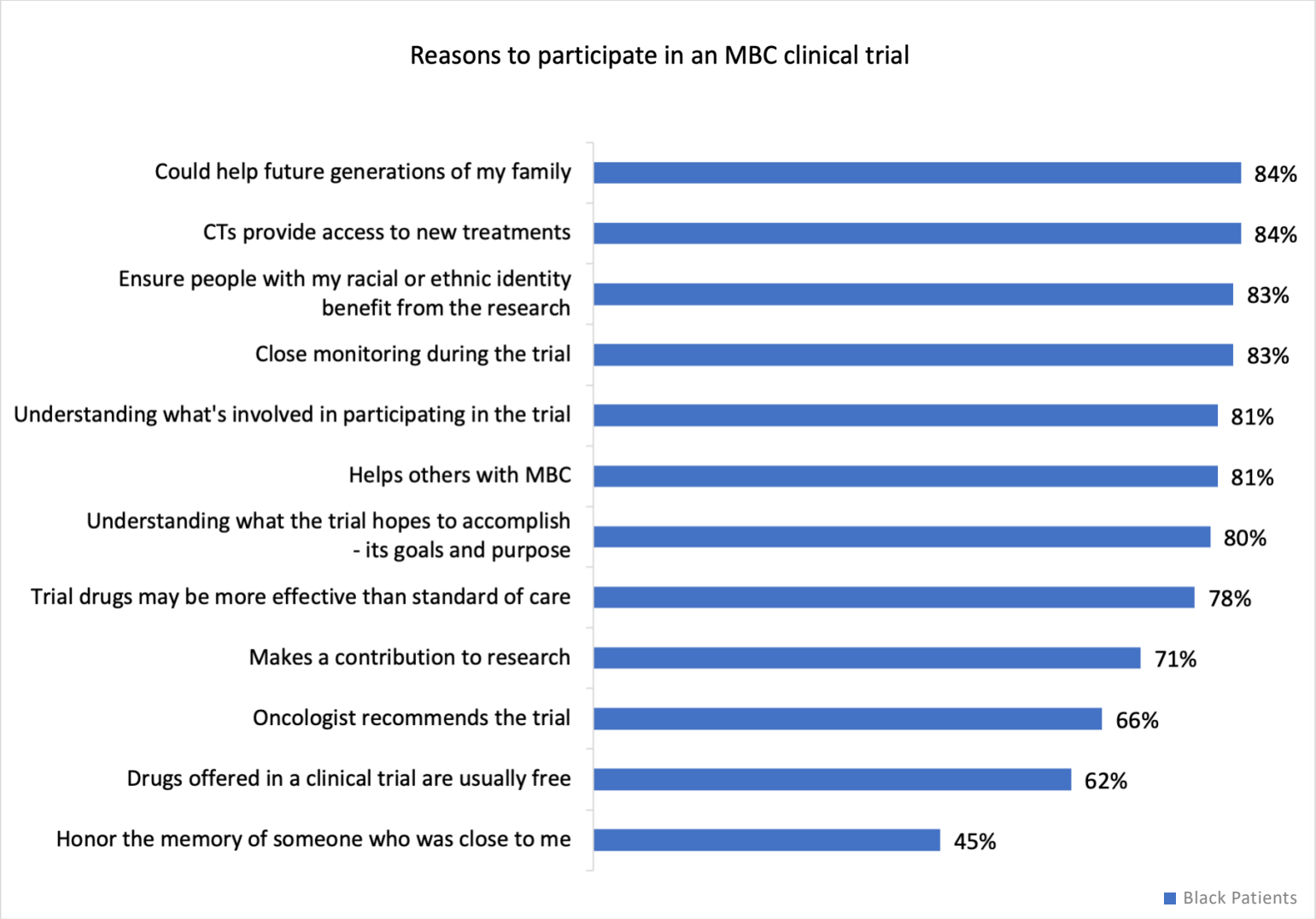


- Black patients were *more likely* than non-Black patients to believe unstudied treatments may be harmful.



The survey also identified reasons Black patients would be willing to participate in a clinical trial, many of which are shared by non-Black patients. A motivation that stood out in terms of being compelling to Black respondents was to "ensure people with my racial or ethnic identity will benefit."





These findings reinforce the need to understand and acknowledge the issues that worry Black patients as well as the reasons that drive their desire to participate in clinical trials. They also underscore the critical importance of communicating clearly, concisely, and truthfully so that Black patients understand the why, what, and how of clinical trial participation.

1.5 Next steps

All stakeholders – including oncology care teams, insurers, hospital systems, researchers and contract research organizations, pharmaceutical and biotech companies, government agencies, cancer and community organizations, and patients/advocates – have a responsibility and a role to play in increasing Black participation in MBC clinical trials.

Next steps include:

- ***Expand survey respondent base.*** In future studies of clinical trial participation, investigators hope to reach a broader group to more fully represent the Black patient experience.
- ***Share results and develop strategies.*** Members of the BECOME initiative will meet with other groups who have recently performed surveys focused on Black women and men with breast cancer to share results and identify strategies to improve care.
- ***Increase Black patient enrollment in clinical trials.*** Activities could include training health care providers to deliver patient-friendly information in an unbiased manner, improved patient education, and helping patients find and access clinical trials.

The comprehensive report sections that follow provide an in-depth description of the BECOME project including:

- **Research phases**
- **Survey development**
- **Participant characteristics**
- **Survey responses by question**
- **Detailed findings**

2.
Methodology:
Research Phases/ Development/ Participant Recruitment

2.1 Objectives

The patient-led BECOME project has two primary objectives:

1) Understand the barriers to participation by Black patients with MBC in clinical trials

2) Identify actions to increase participation

The multi-step research phase included a literature review (completed Fall 2020), qualitative research with interviews of Key Informants (completed Spring 2021), and a survey of people living with MBC (full results in this report).

2.2 Literature review

The MBCA performed a review of carefully selected articles on Black patient participation in cancer clinical trials. This literature review (Appendix B) revealed that barriers to Black patient participation can be categorized into several multifaceted and intersecting categories:

- **Institutional barriers** are system-wide and involve how trials are designed. For example, trial eligibility criteria may result in exclusion of certain populations of patients.
- **Community barriers** are those 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 affect minority populations to a greater degree than other populations.
- **Patient-level barriers** are related to the characteristics of the patient and include factors that may make trial consideration or participation more difficult such as socioeconomic status or mistrust by Black people due to historical harms.

Efforts to overcome these barriers include:

- At the institutional level, various efforts are underway by the NIH, FDA, and other entities. Including more Black volunteers in clinical trial roles is also expected to increase diversity.
- At the community level, interacting and communicating with members of the community, trials run by diverse investigators, and local outreach efforts are expected to positively impact enrollment by diverse

populations. Meeting people in places of worship, beauty parlors, 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 discuss trials with 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.

2.3 Interviews with Key Informants

Using the information from the literature review as a guide, the next step was to conduct interviews with 31 Key Informants (Appendix C) including Black people living with MBC, clinicians involved in breast cancer treatment, hospital and academic research administrators, breast cancer researchers, and administrators within insurance/payer organizations. Key Informants were identified and recruited by the MBCA, and the interviews were conducted on Zoom by CBWhite, a consultancy that specializes in working with nonprofit organizations to develop strategies informed by marketing research.

The interviews identified hypotheses, questions, and ideas for exploration in the survey under development. Many patients who were interviewed reported not having a conversation with their provider/care team about clinical trials. Those who participated in clinical trials reported positive experiences with clinical trials and positive, trusting interactions with their provider/care team. Clinicians perceived that they are engaging with patients regarding clinical trials, and report that all eligible patients are informed and actively recruited to clinical trials. Factors that can influence decisions to inform and recruit a patient include the patient's age, other medical conditions the patient has, and the patient's English proficiency and insurance status. Key Informants unanimously agreed that coordination and support among hospitals, health care providers, and payers reduces barriers, enhances financial capacity, and provides social support.

Patients who were interviewed reported:

- Factors influencing the decision to participate in trials included being well-informed, being motivated by family cancer deaths (including breast cancer), and contributing to the development of treatments for Black women.
- Factors influencing the decision not to participate in trials included ineligibility for clinical trials, not enough information, and general mistrust of their health care provider and/or care team.

Clinicians and researchers who were interviewed reported that Black patients successfully recruited to clinical trials complete the trial similar to other patients. The clinicians and researchers perceive that barriers to clinical trial participation frequently experienced by Black patients include:

- General mistrust of the medical system
- Insurance status (uninsured or have Medicaid, which provides limited coverage for clinical trials in many states)
- Limited financial resources and social support

Administrators who were interviewed reported that hospitals located in rural areas present access challenges, and that patient-identified support can come from patient advocates, friends, spouse/immediate family, their faith community, and their oncologist and care team. Administrators reported that they perceive that barriers frequently experienced by Black patients include:

- General mistrust of the medical system
- Limited medical literacy
- Limited English proficiency
- Pre-existing medical conditions that may lead to clinical trial ineligibility

Clinicians, researchers, and administrators suggested the following strategies to increase participation:

- Establish community advisory boards
- Support in-house patient advocates and navigators and engage Black outreach coordinators
- Participate in community health fairs
- Broaden communication via social media platforms

- Provide critical social support (for example, transportation and parking subsidies)
- Block out time for patient appointments
- Structure treatment when care begins to facilitate trial eligibility/ inclusion criteria

2.4 Survey development

Next, CBWhite drafted a survey focused on people living with MBC, using several inputs: (1) Marina Kaplan's study, (2) the literature review, (3) the Key Informant interviews, and (4) the insights and objectives of the BECOME subcommittee and MBCA. The survey sought to understand:

- Experience with and interest in clinical trials
- Attitudes about and trust in their oncology care team
- Attitudes about, trust in, and awareness of clinical trials
- Motivations to participate and to not participate in trials
- Barriers to participation in trials
- The types of information and support that would increase the likelihood of trial participation

The final survey (Appendix D) was submitted to and approved by the North Star Review Board, and programmed so that people could answer the survey online. A paper version was also available. People were able to respond to the survey between May 18 and August 1, 2021. The principal investigator is Tisha Felder, PhD, MSW, of the University of South Carolina.

2.5 Survey participant recruitment

Eligible participants were people living with MBC who were 18 years of age and over (19 years and older if residing in Alabama or Nebraska) and who lived in the US or US territories, or who were US military members and their spouses stationed outside the US. People of any gender and any race/ethnicity could participate.

Survey participants were recruited through social media posts and emails—from the MBCA, MBCA members, subcommittee members, and ambassadors—to people connected with cancer communities.

3.
Survey Report: Responses/ Detailed Findings

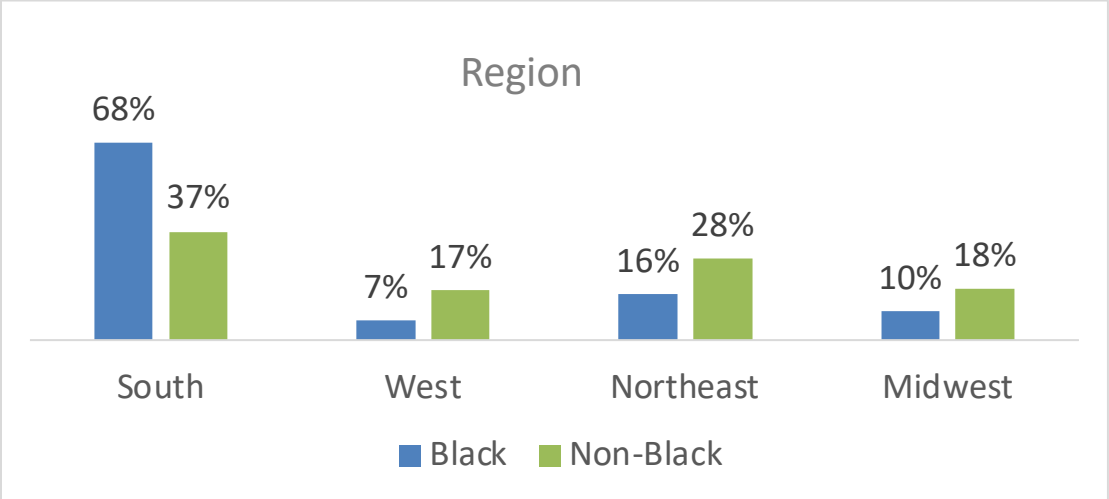
3.1 Characteristics of the people who responded to the survey

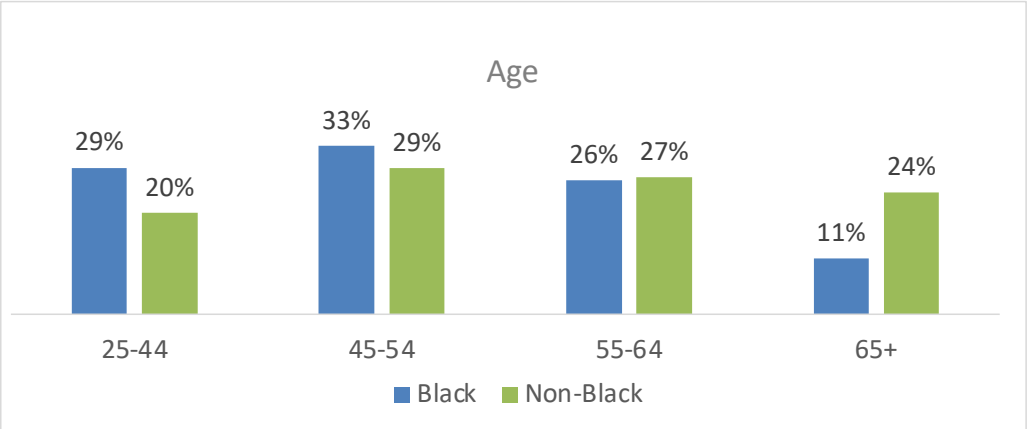
A total of 424 adults living with MBC answered the survey. Almost all self-identified as female (Black, 100%; non-Black 98%).

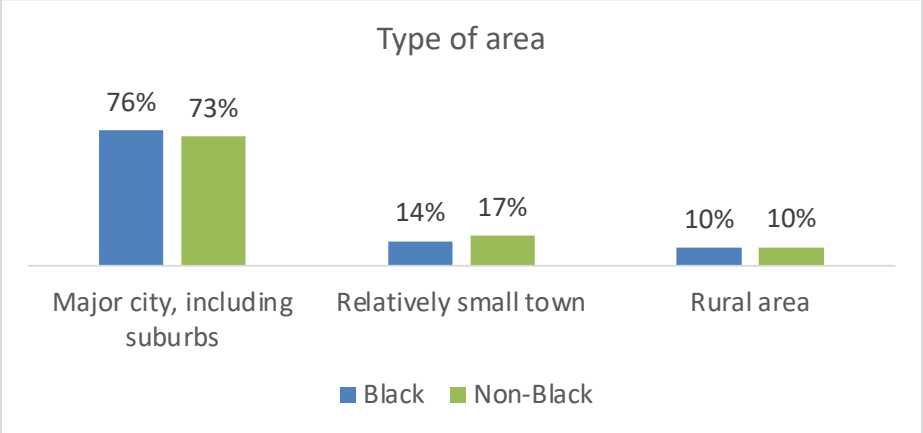
Respondents self-identified their race. Consistent with best practices, respondents were allowed to select more than one racial or ethnic identity. Answer options were Asian or Asian American; Black or African American; Hispanic or Latina, Latino, or Latinx; Native Hawaiian or Other Pacific Islander; White; and self-describe. Respondents could select more than one option. In this report, anyone who selected Black or African American was analyzed in the subgroup of "Black" respondents, even if they also selected another option. People who selected any option(s) other than Black or African American were analyzed in the subgroup of "non-Black" respondents.

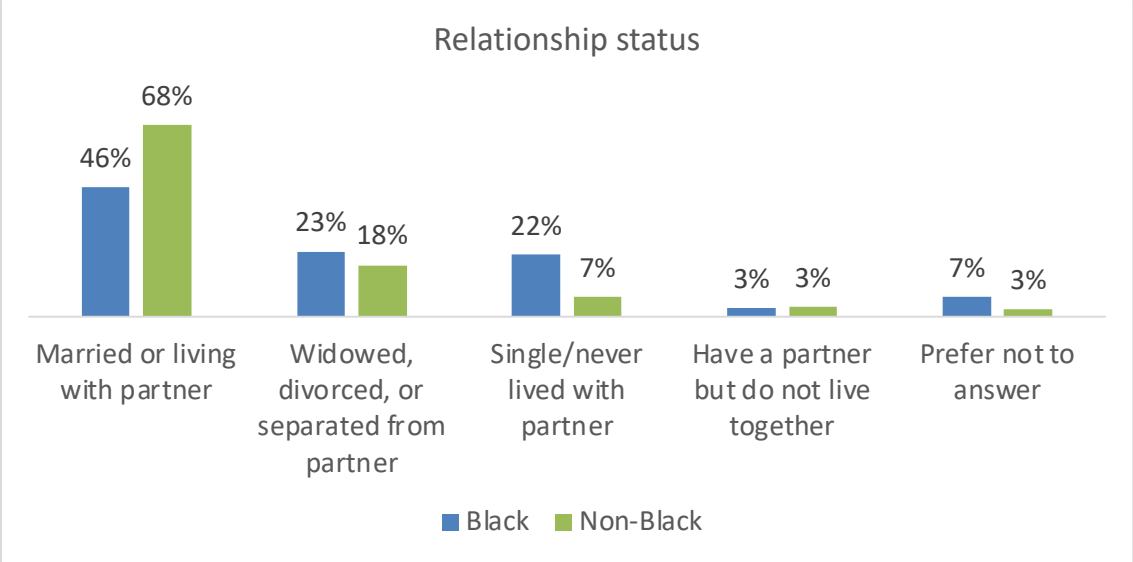
Of the 424 respondents, 102 were Black, and 96 of these selected only Black. Of the 322 non-Black respondents, 294 selected only "White". Two selected white and other non-Black responses. Twenty-six selected responses other than Black or white (11 Latinx, 6 other, 3 American Indian or Alaska Native, 3 Asian or Asian American, 2 Native Hawaiian or Other Pacific Islander, 1 Asian + Latinx). See Appendix E for an explanation of the statistical analysis of characteristics of the people who answered the survey as shown below in Figures 1-3.

Figure 1. Region in the United States, type of area where respondents live, age, and relationship status



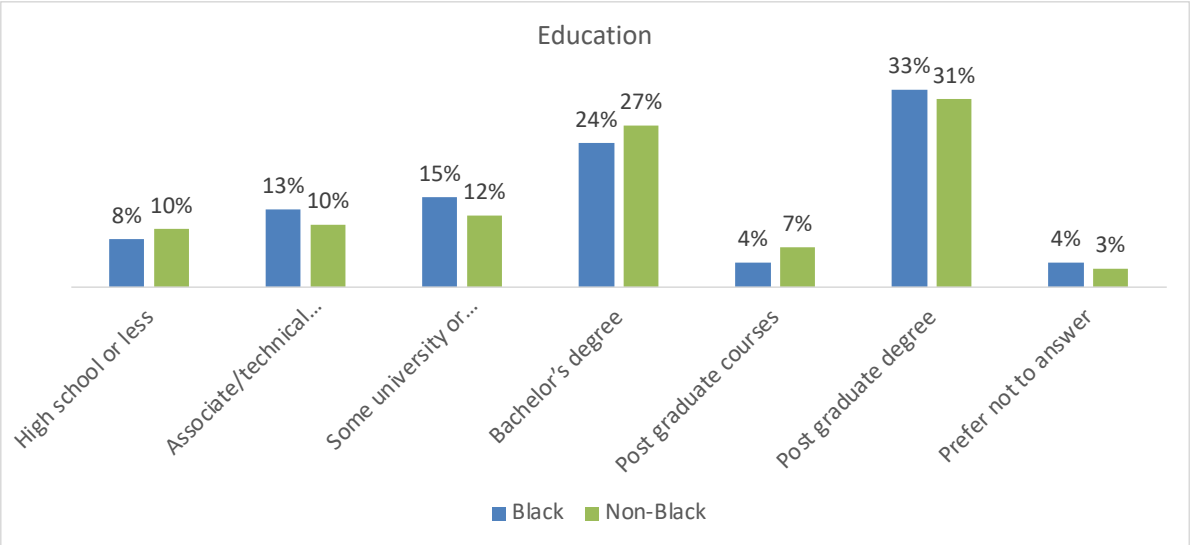


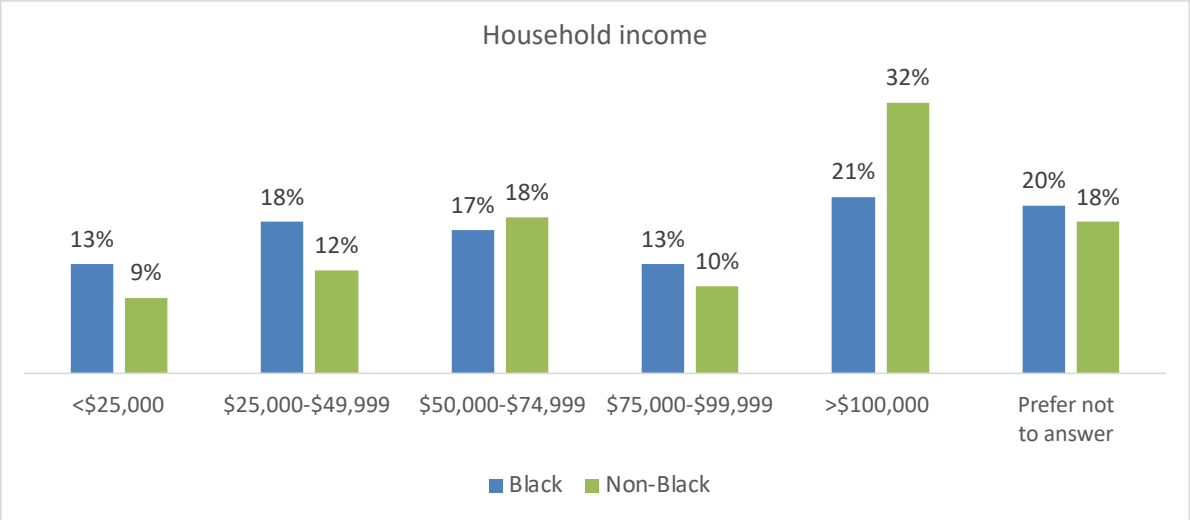


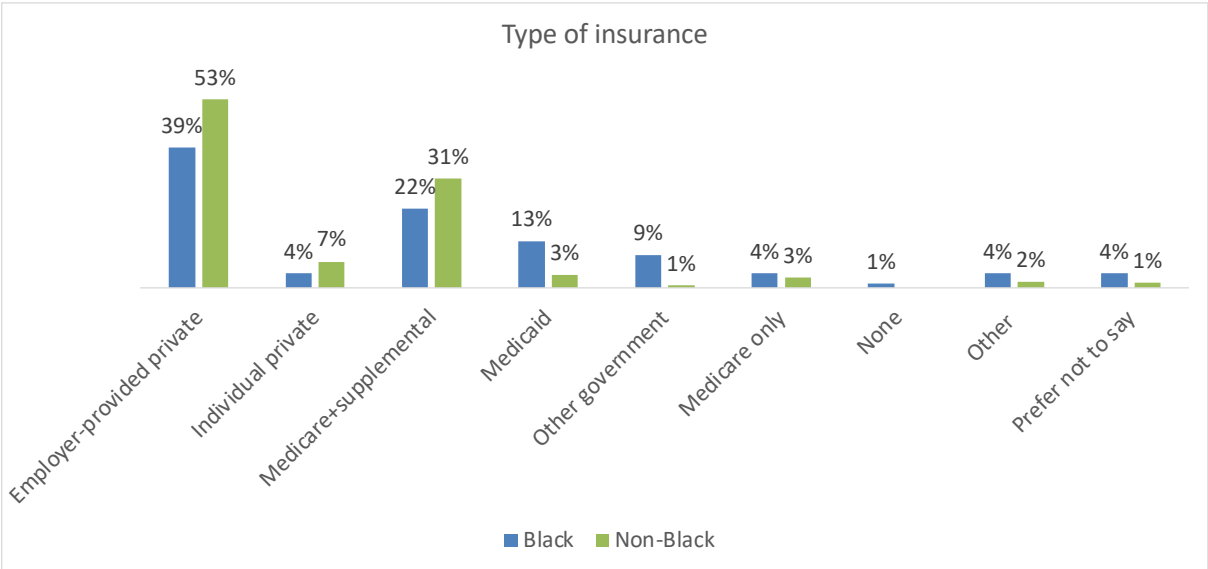


The regional distribution of respondents differed by subgroup, as does the census, and most people lived in a major city or the suburbs. Respondents represented a mix of age groups with Black respondents appearing less likely to be 65 years of age and older compared to non-Black respondents. Black respondents appeared less likely than non-Black respondents to be married or living with a partner.

Figure 2. Education, income, and insurance status of survey respondents

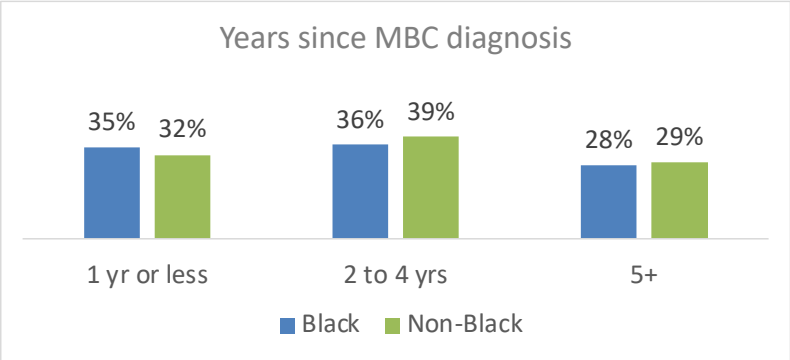


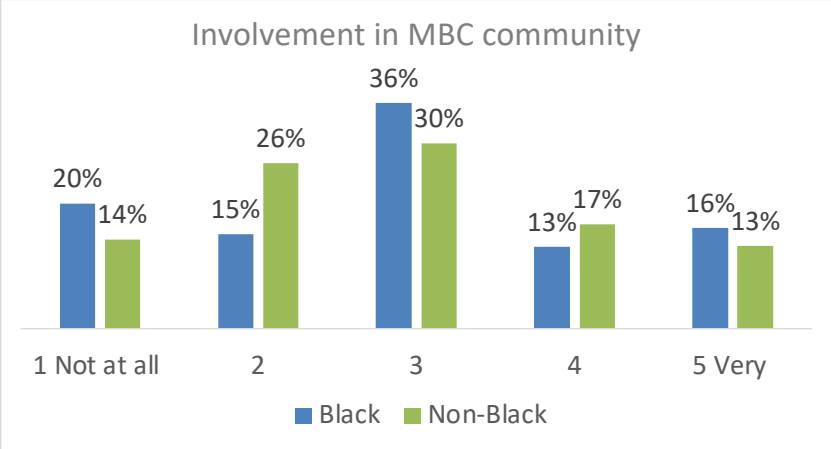


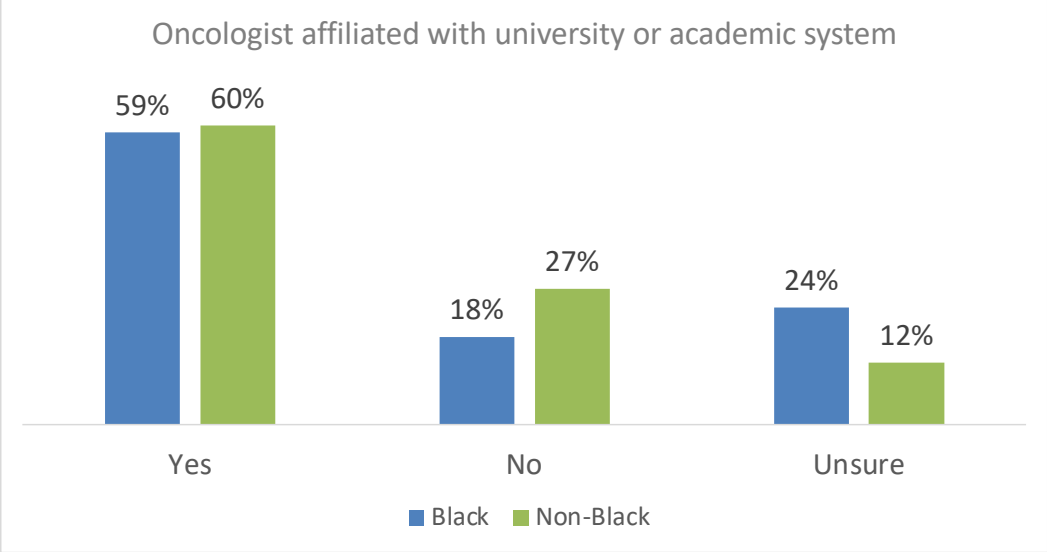


Looking at census data, the sample tended to have high levels of education and high household incomes; Black and non-Black respondent groups were not different from each other. As a whole, the survey respondents tended to be well-insured, with many having private insurance.

Figure 3. Years since MBC diagnosis, MBC treatment facility, and involvement in the MBC community







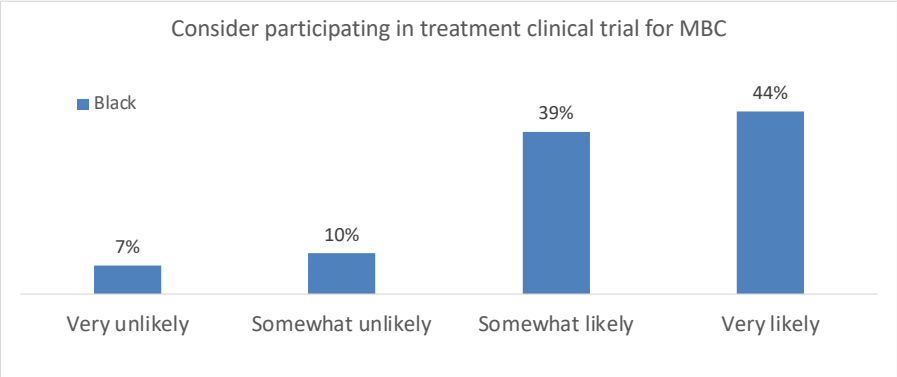
The number of years since MBC diagnosis was mixed, with nearly one-third diagnosed 5 or more years ago. More than half of survey respondents received their MBC care at a medical center that was affiliated with a university or academic medical system. Respondents appeared to be highly involved in the MBC community; this is not surprising given the methods used to recruit participants. Overall, the survey respondents had high levels of resources, including income, insurance, association with an academic medical system, and involvement in the MBC community.

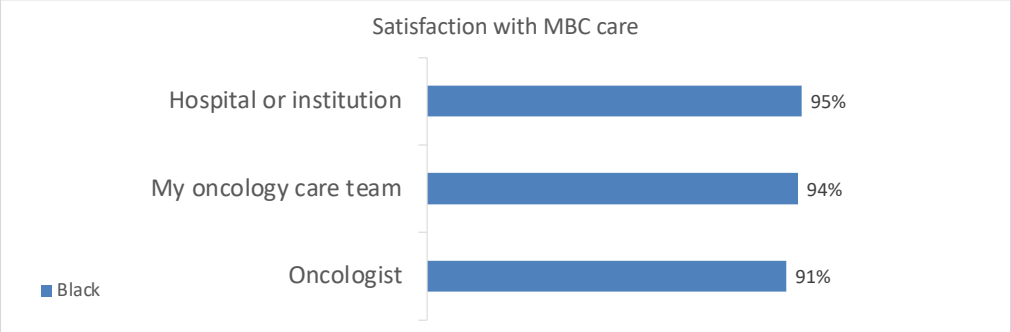
The following sections (3.2-3.7) focus on responses from Black survey participants, shown in blue in the accompanying bar charts. We also identified meaningful differences between answers from Black and non-Black respondents, which are shown in blue and green bars. All comparisons between Black and non-Black respondents can be found in Appendix E. Details about statistical methods used to analyze the comparisons are also found in Appendix E.

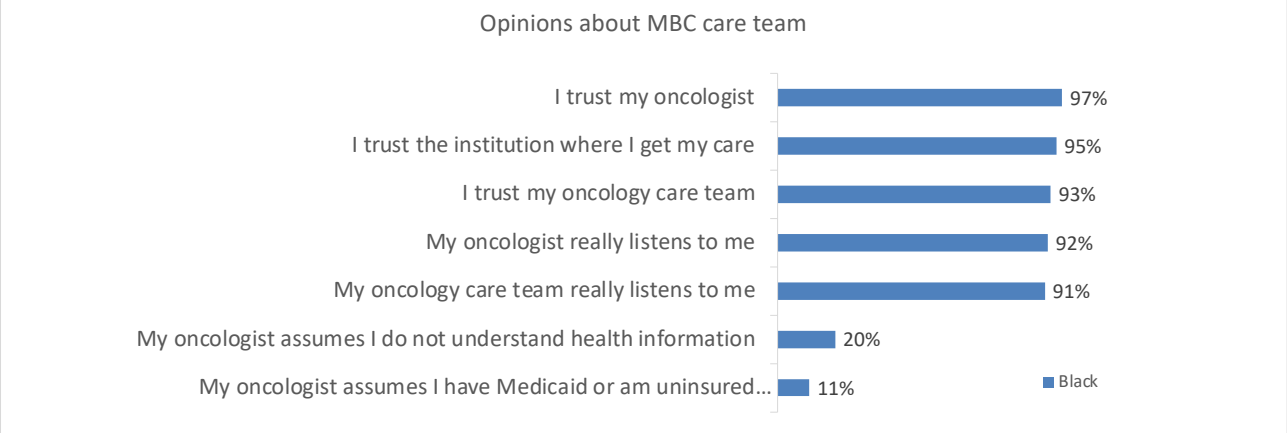
3.2 Satisfaction with MBC care team and interest in participating in MBC clinical trials

The survey explored how likely people are to participate in trials and their opinions of their care team.

Figure 4. Satisfaction with MBC care team and interest in participating in MBC clinical trials. A. Responses to the question: ***How likely would you be to consider participating in a treatment-related MBC clinical trial at some point?*** B. Responses to the question: ***How would you describe your overall satisfaction with your current oncology care team?*** (Answer options: very dissatisfied, somewhat dissatisfied, somewhat satisfied, and very satisfied.) The graph shows the percent who selected "somewhat satisfied" or "very satisfied". C. Responses to the statement: ***Please indicate whether you agree or disagree with each statement.*** (Answer options: strongly disagree, somewhat disagree, somewhat agree, strongly agree.) The graph shows the percent who selected "somewhat agree" or "strongly agree".







Black respondents were somewhat or very likely to consider participating in a clinical trial (83%), showed high levels of trust of and satisfaction with their care team (>90%), and reported that their care team listens to them (91%). Note that respondents knew the survey topic. People who are interested in trials may have been more likely to take the survey.

One out of 10 Black respondents reported that their oncologist assumes they have Medicaid or are uninsured based on their race or ethnicity. One out of five Black respondents reported that their oncologist assumes that they do not understand health information.

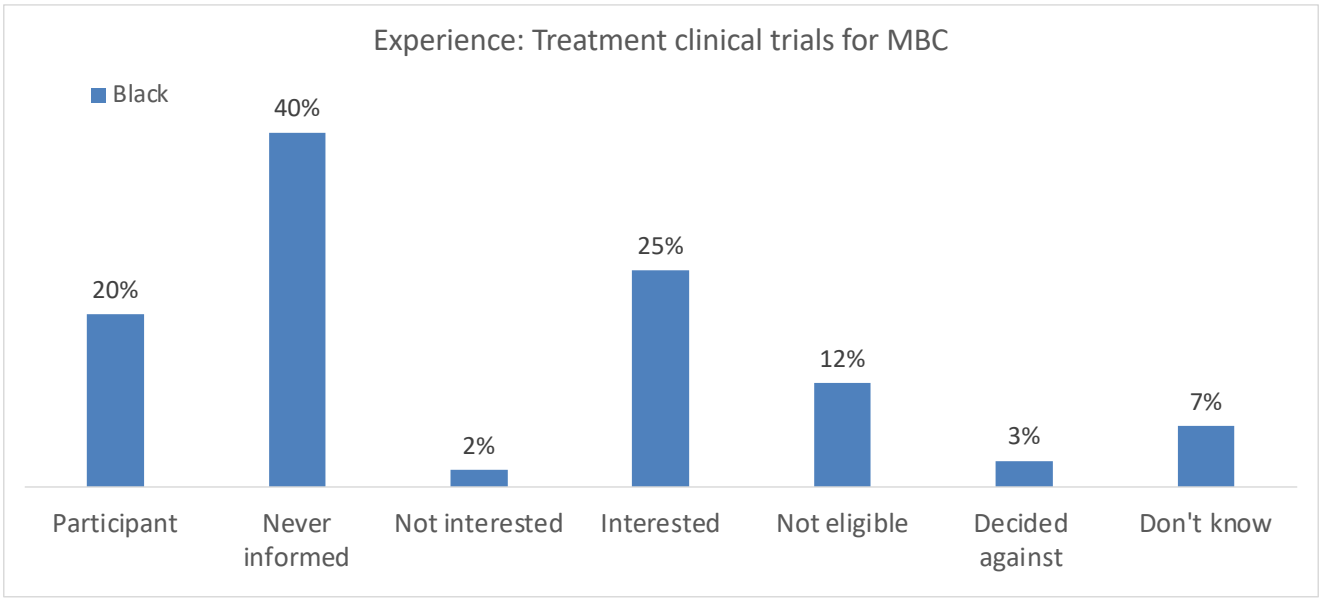
Overall, Black respondents are satisfied with and trust their care team and are likely to participate in an MBC clinical trial.

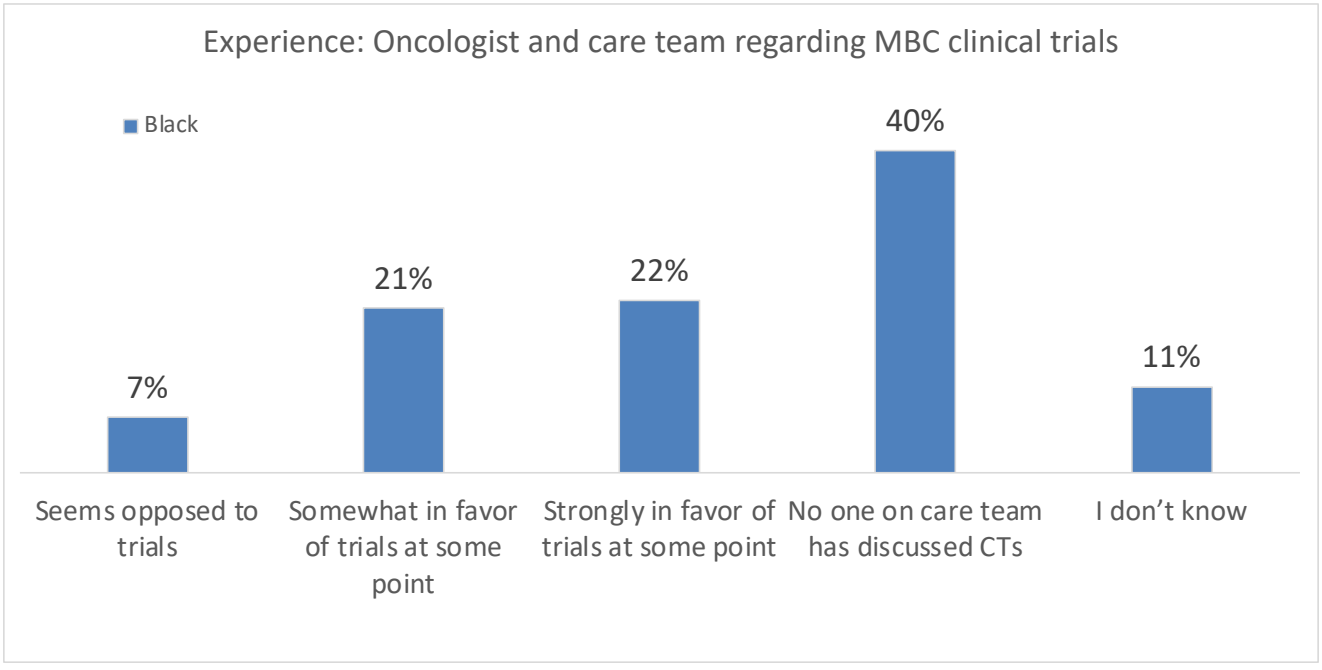
3.3 Experience and interest in clinical trials and oncologists' attitude about trials

Next, the survey explored people's actual experience with clinical trials and their oncologists' attitudes about trials.

> *"Educate the doctors and pair them with a patient advocate team to work along with all patients who are diagnosed. Give us the info and let us decide our options."*
>
> *-Black respondent living with MBC*

Figure 5. Experience and interest in clinical trials. A. Responses to the question: *Which best describes your experience related to clinical trials for **treatment** of MBC?* (Multiple answers were allowed.) B. Responses to the question: *Which best describes your experience with your current oncologist and your oncology care team, overall, regarding MBC clinical trials?* (Only one answer was allowed.)



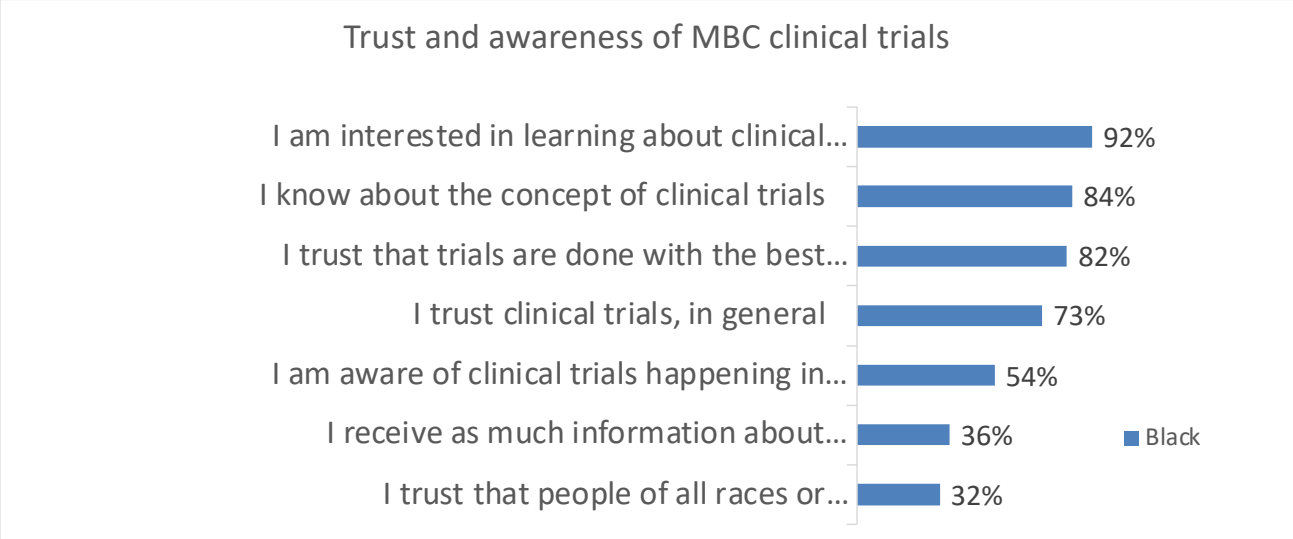


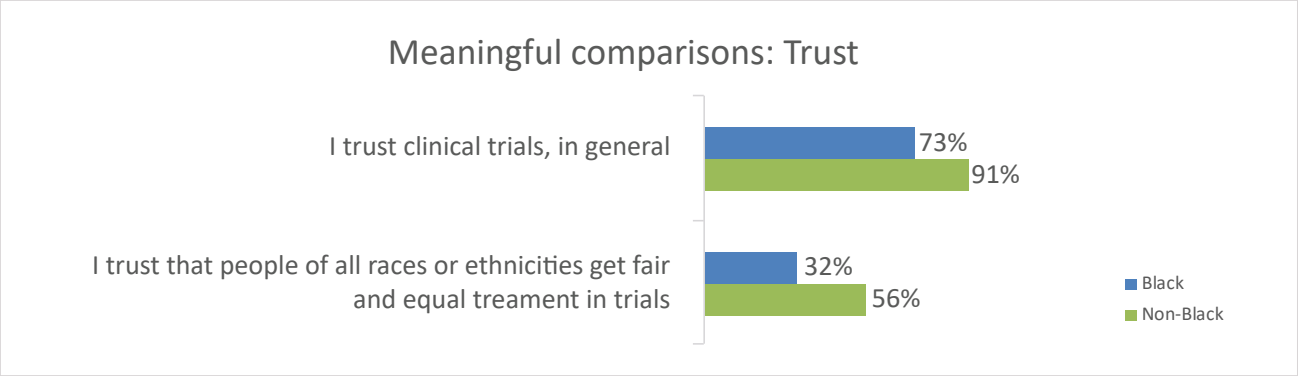
Twenty percent of Black respondents had participated in a clinical trial. This is higher than the 4-6% participation rate cited in published reports [3-9] and suggests that the survey was answered by people with relatively few barriers. In addition, 25% of Black respondents were interested in trials, but 40% had not been told about them. This is notable particularly in light of the data that 40% of Black respondents said no one on their care team has discussed clinical trials with them. This observation is also striking given that the survey respondents had high levels of resources, tended to receive their care from doctors associated with an academic medical system, and had high involvement in the MBC community (Figures 2 and 3).

3.4 Trust and awareness of clinical trials

Overall, Black people living with MBC tend to trust their care team and are interested in participating in MBC clinical trials (Figure 4) but have not been told about them (Figure 5). The survey next explored trust and awareness about clinical trials in more detail.

Figure 6. Trust and awareness about clinical trials. Responses to the statement: ***Please indicate whether you agree or disagree with each statement.*** (Answer options: strongly disagree, somewhat disagree, somewhat agree, strongly agree.) The graphs show the percent who selected "somewhat agree" or "strongly agree". A. Black respondents. B. Meaningful differences compared to non-Black respondents.





Black respondents most frequently reported that they are interested in learning about clinical trials (92%), know about the concept (84%), and trust that trials are done with the best interest of patients in mind (82%). However, only about one-third (36%) receive much information as they would like.

Black survey respondents were less likely than non-Black respondents to indicate that they trust clinical trials (Black: 73%; non-Black 91%) and trust that people of all races or ethnicities get fair and equal treatments in trials (Black: 32%; non-Black 56%). Thus, a gap in trust between Black and non-Black respondents was observed.

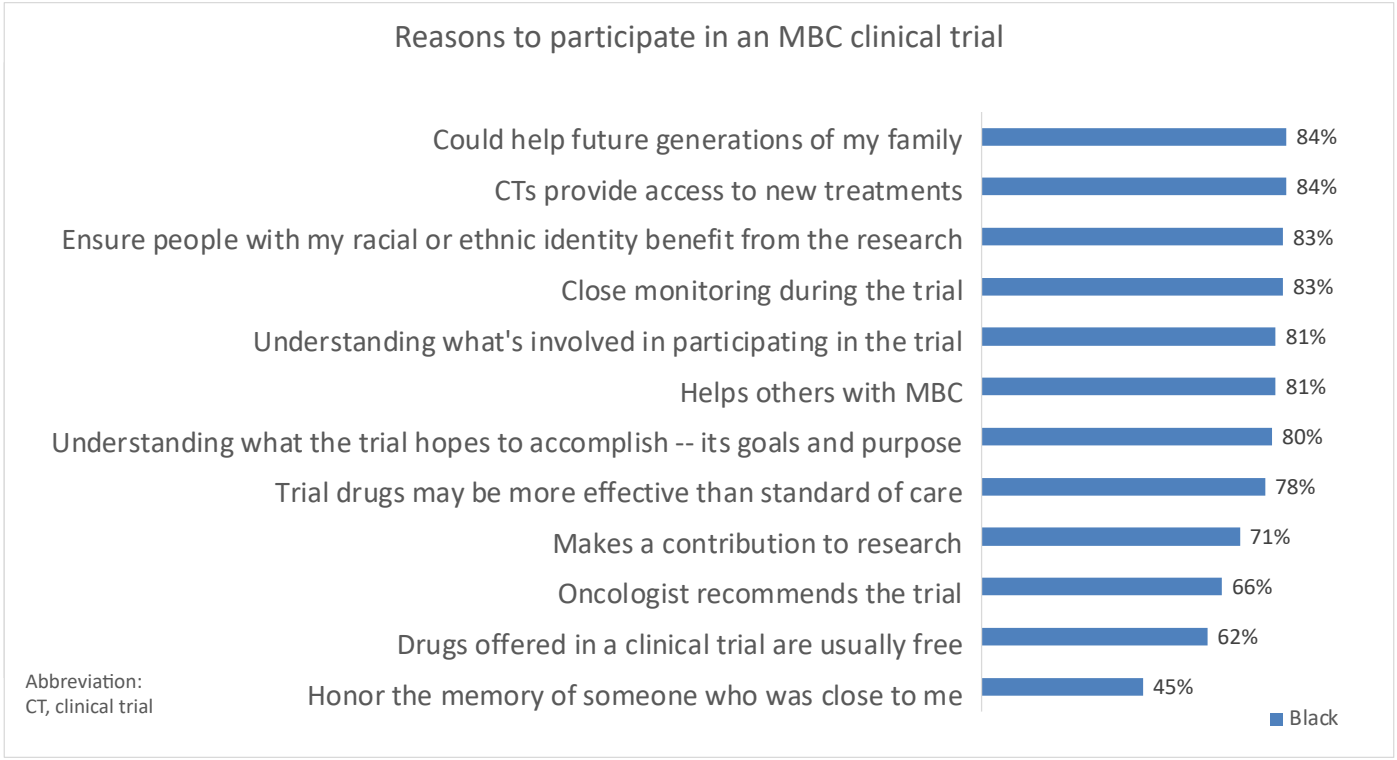
> *"I wish they were offered to me. At least to see if I qualify. I do think my race is a factor as well as lack of knowledge from my doctor."*
>
> *-Black respondent living with MBC*

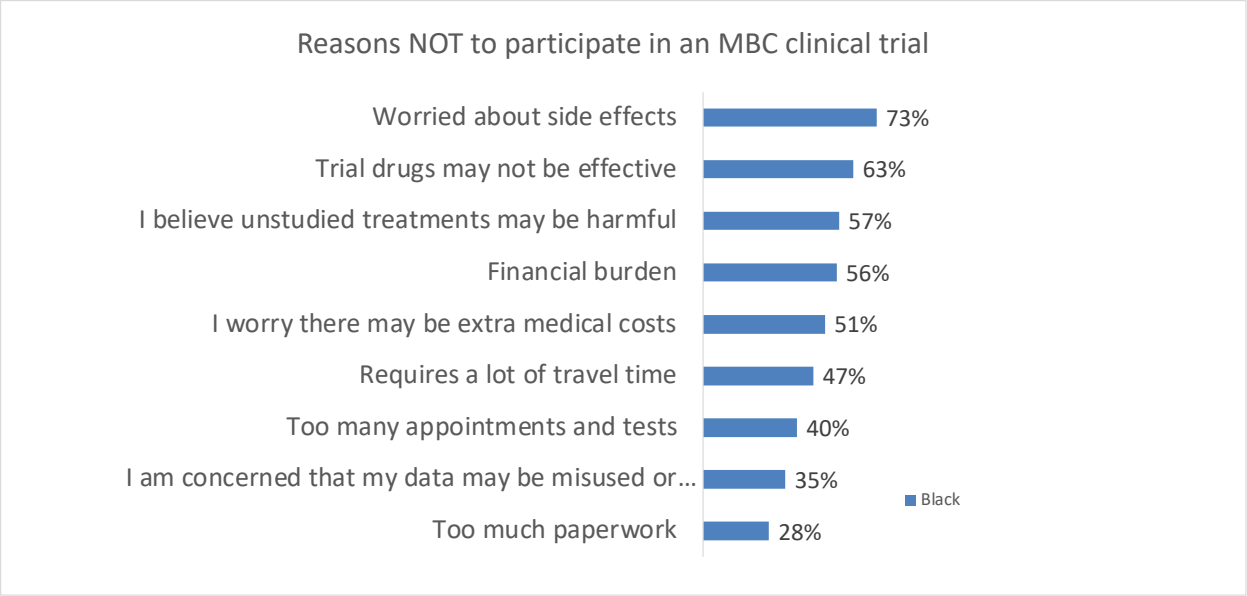
> *"To increase diversity more outreach and information is needed. Go where they are. Present information by someone who looks like and understands your targeted group."*
>
> *-Black respondent living with MBC*

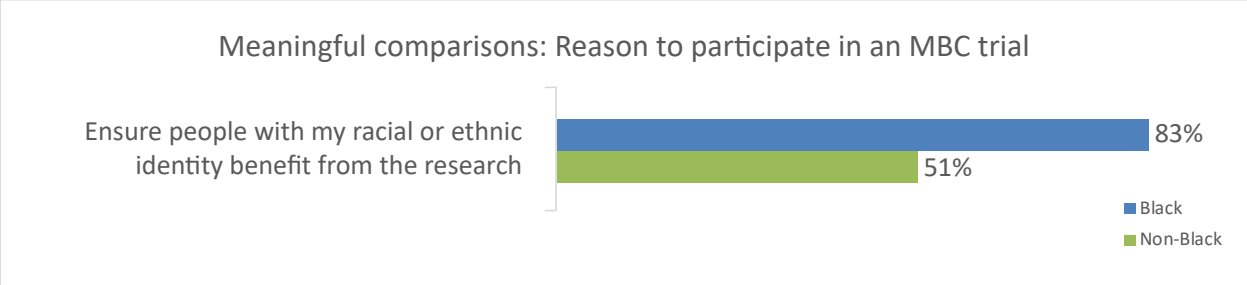
3.5 Motivations to participate and to not participate in MBC clinical trials

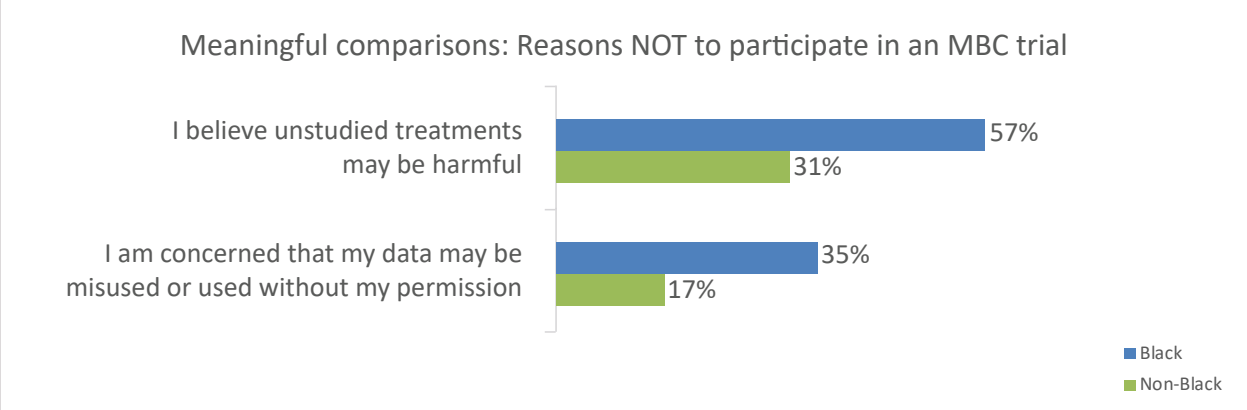
The survey next explored the variety of reasons why people would and would not consider participating in an MBC clinical trial.

Figure 7. Motivations to participate and to not participate in MBC clinical trials. Responses to the question: A. ***If you were presented with a clinical trial as a treatment option, how motivating would each of these possibilities be to you?*** B. ***If you were presented with a clinical trial as a treatment option, how would each of the following impact your decision NOT to participate?*** For each question, respondents rated the reason from 1 to 5, with 1 meaning "**not at all motivating**" to 5 meaning "**very motivating**" (for reasons to participate) or 1 meaning "**not at all impactful**" to 5 meaning "**very impactful**" (for reasons **NOT** to participate). Respondents could also select "no opinion". C, D. Meaningful differences between Black and non-Black respondents about reasons to participate and NOT participate in an MBC clinical trial. Each graph shows the percent of survey respondents who selected 4 or 5.









"I find it even more important to consider clinical trials in light of the disparities within the Black and brown communities."

-Black respondent living with MBC

Black respondents most frequently cited the following reasons to participate: participating in a trial could help future generations of my family (84%), clinical trials provide access to new treatment (84%), desire to ensure that people with my racial or ethnic identity benefit from the research (83%), and I receive close monitoring during the trial (83%). Black respondents most frequently cited the following reasons NOT to participate: worries about side effects (73%), concerns that trial drugs may not be effective (63%), and belief that unstudied treatments may be harmful (57%), which reflects historical harm. Additional worries included cost (56%) and time (47%).

Black respondents were more likely than non-Black respondents to report that clinical trials ensure that people with the same racial or ethnic identity benefit from the research (Black: 83%; non-Black: 51%).

Regarding reasons not to participate in an MBC clinical trial, Black respondents were more likely to believe that unstudied treatments may be harmful (Black: 57%; non-Black: 31%) and were more likely to be concerned that their data would be misused or used without their permission (Black: 35%; non-Black: 17%).

> *"There is a great distrust in the African American community as far as new treatments and clinical trials. […] The distrust from incidents like the Tuskegee Experiment is still an issue that resonates within our community. Trust has to be rebuilt. Seeing people of color participating in clinical trials will help bridge this gap to get much needed data."*
>
> *-Black respondent living with MBC*

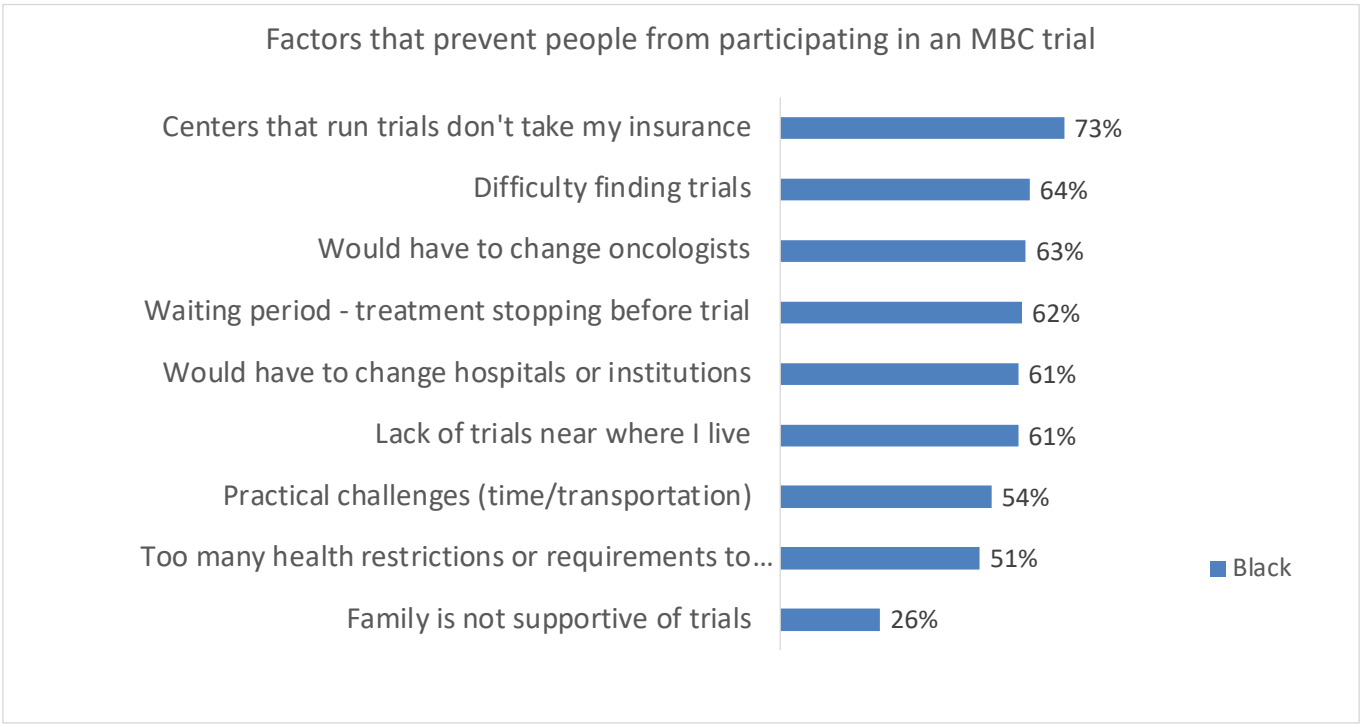
3.6 Factors that prevent people from participating in MBC clinical trials

Certain factors can make participating in an MBC clinical trial difficult or impossible. The survey next explored factors, called barriers, that prevent people from participating in an MBC clinical trial.

Figure 8. Factors that make participating in an MBC clinical trial difficult or impossible. Responses from Black survey respondents to the question: ***How significant of a barrier do you feel each of these are to you when it comes to considering clinical trials?*** Respondents rated the reason from 1 to 5, with 1 meaning "not at all significant" to 5 meaning "very significant". Respondents could also select "no opinion". The graph shows the percent of survey respondents who selected 4 or 5.

The most commonly cited barriers by Black participants were: centers that run trials do not take my insurance (73%), difficulty finding trials (64%), and the need to change oncologists (63%).

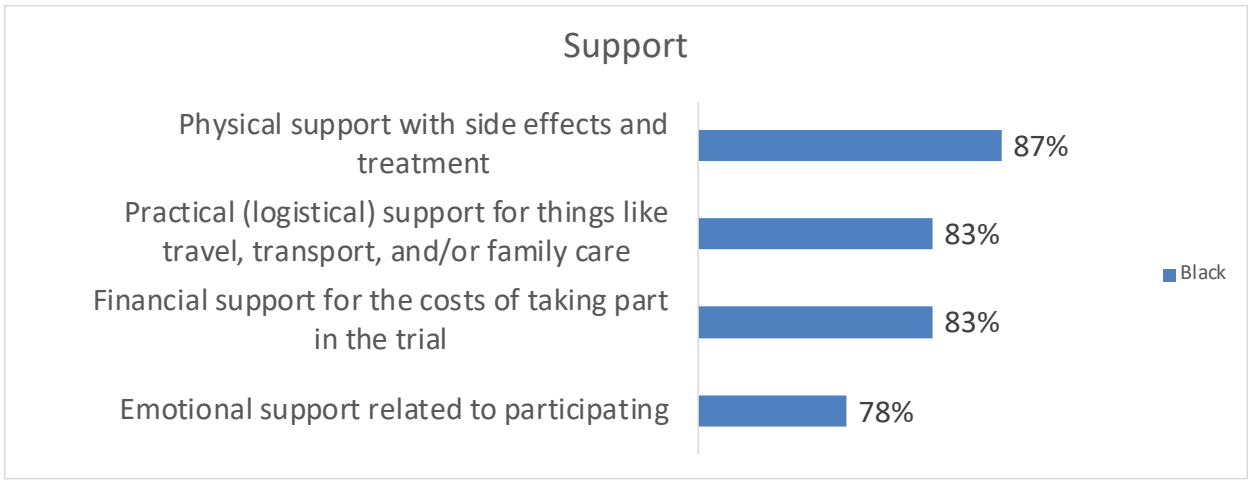
> *"I do feel like the African American community are the last ones to know about these trials or may never know due to the color of our skin. I only found about clinical trials through a nonprofit organization. Even though I found out through them I didn't understand how to go about getting one and proceed forward."*
>
> *-Black respondent living with MBC*

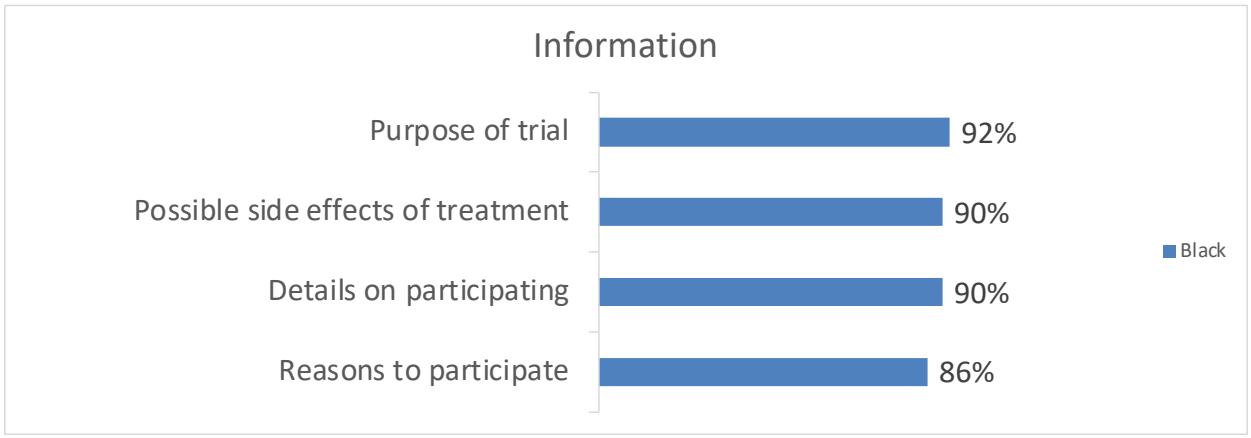


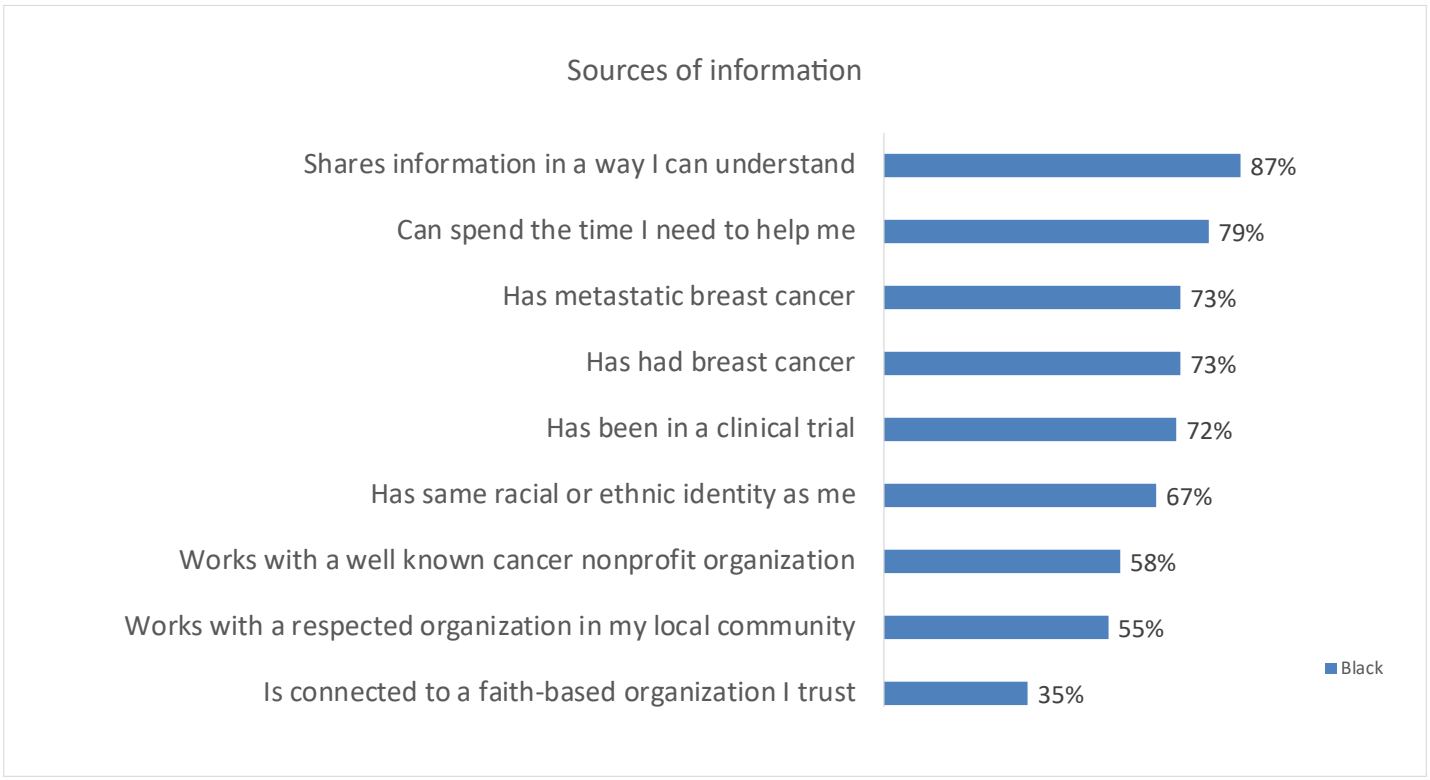
3.7 Information about and support for participation in MBC clinical trials

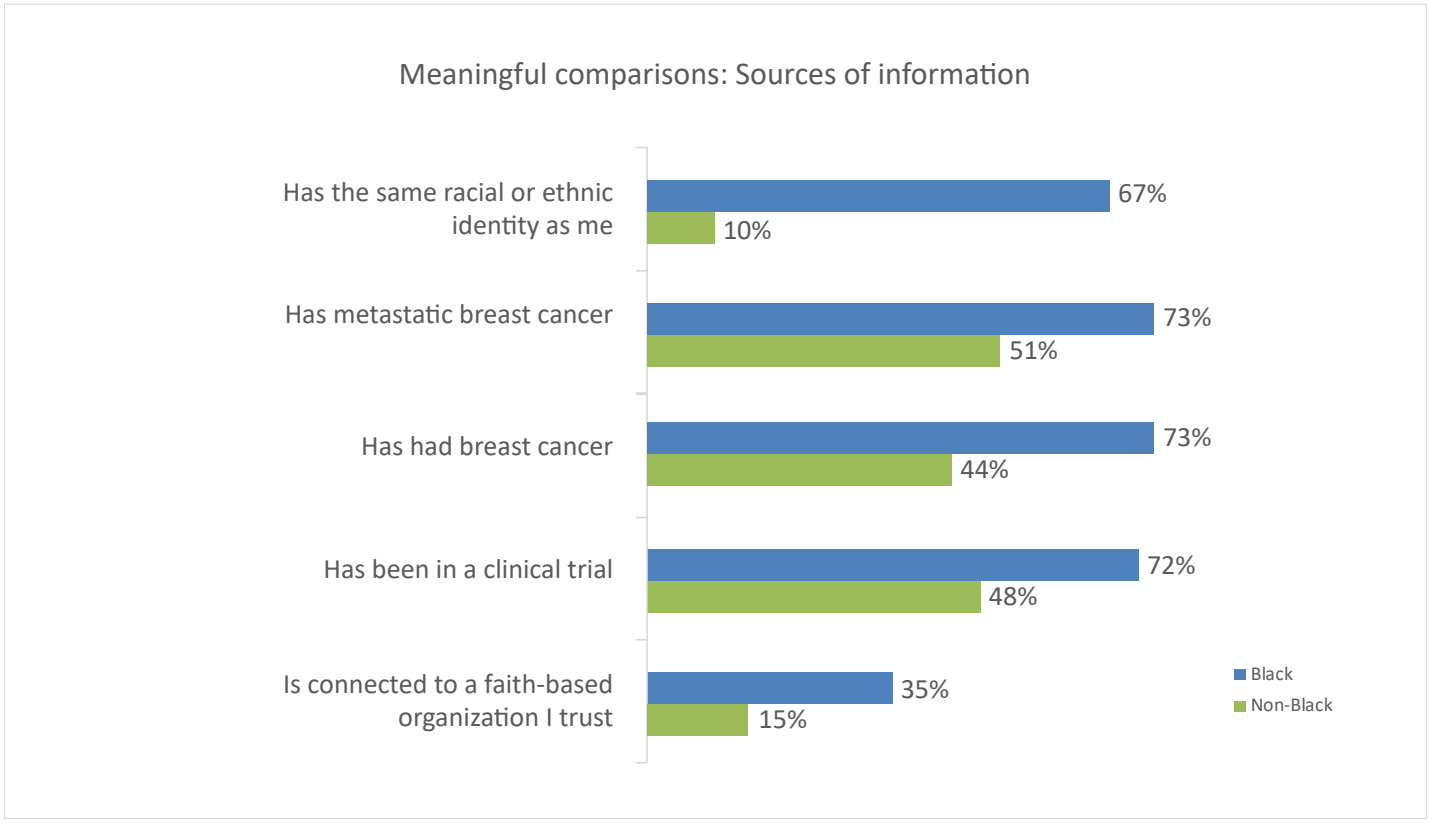
Providing someone with support and reliable and relatable information can make participating in a clinical trial easier. The survey next explored what types of support and information are important to patients.

Figure 9. Responses to the questions: A. *If you were to consider a treatment-related clinical trial for MBC, how important would each type of support be?* B. *If you were to consider participating in an MBC clinical trial, how important would each type of information be?* C. *Some people learn about clinical trials from their doctors. Many hear from others — people such as patient advocates (also known as peer support), patient or nurse navigators (people who work in the hospital system), an oncology nurse, or a community health worker. How important would it be to learn about a clinical trial from someone who…?* Respondents rated each statement from 1 to 5, with 1 meaning "not at all important" to 5 meaning "very important". Respondents could also select "no opinion". D. Meaningful comparisons between Black and non-Black respondents. Each graph shows the percent of survey respondents who selected 4 or 5.






Sources of information
Shares information in a way I can understand
87%
Can spend the time I need to help me
79%
Has metastatic breast cancer
73%
Has had breast cancer
73%
Has been in a clinical trial
72%
Has same racial or ethnic identity as me
67%
Works with a well known cancer nonprofit organization
58%
Works with a respected organization in my local community
55%
Is connected to a faith-based organization I trust
35%
Black


Meaningful comparisons: Sources of information
Has the same racial or ethnic identity as me
67%
10%
Has metastatic breast cancer
73%
51%
Has had breast cancer
73%
44%
Has been in a clinical trial
72%
48%
Is connected to a faith-based organization I trust
35%
15%
Black
Non-Black

"I feel trials are offered more to white people, making me feel as if I don't matter to others. I've never even been given ANY info about [trials] and didn't really know they were even an option."

-Black respondent living with MBC

Black respondents reported that the most important types of support were physical (87%), practical (83%), and financial (83%). The purpose of the trial (92%), possible side effects (90%), and details of participation (90%) were the types of information that were most important to Black respondents. Black respondents would like to hear about clinical trials from someone who shares information in a way that is understandable (87%), who can spend the time needed to be helpful (79%), who has MBC or has had breast cancer (73%), has been in a clinical trial (72%), and has the same racial or ethnic identity (67%). Thus, being able to relate to the person providing the information was very important, both from a health experience standpoint and a racial and ethnic identity standpoint.

"Having an advocate to speak to with with a similar diagnosis that has been through clinical trials would be great."

-Black respondent living with MBC

Regarding the source of the information, Black respondents were more likely than non-Black respondents to report that receiving information from someone who has MBC (Black: 73%; non-Black: 51%), has had breast cancer (Black: 73%; non-Black: 44%), has been in a clinical trial (Black: 72%; non-Black: 48%), has the same racial or ethnic identity (Black: 67%; non-Black: 10%), and who is connected to a trusted faith-based organization (Black: 35%; non-Black: 15%) were very important.

3.8 Additional survey questions and answers

See Appendix F for additional questions and answers from the survey that are not included in this report.

3.9 Actions and next steps

The participation of Black patients in clinical trials is low, despite the BECOME survey's finding that 8 out of 10 Black women and men living with MBC would consider participating. The survey revealed numerous barriers and concerns that prevent participation by Black patients, as well as motivations to participate. The BECOME project seeks to understand the most compelling factors and identify actions that stakeholders can take to propel change.

These actions include:

#1. Better inform.
Black patients want to know about and would consider participating in clinical trials, but they lack information.

#2. Inspire trust.
Black patients are more likely than non-Black patients to want to learn about clinical trials from someone with the same racial or ethnic identity and shared health experience.

#3. Ensure access.
Numerous barriers to Black patient participation in clinical trials – including logistics, finding trials, and expense – persist even in this group of survey respondents with a high level of resources, access (i.e., care at academic medical institutions), education, and insurance.

#4. Address concerns and reinforce motivations.
The survey findings underscore the need to understand and acknowledge the issues that worry Black patients as well as the reasons that drive their desire to participate in clinical trials. In addition, they highlight the critical importance of communicating clearly, concisely, and truthfully so that Black patients understand the why, what, and how of clinical trial participation.

All stakeholders – including oncology care teams, insurers, hospital systems, researchers and contract research organizations, pharmaceutical and biotech companies, government agencies, cancer and community organizations, and patients/advocates – have a responsibility and a role to play in increasing Black participation in MBC clinical trials.

Next steps include:

- ***Expand survey respondent base.*** In future studies of clinical trial participation, investigators hope to reach a broader group to more fully represent the Black patient experience.
- ***Share results and develop strategies.*** Members of the BECOME initiative will meet with other groups who have recently performed surveys focused on Black women and men with breast cancer to share results and identify strategies to improve care.
- ***Increase Black patient enrollment in clinical trials.*** Activities could include training health care providers to deliver patient-friendly information in an unbiased manner, improved patient education, and helping patients find and access clinical trials.

4. Acknowledgements

The Metastatic Breast Cancer Alliance (MBCA) is grateful to the many MBCA member organizations and individuals who participated in the BECOME project and to the people who participated in the interviews and survey.

The project would not have happened without Stephanie Walker, who brought the issue to MBCA and led the subcommittee with passion and dedication. She was joined on the BECOME subcommittee by Thelma Brown, Beth Burnett, Martha Carlson, Sheila Fuhs, Carla Harvey, Janine Guglielmino (LBBC), Reginald Hogans, Caroline Johnson (Twisted Pink), Felicia Johnson, Katrina Johnson (Pfizer), Jeannette Meibach (Gilead), Joanna Morales (Triage Cancer), Sheila Pettiford, Claire Saxton (CSC), and MBCA staff members Laurie Campbell and Dana Mooney. Our committee would also like to acknowledge MBCA committee member Nunny Reece (2/10/78 – 2/1/21), who died of MBC during our work together. Her memory and the memory of all those we have lost to MBC motivate our continued advocacy.

The consulting firm of CBWhite assembled a team of qualitative and quantitative researchers who worked with the subcommittee throughout the process, conducted the interviews, wrote the survey, analyzed and synthesized data (creating much of the material included in this report), facilitated the formation of recommendations, and delivered a webinar for MBCA members.

Tisha Felder, PhD, MSW, served as Principal Investigator and provided insights and guidance throughout the effort. Monique Gary, DO, FACS, FSSO, served as a Sponsor for the ASCO submission and provided thoughtful input.

Kristine De La Torre, PhD, conducted the literature review and prepared this report.

Deborah Render provided copy editing.

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A special "Thank You" to Lilly Oncology for their additional financial support of this project.

5.
Appendices

Session PS1 - PS1. Poster Session 1

P1-16-03. Hear our voice: Patient-driven solutions to increase participation in clinical trials

December 11, 2019, 5:00 PM - 7:00 PM | Hall 1

Authors
Marina Kaplan. LBBC, Atlantic Beach, FL

Disclosures
M. Kaplan: None.

Abstract
Background: The rate of participation in clinical trials is dismally low, slowing the process of drug development and increasing cost. Patients living with metastatic breast cancer (MBC) are often willing to participate in clinical trials, but are frequently faced with insurmountable barriers. There is a dire need for studies identifying actionable patient-driven solutions to help ensure that opportunities to participate in clinical trials becomes more equitable, attractive and feasible for a larger, more diverse pool of potential participants. **Methods:** A mixed-methods design including in-depth interviews and online surveys was used to identify barriers and solutions to participation in clinical trials. Sixty-one participants were invited to be interviewed using purposeful stratified sampling (patient race, age and geographic location; community and academic center oncologists and administrators; researchers and research staff; payers). Interview questions were designed to collect feasible solutions to barriers. Convenience sampling was used to recruit MBC patient survey participants. Online surveys were fielded via nine MBC social media groups reaching approximately 1,500 patients living with MBC. Survey questions included demographics, trial experience, perception of benefits/disadvantages and barriers to trial participation, and ideas for solutions to the barriers. In addition, a short social media poll on trial participation was used. **Results:** A total of 496 women living with MBC completed the online survey. The mean age of survey respondents was 53 years old and mean number of years with MBC was 4.6 years. Respondents generally reported positive attitudes toward trial participation: The opportunity to get innovative treatments, helping others with MBC and contributing to research were rated as extremely important. Potential disadvantages included fear of side effects, possibility that trial drugs may not be effective and financial toxicity. Significant barriers included strict eligibility criteria, broad exclusion criteria and lack of trials nearby. All patients responding to a social media poll indicated they would consider participating in a clinical trial. Fifty-two participants were interviewed. The most frequent themes from patients were suggestions to address rigid eligibility and exclusion criteria by consistently including patients in research design, protocol development and policy decisions. Patients felt that trials should reflect the “real world”, and that opening up eligibility criteria would increase diversity and the number of potential participants. A dominant theme from rural and community-based oncologists was the need to address geographic, logistical and financial barriers using more “portable” multi-institution trials, providing transportation and adequate reimbursement for patients’ expenses. Clinicians in academic described exclusion criteria as a significant barrier for heavily pretreated MBC patients. Health care administrators discussed solutions to high costs associated with trials. Payers shared innovative solutions to out-of-network payment barriers. **Conclusions:** Most patients with MBC are willing to participate in clinical trials, and many are highly motivated to do so. MBC patients generally recognize the benefits that trials can offer and are willing and able to help address the barriers to trial participation by working collaboratively across the board. Multiple sectors of health-care are ready and willing to work together. It is in all our best interests to hasten the development of new treatments, and the time is right to implement a collaborative, systematic solutions-based approach that will make it feasible for more MBC patients to participate in clinical trials. This patient led study shows how this can be done..

Hear our voice: Patient driven solutions to increase participation in clinical trials

Marina Kaplan
Living Beyond Breast Cancer

BACKGROUND

- The rate of participation in clinical trials is dismally low, slowing the process of drug development and increasing cost.
- A critical gap exists in identifying actionable *solutions* to system level barriers.
- Patient-driven solutions ensure that opportunities to participate in clinical trials become more equitable, attractive and feasible for a larger, more representative pool of potential participants.

METHODS

A mixed-methods sequential explanatory design was used:

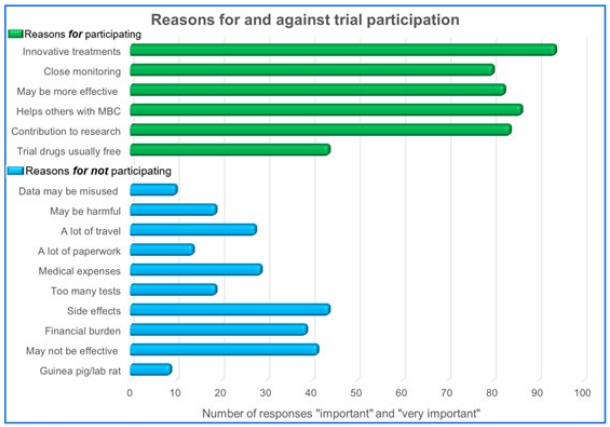
- **Interviews:** Purposeful stratified sampling to include patients, hospital administrators and payers.
  - 52 interviews conducted (28 MBC patients, 8 clinicians, 6 health care administrators, 6 researchers/research staff and 4 payers).
  - Data informed survey development and provided contextual qualitative data.
- **Surveys:** Online survey (based on Kessel *et al*, 2018)* was fielded on MBC social media groups reaching approximately 1,500 women and men. Survey measured:
  - Demographics (race, gender, age, years MBC)
  - Trial participation
  - Relative importance of reasons for/against participating in clinical trials
  - System level barriers
  - Solutions
  - 496 survey respondents (88.71% white, 8.87% Black , 2.42% Asian).
  - Mean age: 53 years old (34 – 74).
  - Mean years with MBC: 4.6 years (ranging from < 1 year --19 years).

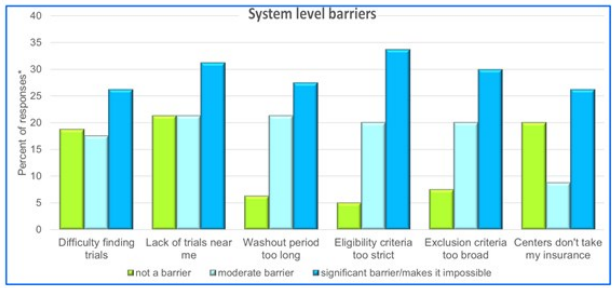
*Kessel KA, Vogel MME, Kessel C, et al. Cancer clinical trials - Survey evaluating patient participation and acceptance in a university-based Comprehensive Cancer Center (CCC). *Clin Transl Radiat Oncol*. 2018;13:44–49. Published 2018 Oct 4. doi:10.1016/j.ctro.2018.10.001

ACKNOWLEDGMENTS

Living Beyond Breast Cancer (LBBC) Hear My Voice Metastatic Breast Cancer Outreach Program. This program trains people living with metastatic disease to become advocates in their communities. For more information: lbbc.org/HearMyVoice.

SURVEY RESULTS





SOLUTIONS

Exclusion and eligibility *…"cherry picking" participants…trials should represent us…*
- ✓ Include patient advocates in research design, protocol development and review

Finding Trials*…Clinical Trials shouldn't be a last resort...*
- ✓ Trials matching services through providers (staffed by support staff/navigator). Every restaging visit includes review of available trials.

Access to information *…necessary information for weighing risk-benefit…*
- ✓ Preliminary findings (null, toxicities, side-effects and adverse events).

Washout period *…Don't tell us it's for patient safety: In the real world we go from treatment to treatment without a break…*
- ✓ Base on half-life of previous drug.
- ✓ Measure in blood chemistries and statistically control.

Isolation *…felt alone and disconnected..*
- ✓ Enable patients to connect with others if they wish.
- ✓ Direct line of communication for PRO.

Financial toxicity *…additional expenses…*
- ✓ Consistent reimbursement for direct costs (co-pays/deductibles, travel, lodging).
- ✓ Cost of procedures/tests not covered by insurance should be met by study sponsor or negotiated with insurance without burdening the patient.

Logistical barriers *...too much travel… too many tests and visits…*
- ✓ Limit scans and labs to minimum necessary.
- ✓ "Portable" multi-institution trials reaching a diverse/representative population.

Disparities*…data doesn't represent men or African Americans..*
- ✓ Identify and build on current community based patient led initiatives
- ✓ Federal fee schedule for clinical trials services ensuring every provider is a "participating provider" avoiding insurance discrimination

CONCLUSIONS

Patients with MBC are highly motivated to participate in clinical trials, recognizing the benefits that trials present: But are faced with significant barriers and exclusions that shut them out. There is a critical need to address these barriers using solutions-based approaches that include the patient voice.

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 were 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 received 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
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
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. 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
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.ciscrp.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://jnccn.org/view/journals/jnccn/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 Niranjan et al. *Cancer*, no link/full citation provided]

[16] Disparities in Clinical Trial Access Across US Urban Areas. 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
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? 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. 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. 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. 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 received 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. 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-af-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]

CBwhite
Market Research & Strategy

B.E.C.O.M.E. PROJECT

(Black Experience of Clinical Trials & Opportunities for Meaningful Engagement)

KEY INFORMANT INTERVIEW SUMMARY

Provided by: Kuliva N. Wilburn, MPH

March 4, 2021

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KEY INFORMANT INTERVIEW ANALYSIS

Executive Summary

In Phase Two of the B.E.C.O.M.E. project (Black Experience of Clinical Trials & Opportunities for Meaningful Engagement) CBWhite conducted qualitative research in the form of virtual interviews to identify relevant issues, concerns, motivations, barriers, and experiences with a focus on access to and participation of Black patients with metastatic breast cancer (MBC) in clinical trials.

The interviews were conducted from December 2020 through February 2021 and served to gather these perspectives from a range of stakeholders, including Black patients and others involved in cancer treatment and research. Specifically, for the purposes of this project, CBWhite interviewed the following stakeholders:

- 13 Black MBC patients
- 8 clinicians involved in breast cancer treatment
- 4 hospital/academic research administrators
- 4 breast cancer researchers
- 2 administrators within insurance/payer organizations

Below key highlights and findings from the interviews conducted with each of the stakeholder groups.

Clinical Trial Participation

Levels of participation

A third of all patients interviewed reported not having a conversation with their provider or a member of their care team about a clinical trial for MBC. Patients who participated in clinical trials report positive experiences, and positive, trusting interactions with their providers and/or care team.

Barriers to or Considerations for Clinical Trial Participation

Patients who did not participate in clinical trials reported factors that influenced their decision including ineligibility, inadequate information about the nature and purpose of clinical trials, and lack of confidence and general mistrust of their provider or care team. Patients that did participate in clinical trials report factors that influenced their decision included being well informed, motivated by cancer deaths in their family, and ensuring clinical trial research benefits other Black women.

Both clinicians and researchers report a range of barriers and considerations for clinical trial participation that, in their opinion, are unique to Black patients. These include mistrust of the medical system, insurance status, limited financial resources and social supports. However, for those Black patients that are successfully recruited into clinical trials, interviewees reported they were onboard with the process and completed the trials.

Administrators in rural areas reported significant barriers to clinical trial participation for Black patients including geographic access, and all administrators reported mistrust of the medical system, medical literacy, limited English proficiency and pre-existing co-morbidities as barriers Black patients experience to clinical trial participation.

Community and Institutional Support for Clinical Trial Participation

Role of Community Support

Patients who participated in clinical trials found support to be very important to their decision-making, and that support included patient-advocates, friends, spouse/immediate family, faith community and

oncologist/care team. Additionally, clinicians, researchers, administrators, and payers all agree that engaging and partnering with Black communities in their region is significantly important in recruiting and retaining Black patients in clinical trials. Successful support strategies deployed by these stakeholders include establishing community advisory boards, creating in-house patient advocates and navigators, participating in community health fairs, and communicating information about clinical trials to the community via social media platforms.

Policies and Procedures to Track Diversity in Clinical Trials

The majority of clinicians, researchers and administrators reported their institutions have policies and procedures to track diversity in clinical trial participants. Of significant note, all institutions that are certified or a grant recipient on the National Cancer Institute follow rigorous protocols regarding tracking metrics to ensure diversity in clinical trial participation. None of the payers interviewed reported having policies or procedures to track diversity in clinical trial participation.

Recruitment and Retention Strategies

Provider and Patient Engagement

All clinicians interviewed reported that all eligible patients receive information about clinical trials, including all eligible Black patients. Factors that influenced which patients received clinical trial generally centered on eligibility criteria, including age, co-morbidities, English proficiency, and limited insurance coverage.

Clinical Trial Recruitment Strategies

Clinicians and researchers interviewed report that community engagement and support is an important factor in successfully recruiting Black patients into clinical trials. Reported successful recruitment strategies include engaging Black outreach coordinators, providing critical social supports (such as transportation and parking subsidies) blocking out time for longer visits with patients to review clinical trial information, and structuring treatment at the onset of care to facilitate clinical trial eligibility and inclusion criteria (if/when the patient becomes eligible).

Clinical Trial Retention Strategies

All interviewees unanimously reported that Black patients successfully recruited into ongoing clinical trials completed them (no withdrawals).

Coordination and Support for Clinical Trial Participation

Across all stakeholder groups (patients, clinicians, researchers, administrators, and payers), all interviewees agree that coordination and support among providers/care teams, researchers, hospitals, and payers would enhance patient recruitment, reduce existing barriers, and provide greater supports for patients experiencing financial and social support constraints.

Interview Summary and Next Steps

A full summary of the findings from the interviews can be found in the attached full report. Data gathered from the interviews will be shared with the Project B.E.C.O.M.E. team to inform Phase Three of the project, which includes survey research.

KEY INFORMANT INTERVIEW ANALYSIS

FULL SUMMARY

Introduction

The B.E.C.O.M.E. project (Black Experience of Clinical Trials & Opportunities for Meaningful Engagement) is supported by CBWhite consulting firm, and all interviews were conducted by CBWhite subcontractor, Kuliva Wilburn, CEO of Wilburn Strategic Solutions. Kuliva has over 15 years of experience in public health, with a concentration on community health and health policy. Trained as a researcher, Kuliva holds a Master's degree in public health, and is a doctoral candidate in the University of Illinois at Chicago School of Public Health DrPH program.

In Phase 2 of the B.E.C.O.M.E. project, CBWhite conducted qualitative research in the form of virtual interviews to identify relevant issues, concerns, motivations, barriers and experiences with a focus on access to and participation of Black patients with metastatic breast cancer (MBC) in clinical trials.

The interviews were conducted from December 2020 through February 2021 and served to gather these perspectives from a range of stakeholders, including Black patients and others involved in cancer treatment and research. Specifically, for the purposes of this project, CBWhite interviewed the following stakeholders:

- 13 Black MBC patients
- 8 clinicians involved in breast cancer treatment
- 4 hospital/academic research administrators
- 4 breast cancer researchers
- 2 administrators within insurance/payer organizations

The stakeholders interviewed represented a range of geographic locations, size and capacity of hospitals and academic research institutions. All patients interviewed were Black. With 30 to 45 minutes spent individually with each person, these results offer the richness and complexity of in-depth interviews, and the results should be understood as exploratory in nature. The purpose of the interviews is to expand our hypotheses and understanding so that the quantitative survey we develop will be based on a solid foundation. Below is an analysis of the interviews conducted with each of the stakeholder groups, and a summary of the findings.

I. PATIENTS

Background

A total of 13 Black, female MBC patients were interviewed for this project. Based on the project theme of MBC clinical trial participation, interview questions covered the following themes:

- Levels of participation
- Barriers to or considerations for participation
- Community support
- Coordination and support for clinical trial participation

Below is a summary of those interviews.

Level of Participation

A third of all interviewees report not having a conversation with their provider or a member of their care team about a clinical trial for MBC. In some cases, this was due to the prognosis of their cancer. Other

patients report talking primarily with their oncologist about MBC clinical trials at the onset of their cancer treatment, with half of interviewees reporting initiating those conversations.
Half of the interviewees report no history of participating in a clinical trial of any kind. Of those who have participated in clinical trials, most report positive experiences. Only two of the interviewees reported negative interactions with their doctor or care team, with all others reporting positive, trusting interactions with their oncologists and/or care team.

Barriers to or Considerations for Clinical Trial Participation

Of those interviewed who did not participate in clinical trials, factors influencing their decision not to participate included:

- Ineligibility for ongoing clinical trials
- Not having adequate information about the nature and purpose of clinical trials
- Lack of confidence and general mistrust of their oncologist or care team

For those interviewed who did participate in clinical trials, factors that informed their decision included:

- Knowing there are people like them [Black women] in clinical trials
- Knowing cancer research has been done and assessed for Black people
- Receiving abundant information about clinical trials by their oncologist and/or care team and adequately answering any/all questions and concerns
- Participating in cancer research conferences, and noting the limited number of Black participants, and the limited representation of Black women in the research presented
- Feeling motivated by cancer deaths in their family

Community Support

Interviewees who participated in clinical trials found support to be very important to their decision-making, and that support included patient advocates, friends, spouse and immediate family, faith community, and oncologist/care team. For those patients who did not participate in clinical trials, they reported that the support they needed but didn't receive included abundant information about the nature, benefits and concerns about clinical trials, adequate answers to question about ongoing clinical trials, patient navigators, family and faith community support, and coordination with their oncologist and/or care team.

Coordination and Support for Clinical Trial Participation

All 13 interviewees unanimously agreed that their willingness to participate in clinical trials would increase if there was coordination among their care team, hospital, and insurance provider, taking the burden off individual patients navigating complex systems without support, having additional trusted partners to inform decision-making, and increasing confidence in the medical system's investment in positive health outcomes for patients.

II. CLINICIANS

Background

A total of eight clinicians were interviewed for this project. Based on the project theme of MBC clinical trial participation, interview questions covered the following themes:

- Provider and patient engagement
- Barriers to or considerations for participation in clinical trials for Black patients
- Hospital system support for clinicians engaged in clinical trials
- Coordination and support for clinical trial participation

Below is a summary of those interviews.

Provider and Patient Engagement

Interviewees reported between 5%-25% of their patient population identify as Black and the variation can be attributed to geographic location of the hospital/research institution and concentration of Black residents. All interviewees reported talking about clinical trials with all of their eligible patients, including Black patients. Factors that influenced who clinicians talked to about clinical trials primarily factored patients who fail to meet eligibility criteria including age, co-morbidities, English proficiency, and limited insurance coverage. The majority of interviewees report lower health literacy, lower education attainment, limited financial resources and insurance coverage as factors influencing patient willingness to participate in clinical trials.

Barriers and Considerations for Clinical Trial Participation for Black Patients

Interviewees report a range of barriers and considerations to clinical trial participation that are unique to Black patients, including:

- Mistrust of the medical system (based on historical precedence)
- Insurance status
- Financial resources
- Social supports (like childcare and transportation)

Nearly all clinicians report that although these are barriers and considerations for Black patients when participating in clinical trials, they should not be and could be overcome with social and community supports linked to a deeper understanding of the root causes.
All clinicians report that Black patients who participate in clinical trials complete the trials, similar to all other patients. Once successfully recruited, the patients are on board with the process and completing the trial.

Hospital System Support

All but one interviewee reported racial equity in clinical trials as a priority at their hospital or research institution. Those interviewees working in National Cancer Institute (NCI) certified and funded institutions reported having systems to track and evaluate racial equity in clinical trial participation.

Community Support

There was unanimous consensus that community support is significantly important in recruiting and retaining Black patients in clinical trials, and examples provided by interviewees included family members, neighbors, faith leaders, community advisory boards, and patient advocates and navigators. Interviewees also report that specific support needed to recruit and retain Black patients in clinical trials include financial support, peer support, and patient advocates.

Coordination and Support for Clinical Trial Participation

Interviewees reported unanimous consensus on the positive impact collaboration can play in supporting patients in MBC clinical trials including:

- Much of the collaboration, as it pertains to Black patients participating in clinical trials, isn't happening but is necessary
- What is missing across stakeholders is coordination of care, coordination with trial sponsors, and coordination across institutions (other hospitals and other research institutions)
- Considerations for life impacts and needs should be factored into the clinical trial design to lessen the burdens of clinical trial participation
- When all stakeholders are agnostic to where the patient goes for treatment, what resources are provided (and from whom) and focus on the patient, the outcomes are better for them

III. RESEARCHERS

Background

A total of four researchers were interviewed for this project. Based on the project theme of MBC clinical trial participation, interview questions covered the following themes:

- Patient recruitment strategies
- Institutional policies and procedures to track diversity in clinical trial participation
- Clinical trial retention strategies
- Barriers, incentives, and support for clinical trial participation
- Coordination and support for clinical trial participation

Below is a summary of those interviews.

Clinical Trial Patient Recruitment Strategies

Overall, researchers report their recruitment strategies to be successful, specifically when:

- Outreach coordinators are the same race/ethnicity as the patients recruited
- Blocking out time for longer visits with patients to review clinical trial information
- Treatment is structured at the onset to facilitate eligibility and inclusion criteria, should the patient become eligible for clinical trial participation

Interviewees with the highest percentage of Black patients participating in clinical trials are located in geographies with a significant number of Black residents, public transportation access to the hospital, and patient outreach, coordination and advisors who are Black. These same interviewees also report specific strategies to support recruiting Black patients for clinical trials, including:

- Personally recruiting patients with an eye towards patient populations who are historically absent from clinical trial participation
- Working with patients advocates to talk with patients about clinical trials, as well as stratifying recruitment strategies by race, ethnicity, and gender
- Ensuring clinical trials are part of the engagement conversation at the start of treatment, and if trials aren't available, referring patients out to other institutions within the region

Policies and Procedures to Track Diversity in Clinical Trial Participation

All but one interviewee reported having policies and procedures at their hospitals/research institutions to track the diversity of clinical trial participation. These strategies include utilizing health outreach coordinators and community health workers to help collect and track data as well as hospital-based policies for diversity and equity in clinical trials.

Clinical Trial Retention Strategies

All interviewees report having no patients withdraw from clinical trials, including Black patients.

Barriers, Incentives and Support for Clinical Trial Participation

Based on engagement with Black patients, interviewees reported the following barriers to clinical trial participation:

- Whether or not clinical trials are offered to patients
- Lack of trust of the medical system
- Logistical and financial costs incurred in clinical trial participation
- Representation (or lack thereof) in who presents the information

Interviewees recommended providing direct financial and logistical support as well as increasing accessibility to clinical trials (proximity, comfort with trial procedures, and consenting) as incentives to support Black patients in clinical trial participation.

To support Black patients participating in clinical trials, interviewees recommended increasing health literacy, focusing on reducing structural barriers to clinical trial participation, and advocating for policy change within state Medicaid divisions to include coverage for clinical trial participation.

Coordination and support for clinical trial participation

Interviewees report that coordination across institutions and stakeholders would increase knowledge sharing and solutions to the challenges patients face when participating in clinical trials and help to put patients first in clinical trial research.

IV. ADMINISTRATORS

Background

A total of four hospital and academic research institutions were interviewed for this project. Based on the project theme of MBC clinical trial participation, interview questions covered the following themes:

- Role of hospitals in supporting clinical trials
- Institutional support for providers and researchers engaged in clinical trials
- Institutional support for clinical trial participants
- Engaging insurers/payers
- Engaging the community
- Coordination and support for clinical trial participation

Below is a summary of those interviews.

Role of Hospitals in Supporting Clinical Trials

Interviewees report a range of strategies that hospitals can deploy to support ongoing clinical trials, including increasing staff to assist with consenting patients, completing paperwork, and financial support. Increased administrative and operational support were also reported as strategies to support ongoing clinal trials, including time for providers to engage with patients and supporting relationships with organizations that offer clinical trials to increase options for researchers and patients.
All interviewees also reported organization/institutional policies and procedures to track data and metrics to ensure diversity in clinical trials. Reported strategies to track data and metrics included quarterly accruals tracked by race, ethnicity, gender, and geography.

Institutional Support for Providers and Researchers Participating in Clinical Trials

Interviewees report a range of strategies their hospitals/research institutions have implemented to support providers and researchers engaged in clinical trial research including:

- Investing in marketing and communication about ongoing clinical trials with partners and communities
- Providing enrollment support for providers enrolling patients into clinical trials by increasing nursing, administrative, and technical support to allow providers more time with patients to provide education and information
- Providing clinical trial coordinators, who engage and support patients
- Within membership agreements with partner cancer centers where patients can be referred for ongoing clinical trials, ensuring there are sufficient research coordinators, patient advocates and navigators to provide adequate patient support

- Supporting/establishing monthly group calls to train physicians and researchers about ongoing clinical trials
- Provide funding to support disparity research

All interviewees reported a range of personal and structural barriers to recruiting a diverse pool of clinical trial participants including:

- Mistrust of the medical establishment among patients was mentioned across all interviewees
- Significant barriers reported by administrators in rural regions included medical literacy and limited English proficiency
- Clinical trial exclusion criteria often eliminate many Black patients in rural regions, who often have high rates of co-morbidities
- Location of academic medical center far from communities of color within the region makes trial participation logistically complex

Institutional Support for Clinical Trial Participants

Only one out of four administrators report providing support for patients overall (including recruitment incentives) and for Black patients specifically (including targeted recruitment efforts). Rural administrators report their providers serving on national cancer research boards raise awareness of the restrictive impact of clinical trial eligibility criteria on Black patients.

Engaging Insurers/Payers

All interviewees report that payers have a critical role in supporting patients interested in participating in clinical trials. Recommended strategies included encouraging members to participate in clinical trials, clarity on payment responsibilities for patients and payers, and reducing delays in payer approvals (which can lead to disqualification).

Engaging the community

All interviewees reported at least one community engagement strategy, including health fairs, participating in community-based events and social media formats (Facebook and Twitter). For the rural administrator, strategies to engage the community also included utilizing patient advocates and navigators (knowledgeable about clinical trials) to engage the community on a routine basis.
No interviewees reported engaging or partnering directly with the Black community.

Coordination and support for clinical trial participation

All interviewees unanimously agreed that collaboration across institutions plays an important role in supporting patients participating in clinical trials, though no interviewees report such coordination within their own hospitals/research institutions.

V. PAYERS

Background

A total of two insurers (or payers) were interviewed for this project. Based on the project theme of MBC clinical trial participation, interview questions covered the following themes:

- Institutional/organizational policies for clinical trials
- Clinical trial barriers and needed supports
- Promoting diversity in clinical trial participation
- Coordination and support for clinical trial participation

Below is a summary of those interviews.

Institutional Policies for Clinical Trials

No Interviewees reported institutional policies for member trial participation, but their institutions do follow state and federal mandates for clinical trial coverage. Interviewees also reported perceptions that clinical trials are considered experimental therapies that may result in increased hospitalizations and overall costs.

Clinical Trial Barriers and Needed Supports

No interviewees reported their institutions provided direct supports to patients participating in clinical trials, and that in their view, no institutional policies create disproportionate barriers for Black patients.

Promoting Diversity in Clinical Trial Participation

Interviewees recognized the significance of transportation, housing, and food needs for many patients, which payers offset to reduce health care costs, or the healthcare cost trends. Providing these supports through the patient's insurance provider would likely require an economic justification that defends the need to keep costs down, including fewer hospitalizations, improved health outcomes, and extended lives, which are the goals of payers. However, this may not be enough to shift current payer perceptions about potential cost increases associated with clinical trial participation.

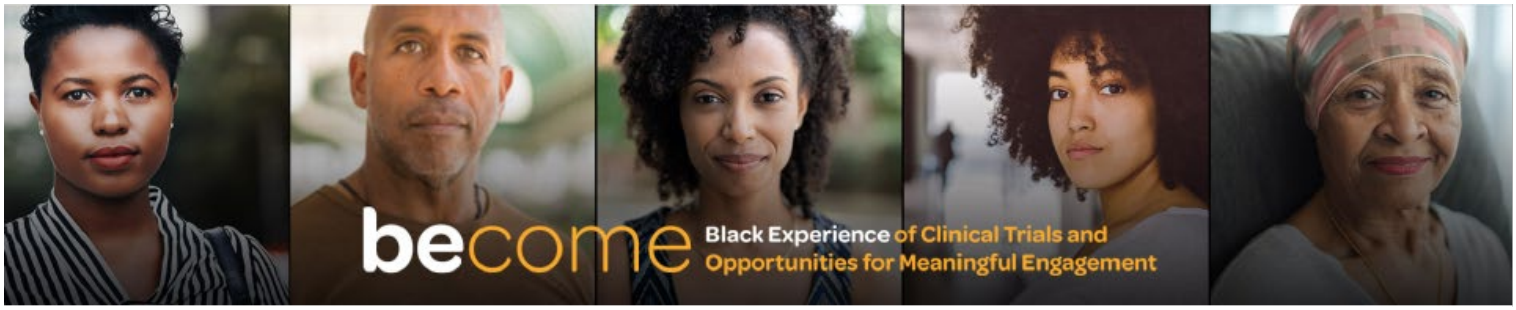
Promoting Diversity in Clinical Trial Participation

Interviewees report supports payers can provide to increase Black patient participation in clinical trials include:

- Providing a return on investment that demonstrates support for clinical trial coverage will reduce overall hospitalization and patient-care related costs
- Investing in diversifying clinical trials
- Reducing co-pays and premiums which disproportionately impact Black patients

Coordination and Support for Clinical Trial Participation

Interviewees agree that having all stakeholders communicate together to identify what works for the patient helps to provide positive health outcomes. Additionally, when payers inform patients that the clinical trial is covered under their plan, all the other entities (such as clinicians, researchers and hospitals) can then fill in other needed supports, including social and emotional supports patients often report are critical to their ability to participate in clinical trials successfully.



Thank you for your interest in the survey! Your input is vitally important and will be used by the Metastatic Breast Cancer Alliance to help make clinical trials available to everyone living with MBC who wants to participate.

This survey is available via the internet at **www.mbca.me/surveyBECOME**, and you may find it easier to complete there. However, if you prefer to take it on paper, please mail it as soon as possible, preferably by **June 7, 2021**. All surveys received by June 15, 2021, will be included in our analysis.

Please send your completed survey to:

BECOME
4080 Broadway, #311
New York, NY 10032

On the next page, you will see an "information document" that is part of responsible survey practice. It may look like there's a lot to read. After the information document, the survey is available. We estimate it will take you 15 minutes to complete the survey.

Information Document

Welcome to the Black Experience of Clinical Trials and Opportunities for Meaningful Engagement (BECOME) survey, sponsored by the Metastatic Breast Cancer Alliance (MBCA). This survey is for adults living with MBC in the US.

Purpose: The survey and its findings will help us understand the experiences and barriers to participation in cancer clinical trials. We hope that adults who are diagnosed with MBC in the future will benefit from the thoughts you share.

Process: This survey should take only 10 to 15 minutes to complete.

Benefits and Costs: You will not benefit directly from taking this survey and you will not incur any costs, other than standard internet provider costs If you choose to print and complete a paper version of the survey, you will incur the cost of postage.

Risks: It is possible that some questions may make you feel uncomfortable. We do not anticipate any other risks.

Privacy: The survey is anonymous and confidential. We will not request any information that could identify you.

Alternatives: Taking this survey is voluntary.

Withdrawal: You may stop taking the survey at any time. After it is completed, it may not be withdrawn.

Questions: If you have any questions about this study, please contact the North Star Review Board, who is the Institutional Review Board (IRB) for this study.

Toll free: 877-673-8439
info@northstarreviewboard.org

I have read and understand the information above. I agree to continue with the BECOME survey questions. **Please mark the boxes below.**

☐ I have been diagnosed with metastatic breast cancer — which is also called Stage IV (or Stage 4) breast cancer that has spread beyond the breast and surrounding lymph nodes, most often to the bones, liver, lung, or brain, although it can spread elsewhere — and I am over the age of 18 years, or 19 years if I live in Alabama or Nebraska. I live in the US, a US territory, or am a member of the US military (or their spouse) who is stationed outside the US. **(You are required to mark this box if you want your survey to be included.)**

☐ I agree to participate. **(You are required to mark this box if you want your survey to be included.)**

After marking both boxes with an "X" please continue with the survey on the next page.

Thank you for your interest in the BECOME survey.

This survey is being shared in many ways. If you realize you have already taken it, simply stop so you only take it one time. Thank you!

A few helpful notes:

- **Your responses will be anonymous**
- If you select "other," you may write in your own words
- For our analysis, some questions are required. They are designated with an asterisk (*) by the number.
- You may mark your answers with a pen or pencil, trying to put a clear "X" by your choice.
- In some places, you may write in your own answer. Please write as legibly as possible.

We'll start with just a few basic questions about you.

1*. How long ago were you diagnosed with **metastatic** breast cancer? Please mark one box.

- ☐ Within the last year
- ☐ Write in number of years ago: _____

2*. How old are you now? Please mark one box.

☐ 18-24	☐ 55-64
☐ 25-34	☐ 65-74
☐ 35-44	☐ 75 or older
☐ 45-54	

3*. Where do you live? Please mark one box.

- ☐ One of the 50 United States

Write in which state: _____

☐ D.C.	☐ Guam
☐ US Virgin Islands	☐ American Samoa
☐ Puerto Rico	☐ Northern Marianas Islands
☐ Serving (or spouse) in US military, stationed outside the US	

We have just a few more background questions. These are important for helping us understand how health care is experienced by people from different racial and ethnic groups.

4*. Which describes you? Please check all that apply.

- ☐ Asian or Asian American
- ☐ Black or African American
- ☐ Hispanic or Latina, Latino, or Latinx
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White
- ☐ If you don't see yourself in the list provided, please self-describe: _____

5*. Which best describes the area you live in? Please mark one box.

- ☐ In or near a major city, including suburbs (you may skip the next question)
- ☐ In a relatively small town
- ☐ In a rural area

6*. How far do you live from a major city? (Skip this if you live in or near a major city.)

- ☐ Less than an hour by car
- ☐ 1 to 2 hours by car
- ☐ More than 2 hours by car

7*. Which best describes you? Please mark one box.

- ☐ Female
- ☐ Male
- ☐ Transgender
- ☐ Non-binary / genderqueer / third gender
- ☐ Prefer to self-describe: _____
- ☐ Prefer not to say

Thank you for those answers. Next, we will get into the main topic of the survey and want to emphasize that there are NO right or wrong answers to these questions! Your experience and opinions are important.

Before moving to the next questions, here are some terms that may be helpful.

- **Metastatic breast cancer (also known as Stage IV or Stage 4)** is cancer that has spread beyond the breasts or lymph nodes to other parts of the body. We will refer to it as **MBC** for short.
- **A clinical trial** is a research study that seeks to find new ways to prevent, diagnose or treat illness.
- **Treatment** refers to the drugs and procedures people receive to treat illness or side effects.

In this survey, we are focused on clinical trials that study treatments.

8*. Which best describes your experience related to clinical trials for **treatment** of MBC? Please check all that apply.

- ☐ Participant: Have participated or are currently participating in a trial
- ☐ Never informed: Have not been told about the option of a trial
- ☐ Not interested: Have been told about the option of a trial but was not interested
- ☐ Interested: Have been told about the option of a clinical trial and am or was interested
- ☐ Not eligible: Considered a trial but did not qualify or was not eligible
- ☐ Decided against it: Considered a trial and qualified but decided against doing it
- ☐ Don't know

9*. Which kinds of health-related clinical trials have you participated in that are NOT related to MBC? Please check all that apply.

- ☐ For treatment of early-stage breast cancer
- ☐ For treatment of any other health condition
- ☐ None (have not participated in a treatment-related clinical trial)

10*. How likely would you be to consider participating in a treatment-related MBC clinical trial at some point? Please mark one box.

- ☐ Very unlikely
- ☐ Somewhat unlikely
- ☐ Somewhat likely
- ☐ Very likely

Our next questions are about your oncology (cancer) care team -- the oncologist, nurses, physician assistants, and nurse practitioners. While we realize you may have other healthcare providers, this survey is focused on the oncology (cancer) care team.

11. To the best of your knowledge, is your current oncologist affiliated with a university or academic system? This means the doctor is connected to a hospital that is part of a university system, teaches medical students, and takes part in research studies. Please mark one box.

- ☐ Yes
- ☐ No
- ☐ Unsure

12. Have you switched oncologists during your care for MBC? Please mark one box.

- ☐ Yes
- ☐ No (you may skip the next question)

13. Which best describes the main reason you switched oncologists? Please mark one box.

- ☐ Insurance
- ☐ Moved
- ☐ My preference
- ☐ Other - describe: _____
- ☐ Prefer not to answer

14*. How would you describe your overall satisfaction with your current oncology care team? Please put an X in one box in **each** row.

	VERY DISSATISFIED	SOMEWHAT DISSATISFIED	SOMEWHAT SATISFIED	VERY SATISFIED
Oncologist	☐	☐	☐	☐
My oncology care team	☐	☐	☐	☐
Hospital or institution	☐	☐	☐	☐

15*. Please indicate whether you agree or disagree with each statement. As mentioned earlier, there are no wrong answers! Please put an X in one box in each row.

	STRONGLY DISAGREE	SOMEWHAT DISAGREE	SOMEWHAT AGREE	STRONGLY AGREE
My oncologist really listens to me	☐	☐	☐	☐
My oncology care team really listens to me	☐	☐	☐	☐
I trust my oncologist	☐	☐	☐	☐
I trust my oncology care team	☐	☐	☐	☐
I trust the institution where I get my care	☐	☐	☐	☐
My oncologist assumes I have Medicaid or am uninsured based on my race or ethnicity	☐	☐	☐	☐
My oncologist assumes I do not understand health information	☐	☐	☐	☐

16*. Please indicate whether you agree or disagree with each statement. As mentioned earlier, there are no wrong answers! Please put an X in one box in each row.

	STRONGLY DISAGREE	SOMEWHAT DISAGREE	SOMEWHAT AGREE	STRONGLY AGREE
I am interested in learning about clinical trials	☐	☐	☐	☐
I receive as much information about clinical trials as I want from my oncologist and the care team	☐	☐	☐	☐
I know about the concept of clinical trials	☐	☐	☐	☐
I am aware of clinical trials happening in MBC	☐	☐	☐	☐
I trust clinical trials, in general	☐	☐	☐	☐
I trust that people of all races or ethnicities get fair and equal treatment in trials	☐	☐	☐	☐
I trust that trials are done with the best interest of patients in mind	☐	☐	☐	☐

17*. Which best describes your experience with your current oncologist and your oncology care team, overall, regarding MBC clinical trials? Please mark one box.

- ☐ Seems strongly opposed to trials for me
- ☐ Seems somewhat opposed to the idea of trials for me
- ☐ Seems somewhat in favor of the idea of trials for me at some point
- ☐ Seems strongly in favor of the idea of trials for me at some point
- ☐ No one on the care team has discussed clinical trials with me
- ☐ I don't know

In many of the next questions, you will see a scale of 1 to 5, where 1 means "not at all" and 5 means "very." Please feel free to use all the numbers from 1 to 5 (as you move from row to row) to tell us how much something matters to you or how you feel about it. Also, you have the option to say you have "no opinion."

18. People participate in clinical trials for a wide variety of reasons. If you were presented with a clinical trial as a treatment option, how motivating would each of these possibilities be to you? Please put an X in one box in each row.

	NOT AT ALL MOTIVATING 1	2	3	4	VERY MOTIVATING 5	NO OPINION
Drugs offered in a clinical trial are usually free	☐	☐	☐	☐	☐	☐
Makes a contribution to research	☐	☐	☐	☐	☐	☐
Helps others with MBC	☐	☐	☐	☐	☐	☐
Trial drugs may be more effective than standard of care	☐	☐	☐	☐	☐	☐
Close monitoring during the trial	☐	☐	☐	☐	☐	☐
Clinical trials provide access to new treatments	☐	☐	☐	☐	☐	☐
Could help future generations of my family	☐	☐	☐	☐	☐	☐
Ensure people with my racial or ethnic identity benefit from the research	☐	☐	☐	☐	☐	☐
Honor the memory of someone who was close to me	☐	☐	☐	☐	☐	☐
Oncologist recommends the trial	☐	☐	☐	☐	☐	☐
Understanding what the trial hopes to accomplish – its goals and purpose	☐	☐	☐	☐	☐	☐
Understanding what's involved in participating in the trial	☐	☐	☐	☐	☐	☐

19. People also decide not to participate in clinical trials for a wide variety of reasons. If you were presented with a clinical trial as a treatment option, how would each of the following impact your decision **not** to participate? Please put an X in one box in each row.

	NOT AT ALL IMPACTFUL 1	2	3	4	VERY IMPACTFUL 5	NO OPINION
Trial drugs may not be effective	☐	☐	☐	☐	☐	☐
Financial burden (for example, from taking time off work or money needed to travel)	☐	☐	☐	☐	☐	☐
Worried about side effects	☐	☐	☐	☐	☐	☐
Too many appointments and tests	☐	☐	☐	☐	☐	☐
I worry there may be extra medical costs	☐	☐	☐	☐	☐	☐
Too much paperwork	☐	☐	☐	☐	☐	☐
Requires a lot of travel time	☐	☐	☐	☐	☐	☐
I believe treatments that have not been studied may be harmful	☐	☐	☐	☐	☐	☐
I am concerned that my data may be misused or used without my permission	☐	☐	☐	☐	☐	☐

20. How significant of a barrier do you feel each of these are to you when it comes to considering clinical trials? Please put an X in one box in each row.

	NOT AT ALL SIGNIFICANT 1	2	3	4	VERY SIGNIFICANT 5	NO OPINION
Difficulty finding trials	☐	☐	☐	☐	☐	☐
Lack of trials near where I live	☐	☐	☐	☐	☐	☐
Waiting period - a time that treatment may need to stop before start of trial (referred to as a "washout" period)	☐	☐	☐	☐	☐	☐
Too many health restrictions or requirements to be in trial (such as no diabetes, no high blood pressure, restrictions on how much treatment someone has had, or requirements/restrictions on types of metastasis)	☐	☐	☐	☐	☐	☐
Centers that run trials don't take my insurance	☐	☐	☐	☐	☐	☐
Would have to change oncologists	☐	☐	☐	☐	☐	☐
Would have to change hospitals or institutions	☐	☐	☐	☐	☐	☐
Family is not supportive of trials	☐	☐	☐	☐	☐	☐
Practical challenges (such as transportation, family care, conflicts with work schedule, etc.)	☐	☐	☐	☐	☐	☐

Our next questions relate to the support and information people receive and need when it comes to clinical trials.

21. If you were to consider participating in an MBC clinical trial, how important would each type of support be? Please put an X in one box in each row.

	NOT AT ALL IMPORTANT 1	2	3	4	VERY IMPORTANT 5	NO OPINION
Financial support for the costs of taking part in the trial	☐	☐	☐	☐	☐	☐
Practical (logistical) support for things like travel, transport, and/or family care	☐	☐	☐	☐	☐	☐
Physical support with side effects and treatment	☐	☐	☐	☐	☐	☐
Emotional support related to participating	☐	☐	☐	☐	☐	☐

22. If you were to consider a treatment-related clinical trial for MBC, how important would each type of information be? Please put an X in one box in each row.

	NOT AT ALL IMPORTANT 1	2	3	4	VERY IMPORTANT 5	NO OPINION
Purpose of trial	☐	☐	☐	☐	☐	☐
Details on participating	☐	☐	☐	☐	☐	☐
Reasons to participate	☐	☐	☐	☐	☐	☐
Possible side effects of treatment	☐	☐	☐	☐	☐	☐

23. Some people learn about clinical trials from their doctors. Many hear from others — people such as patient advocates (also known as peer support), patient or nurse navigators (people who work in the hospital system), an oncology nurse, or a community health worker. Please put an X in 1 box in **each** row.

How important would it be to learn about a clinical trial from someone who:	NOT AT ALL IMPORTANT 1	2	3	4	VERY IMPORTANT 5	NO OPINION
Has had breast cancer	☐	☐	☐	☐	☐	☐
Has metastatic breast cancer	☐	☐	☐	☐	☐	☐
Has been in a clinical trial	☐	☐	☐	☐	☐	☐
Works with a well-known cancer nonprofit organization	☐	☐	☐	☐	☐	☐
Works with a respected organization in my local community	☐	☐	☐	☐	☐	☐
Is connected to a faith-based organization I trust	☐	☐	☐	☐	☐	☐
Has same racial or ethnic identity as me	☐	☐	☐	☐	☐	☐
Can spend the time I need to help me	☐	☐	☐	☐	☐	☐
Shares information in a way I can understand	☐	☐	☐	☐	☐	☐

Thank you for answering all these questions about clinical trials and cancer care. We want to give you a chance to write in your own thoughts on our key questions, in case there's anything else you want to share. We are eager to learn from you! (Please do not include your name or any other personally identifying information. In case anyone accidentally shares personally identifying information, the MBCA will delete it.)

24. Is there anything else you would like to share on the topic of participation in clinical trials for treatment of metastatic breast cancer? Write in what you wish.

_____

_____

_____

_____

_____

25. Is there anything else you would like to share, specifically about racial disparities related to clinical trials for treatment of metastatic breast cancer? This may include ideas, solutions, problems, or experiences. Write in what you wish.

_____

_____

_____

_____

_____

8

Our last few questions — anonymous like all the others — are just to give us a little more background about you.

26. What type of health insurance coverage do you currently have (whether it's through you or through your spouse/partner)? Please mark one box.

- ☐ None
- ☐ Medicaid
- ☐ Medicare only
- ☐ Medicare and a supplemental plan
- ☐ Other government-sponsored health care (for example, TRICARE, VA, Indian Health Service)
- ☐ Employer-provided private insurance
- ☐ Individual private insurance (that you buy directly from an insurance company or from the state health insurance marketplace)
- ☐ Other – describe: _____
- ☐ Prefer not to say

27. How would you describe your level of involvement in the metastatic breast cancer community? Use a 1 to 5 scale where 1 means not at all and 5 means very involved. Please mark one box.

- ☐ 1 Not at all involved
- ☐ 2
- ☐ 3
- ☐ 4
- ☐ 5 Very involved

28. Are you the parent or caregiver of any children under 18 years old who regularly live with you? Please mark one box.

- ☐ Yes
- ☐ No
- ☐ Prefer not to answer

29. Do you provide care for any adults who are in your life (not as your paid job)? Please mark one box.

- ☐ Yes, but none who regularly live with me
- ☐ Yes, including one or more who regularly live with me
- ☐ No
- ☐ Prefer not to answer

30. Which best describes your relationship status? Please mark one box.

- ☐ Single/never lived with partner
- ☐ Have a partner but do not live together
- ☐ Married or living with partner
- ☐ Widowed, divorced, or separated from partner
- ☐ Prefer not to answer

31. What is the highest level of school that you have completed? Please mark one box.

☐ Less than 9th grade	☐ Associate's or technical degree
☐ 9th to 12th grade	☐ Some university or college
☐ 9th to 12th grade	☐ Bachelor's degree
☐ High school graduate or GED	☐ Post graduate courses
☐ Post graduate degree	☐ Prefer not to answer

32. Which category best describes your total household income? Please mark one box.

☐ Less than $15,000	☐ $75,000 to $99,999
☐ $15,000 to $24,999	☐ $100,000 or more
☐ $25,000 to $49,999	☐ Don't know
☐ 50,000 to $74,999	☐ Prefer not to answer

Thank you for taking the time to complete this survey! Your input is incredibly important to the Metastatic Breast Cancer Alliance.

We want to make sure you have the opportunity to see the results.

If you would like to receive an email when the public report is available, please go to this site — http://mbca.me/BECOMEfindings — and enter your email address in the box below *See the Survey Findings*. This email address will not (and cannot) be connected to your responses. It will also not be used for any other purpose.

Appendix E: Statistical analyses and all comparisons between Black and non-Black survey respondents, including p values

Analysis of who participated in the survey (Figures 1-3)
In the sample description (Figures 1-3, main text), the two groups were analyzed using a chi-squared test. The test measures whether two categorical variables interact with each other. The Analysis was performed using the R Package for Statistical Computing: R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. (https://www.R-project.org/).

Multivariate analysis (Figures 4-9)
To compare the two groups (Black and non-Black), multivariate methods were used to analyze the data shown in Figures 4-9 (main text and below). These multivariate methods were used to rule out the influence of some key factors that are connected to race. The purpose of such analysis is to attempt to report differences that are connected to race and not just to some other variable that is also connected to race. This analysis accounted for the influence of age, years since MBC diagnosis, region, and income. Thus, differences that remain are due to race. Below is additional information about multivariate analysis.

When we have multiple variables that are related to each other, it becomes difficult to know how much each variable contributes to the finding. As an example, consider the relationship between race, gender, and income. If we are investigating the income of a Black female, is the observed income influenced by her race or by her gender or both? Multivariate analysis allows us to measure the different effect that each variable, race and gender, will have on the overall income. This becomes especially important when we are primarily interested in one of the variables. To say that income is related to race, we need to account for or "control" for the other variables that would also impact income, so that we do not falsely attribute to race an effect that is due to something else.

Participation in clinical trials is related to a number of different factors, but we are primarily interested in the impact race has on participation. Some of these factors are correlated with race such as income or the region of the country somebody lives in. We use multivariate analysis to make sure that we are not falsely attributing an impact to race when it is really a combination of multiple factors.

The analysis for Figures 4-9 was performed using logistic regression. The dependent variable was re-coded as necessary (for the questions using four- and five-point rating scales) using a "top-two box" rule. If a response was one of the two most positive responses, it was coded as a success; otherwise the response was coded as a failure. This was done for consistency in the reporting and to accommodate a wide variety of scale use heterogeneity. We considered a number of control variables to include in the study, not all of which made it into the final analysis. The control variables were chosen carefully to ensure consistency in the data analysis process. To be excluded, the variable needed to have a very low correlation with race and not be a significant predictor in most of the individual questions. In addition, judgment was used when two variables appeared to be measuring the same underlying phenomenon. Variables considered and later dropped include marital status and insurance coverage.
The analysis was performed using the R Package for Statistical Computing (R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. (https://www.R-project.org/)).

Statistical significance and testing

In the charts below, we use red arrows to indicate a "significant" difference ($p < .01$) and white arrows to indicate a "marginally significant" difference ($p > .01$ and $< .05$). The actual p values are reported below each set of graphs. We realize these cut-offs are different from what readers may be used to seeing in other literature. This was done to balance the need to balance "false positives" (identifying an effect or difference that does not really exist) versus "false negatives" (failing to identify a real effect or difference).

"Significant" and "marginally significant" are statistical terms to indicate the confidence we have that a finding is not due to chance or our specific sample. The term '"significant" indicates a high level of confidence that the result is real and would be consistently found. "Marginally significant" indicates a lower level of confidence. Marginally significant results are suggestive, but there is an unacceptably high probability that the result indicates a false positive to make a strong claim. Another way to put this is that a significant result is probably real, and a marginally significant result is possibly real. The exploratory nature of this research means that we want to highlight both the effects that we are confident will hold as well as effects that merit further investigation in future studies.

It should also be noted that the choice of cut-offs for p-values is highly subjective. This has an important impact on how the results are interpreted and presented. The primary factor affecting the choice of p-values is the acceptable level of risk that a researcher is willing to take when making a claim. In social and medical sciences, a 1 in 20 chance of identifying a false positive has been considered acceptable, leading to a $p < .05$ cut-off. A $p < .01$ cut-off implies a 1 in 100 chance of a false positive. When multiple tests are run, the chance of identifying a false positive can increase dramatically. For example, if two tests were run, the overall chance of making a false claim would be nearly 1 in 10 instead of the 1 in 20 that was implied. This means that to maintain the same overall level of confidence we need to decrease the p-value cut-off used for identifying significant results. With so many questions in this study, we ended up running more than 70 tests to account for all the factors measured.

False positives are not the only challenge. As we minimize the potential for false positives by using more stringent significance cut-offs, we increase the chance of identifying false negatives. In exploratory research such as this study, false negatives present a significant risk that an important difference will go uninvestigated and addressed. In this study, we have taken a balanced approach by recognizing that false positives are a potential problem and adjusting the significance cut-offs, but also seeking to minimize the number of false negatives by not adjusting them to be as conservative as would be appropriate in confirmatory research. There are other approaches used to set significance levels when running a high number of tests, such as a Bonferroni or Tukey correction, but these correction methods would have been even **more** conservative. They would have likely led to a much higher false negative rate, meaning that differences that might be significant may have been missed. Balancing these two factors is a matter of judgment, and we have presented raw p-values along with the significance measures in case the reader wishes to consider a different balance between the two factors.

All comparisons and associated p values

Figure 4. Satisfaction with MBC care team and interest in participating in MBC clinical trials. A. Responses to the question: *How likely would you be to consider participating in a treatment-related MBC clinical trial at some point?* B. Responses to the question: *How would you describe your overall satisfaction with your current oncology care team?* (answer options: very dissatisfied, somewhat dissatisfied, somewhat satisfied, and very satisfied) The graph shows the percent who selected "somewhat satisfied" or "very satisfied". C. Responses to the question: *Please indicate whether you agree or disagree with each statement* (answer options: strongly disagree, somewhat disagree, somewhat agree, strongly agree). The graph shows the percent who selected "somewhat agree" or "strongly agree".

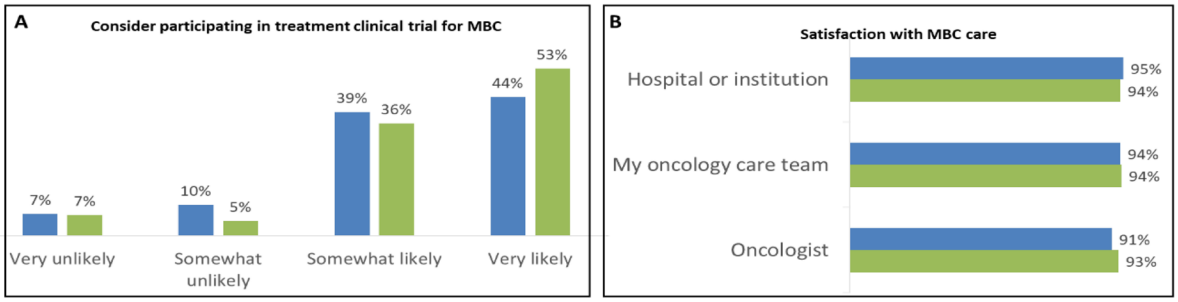


Table: p values for Figures 4A & 4B

Figure number	Question and answer options (abbreviated)	p value
4A	How likely would you be to consider participating in a treatment-related MBC clinical trial at some point?	0.1993
4B	How would you describe your overall satisfaction with your current oncology care team?	
	Satisfied with Oncologist	0.9193
	Satisfied with Oncology Care Team	0.3876
	Satisfied with hospital or institution	0.18402

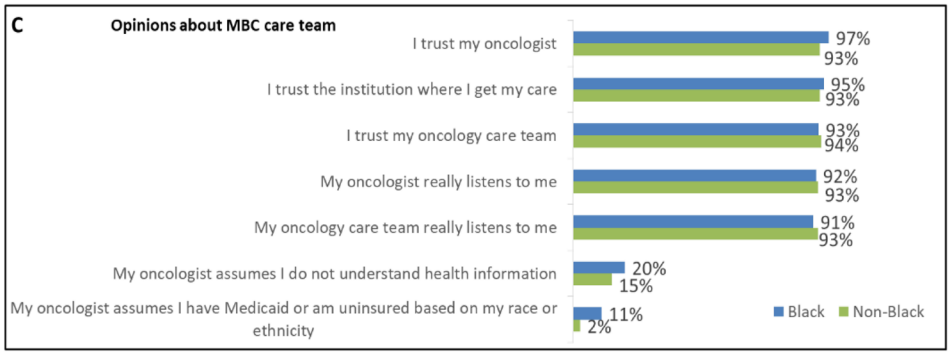
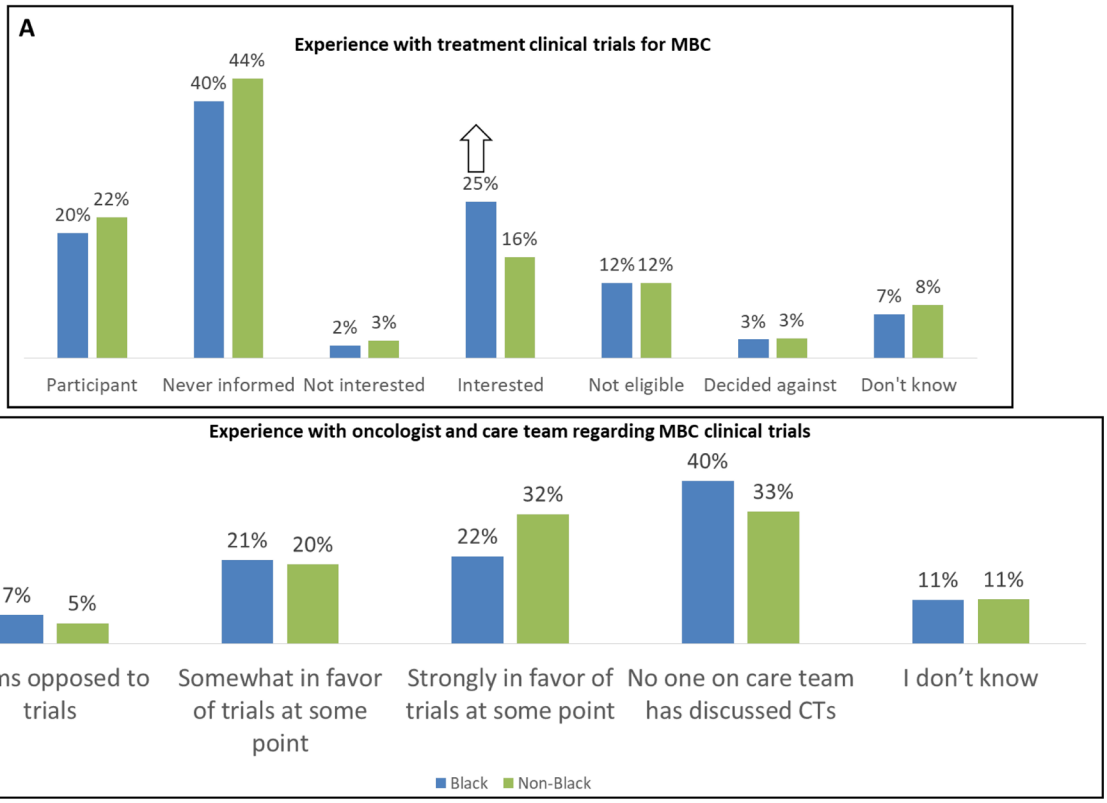


Table: p values for Figure 4C

Trust oncologist	0.11823
Trust institution	0.6419
Trust oncology care team	0.8
Oncologist listens	0.635
Oncology care team listens	0.632
Oncologist assumes I do not understand health info	0.89364
Oncologist assumes Medicaid/uninsured based on race/ethnicity	0.11823

Figure 5. Experience and interest in clinical trials. A. Responses to the question: *Which best describes your experience related to clinical trials for **treatment** of MBC?* (multiple answers were allowed). B. Responses to the question: *Which best describes your experience with your current oncologist and your oncology care team, overall, regarding MBC clinical trials?* (only one answer was allowed). The white arrow indicates a marginally significant difference.



Abbreviation: CT, clinical trial

Table: p values for Figure 5

Figure number	Question and answer options (abbreviated)	p value	Significance level
5A	Which best describes your experience related to clinical trials for treatment of MBC?		
	Participant	0.315857	
	Never informed	0.45795	
	Not interested	0.77	
	Interested	0.0473	*
	Not eligible	0.93923	
	Decided against	0.8336	
	Don't know	0.8941	
5B	Which best describes your experience with your current oncologist and your oncology care team, overall, regarding MBC clinical trials?	0.10831	

* p > 0.01 and < 0.05. This difference may be considered "marginally significant".

Figure 6. Trust and awareness about clinical trials. Responses to the question: *Please indicate whether you agree or disagree with each statement* (answer options: strongly disagree, somewhat disagree, somewhat agree, strongly agree). The graph shows the percent who selected "somewhat agree" or "strongly agree". Red arrows pointing down mean that Black respondents less frequently agreed with the statement shown. The white arrow indicates a marginally significant difference.

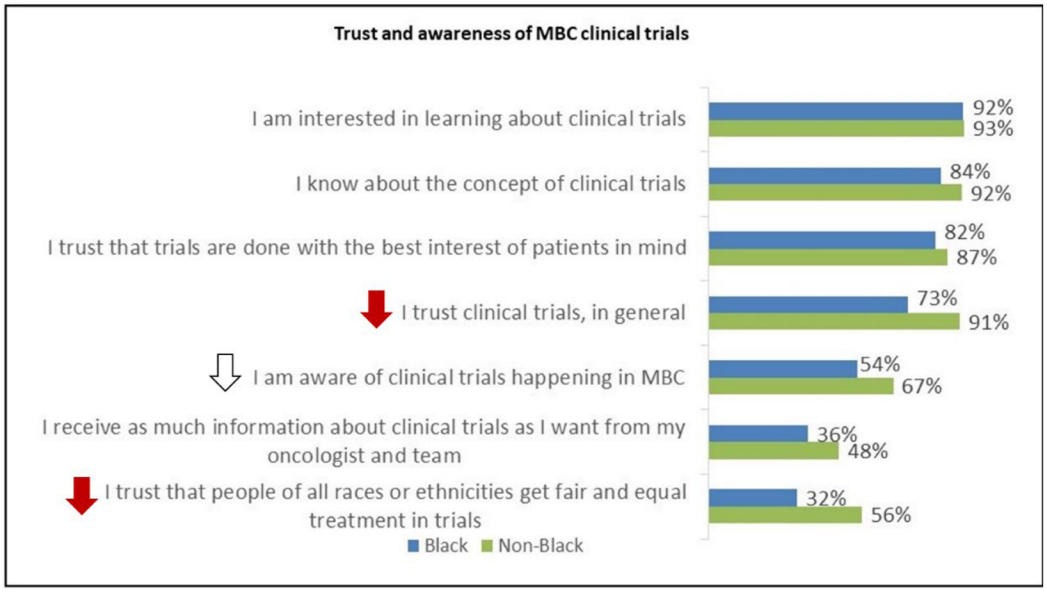
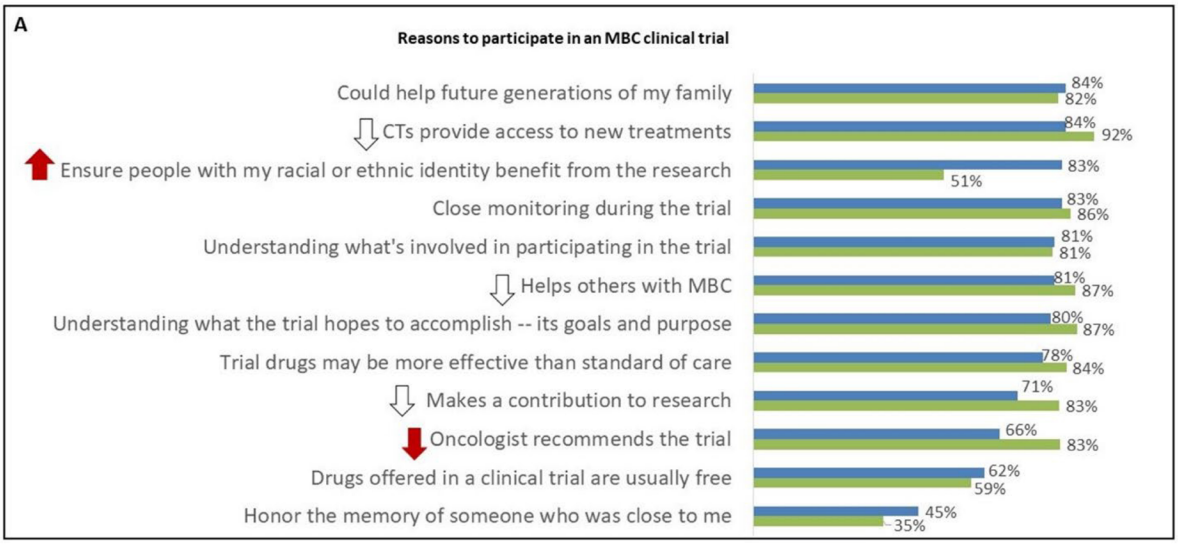


Table: p values for Figure 6

Question and answer options (abbreviated)	p value	Significance level
Please indicate whether you agree or disagree with each statement		
Are aware of clinical trials in MBC	0.0457	*
Trust CTs in general	4.30E-05	**
Trust fair and equal treatment	4.52E-05	**
Interested in learning about trials	0.61581	
Know about concept of trials	0.08813	
Trust that trials are done with best interest of patients	0.3982	
Receive as much info about trials as desired	0.2278	

* p > 0.01 and < 0.05. This difference may be considered "marginally significant".
** p < 0.01. Significant difference

Figure 7. Motivations to participate and to not participate in MBC clinical trials. Responses to the question: A. *If you were presented with a clinical trial as a treatment option, how motivating would each of these possibilities be to you?* B. *If you were presented with a clinical trial as a treatment option, how would each of the following impact your decision **NOT** to participate?* For each question, respondents rated the reason from 1 to 5, with 1 meaning "not at all motivating" to 5 meaning "very motivating" (for reasons to participate, panel A) or 1 meaning "not at all impactful" to 5 meaning "very impactful" (for reasons **NOT** to participate, panel B). Respondents could also select "no opinion". Each graph shows the percent of survey respondents who selected 4 or 5. The red arrows pointing up mean that Black respondents more frequently selected the statement shown. The red arrow pointing down means that Black respondents less frequently selected the statement shown. White arrows indicate a marginally significant difference.



Abbreviation: CT, clinical trial

Table: p values for Figure 7A

Question and answer options (abbreviated)	**p value**	**Significance level**
If you were presented with a clinical trial as a treatment option, how motivating would each of these possibilities be to you?		
Contribution to research	0.0137	*
Access to new treatments	0.026767	*
Oncologist recommendation	0.001399	**
Helping others with MBC	0.0473	*
Race or ethnicity	2.37E-07	**
Could help future generations	0.571	
Close monitoring	0.1872	
Understanding what's involved	0.916	
Understanding goals and purpose	0.0998	
Trial drugs may be more effective	0.066231	
Drugs offered usually free	0.484	
Honor memory	0.072	

* p > 0.01 and < 0.05. This difference may be considered "marginally significant".

** p < 0.01. Significant difference

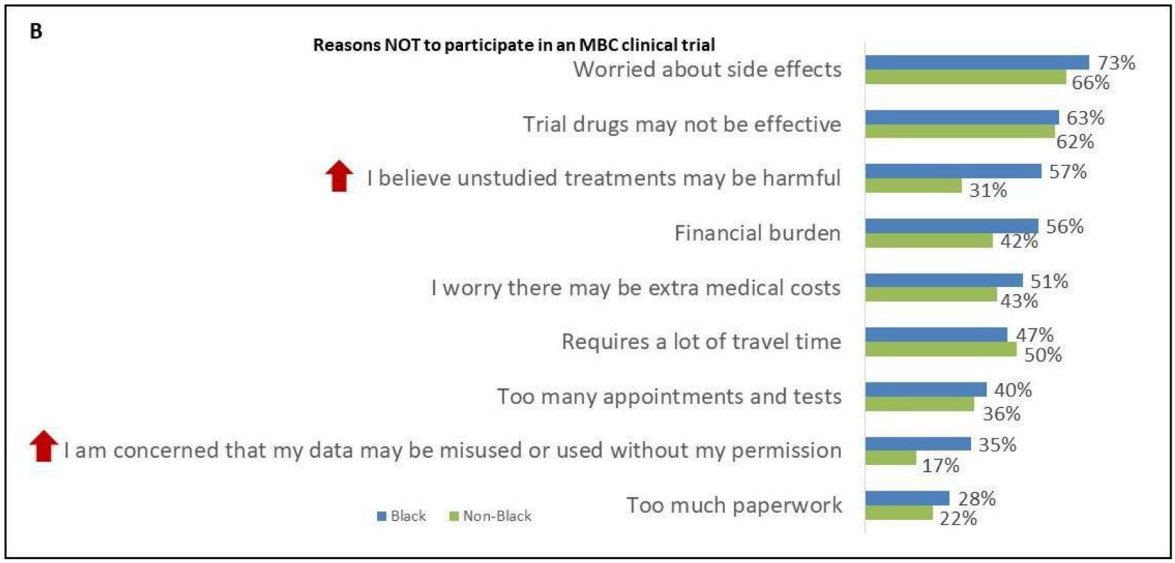


Table: p values for Figure 7B

Question and answer options (abbreviated)	p value	Significance level
If you were presented with a clinical trial as a treatment option, how would each of the following impact your decision **NOT** to participate?		
Unstudied treatments may be harmful	3.34E-05	**
Concerned data may be misused	0.000871	**
Worried about side effects	0.21	
Trial drugs may not be effective	0.8386	
Financial burden	0.0513	
Extra medical costs	0.292829	
Travel time	0.378	
Too many appointments and tests	0.665	
Too much paperwork	0.3448	

* p > 0.01 and < 0.05. This difference may be considered "marginally significant".
** p < 0.01. Significant difference

Figure 8. Factors that make participating in an MBC clinical trial difficult or impossible. Responses to the question: *How significant of a barrier do you feel each of these are to you when it comes to considering clinical trials?* Respondents rated the reason from 1 to 5, with 1 meaning "not at all significant" to 5 meaning "very significant". Respondents could also select "no opinion". The graph shows the percent of survey respondents who selected 4 or 5. White arrows indicate a marginally significant difference.

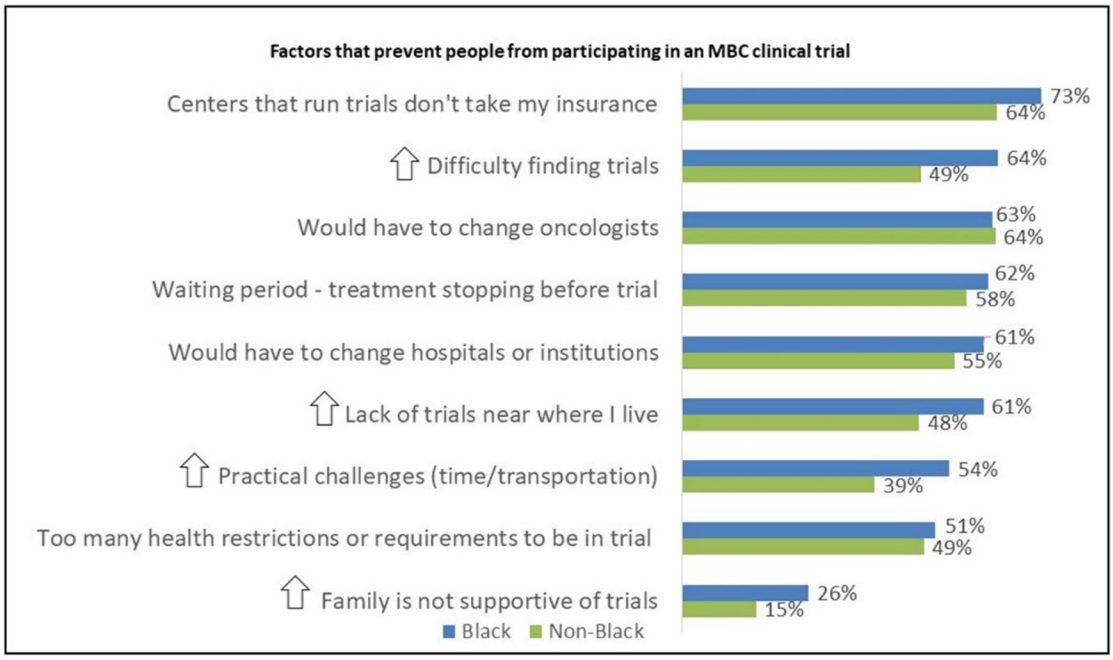


Table: p values for Figure 8

Question and answer options (abbreviated) How significant of a barrier do you feel each of these are to you when it comes to considering clinical trials?	**p value**	**Significance level**
Finding trials	0.0112	*
Family not supportive	0.0124	*
Practical challenges	0.0173	*
Lack of trials near where I live	0.0483	*
Centers don't take my insurance	0.073424	
Change oncologist	0.62087	
Waiting period	0.484	
Change hospitals	0.165	
Health restrictions or requirements	0.7355	

* $p > 0.01$ and < 0.05. This difference may be considered "marginally significant".

Figure 9. Responses to the questions: A. *If you were to consider a treatment-related clinical trial for MBC, how important would each type of support be*? B. *If you were to consider participating in an MBC clinical trial, how important would each type of information be?* C. *Some people learn about clinical trials from their doctors. Many hear from others — people such as patient advocates (also known as peer support), patient or nurse navigators (people who work in the hospital system), an oncology nurse, or a community health worker. How important would it be to learn about a clinical trial from someone who…* Respondents rated each statement from 1 to 5, with 1 meaning "not at all important" to 5 meaning "very important". Respondents could also select "no opinion". Each graph shows the percent of survey respondents who selected 4 or 5. Red arrows pointing up mean that Black respondents more frequently selected the statement shown. White arrows indicate a marginally significant difference.

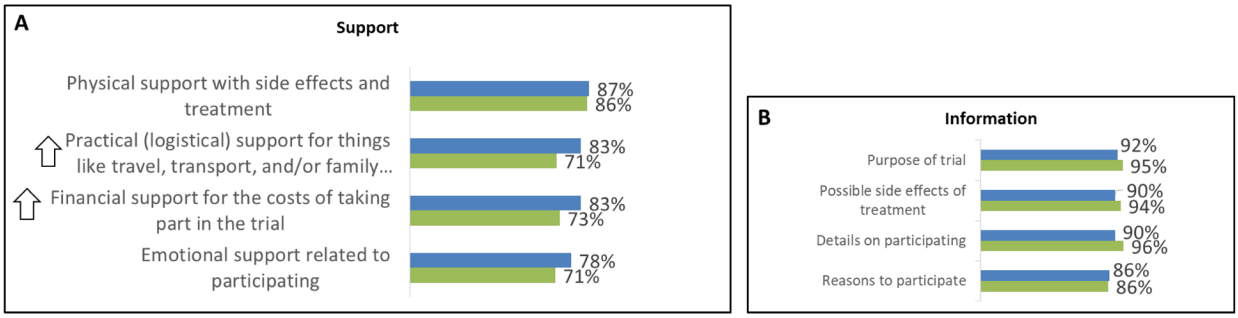


Table: p values for Figures 9A & 9B

Figure number	Question and answer options (abbreviated)	p value	Significance level
9A	If you were to consider a treatment-related clinical trial for MBC, how important would each type of support be?		
	Physical support	0.44708	
	Emotional support	0.1226	
	Practical [logistical] support	0.016371	*
	Financial support	0.03896	*
9B	If you were to consider participating in an MBC clinical trial, how important would each type of information be?		
	Purpose of trial	0.637	
	Possible side effects	0.394	
	Details on participating	0.0994	
	Reasons to participate	0.935	

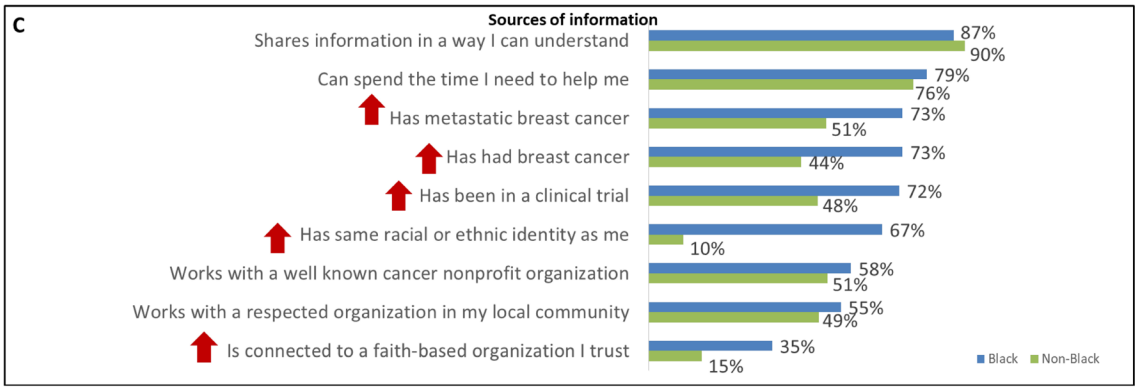


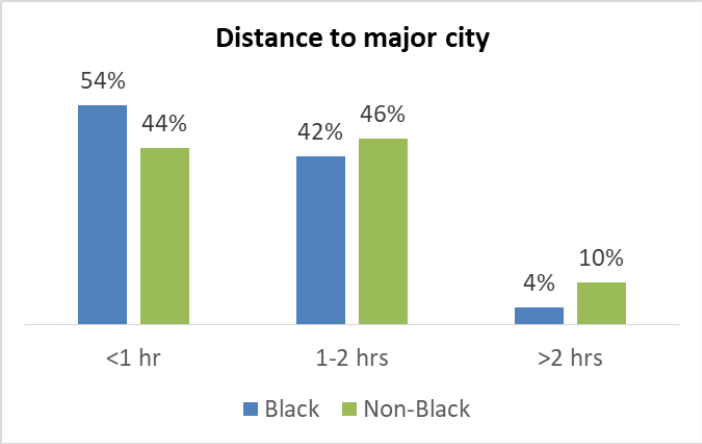
Table: p values for Figure 9C

Question and answer options (abbreviated)	p value	Significance level
How important would it be to learn about a clinical trial from someone who…		
Same race or ethnicity	<2e-16	**
Has had BC	4.86E-06	**
Faith-based	1.54E-05	**
Has had MBC	0.000793	**
Has been in a CT	0.000204	**
Shares info in a way I understand	0.985979	
Can spend time I need	0.4449	
Works with well-known cancer nonprofit	0.2541	
Works with respected org in local community	0.2182	

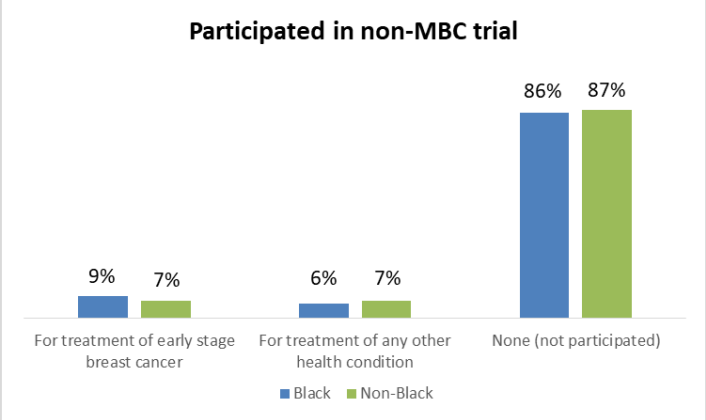
* p > 0.01 and < 0.05. This difference may be considered "marginally significant".
** p < 0.01. Significant difference

Appendix F: Additional survey questions and answers not included in the main report

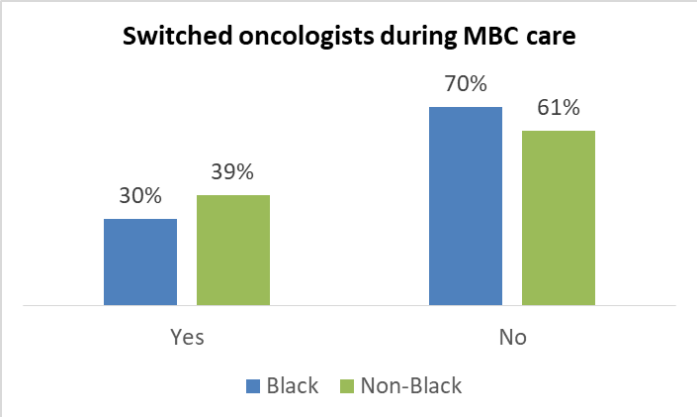
How far do you live from a major city? (Only asked of those who selected “small town” or “rural” in Figure 1B)



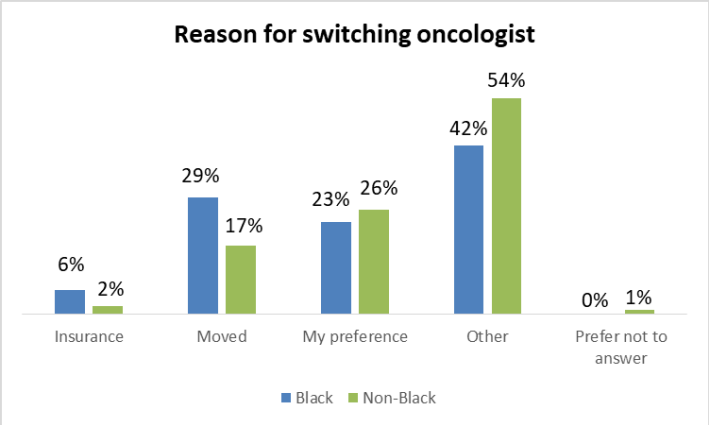
Which kinds of health-related clinical trials have you participated in that are NOT related to MBC? Please check all that apply.



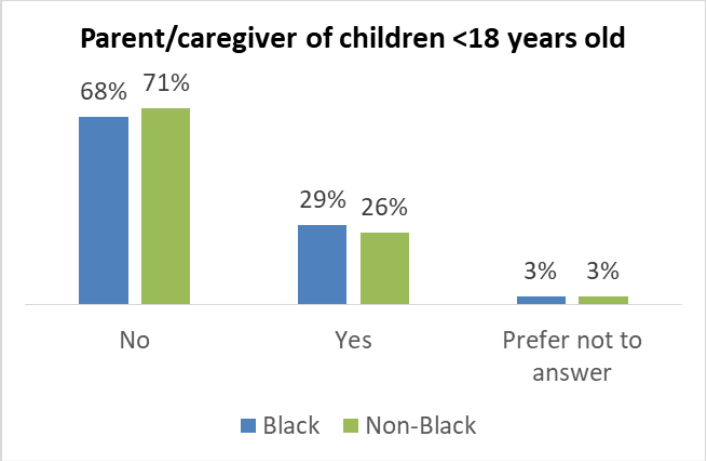
Have you switched oncologists during your care for MBC?



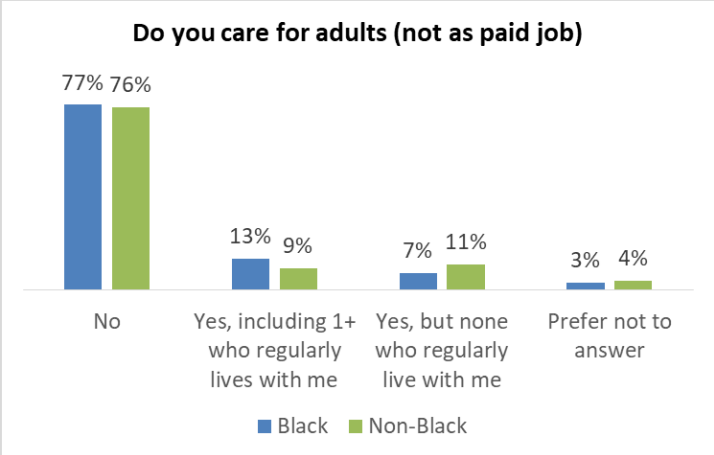
Which best describes the main reason you switched oncologists? (Only asked of those who had switched)



Are you the parent or caregiver of any children under 18 years old who regularly live with you?



Do you provide care for any adults who are in your life (not as your paid job)?



Appendix G: References

[1] Green A. African Americans Are Largely Excluded From Cancer Clinical Trials - Cancer Health (accessed July 27, 2022)

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