

# Participation of Black Americans in Cancer Clinical Trials: Current Challenges and Proposed Solutions

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## INTRODUCTION

Clinical trials provide the highest level of evidence in evaluating the safety and efficacy of new cancer therapies. Lack of participation in clinical trials was associated with worse survival outcomes in some malignancies. Moreover, clinical trial participants were reported to live longer than patients receiving Medicare who were treated with US Food and Drug Administration (FDA)-approved cancer drugs.<sup>1,2</sup> For some patients with cancer, a clinical trial may be the only remaining treatment option.<sup>3</sup>

Black Americans constitute at least 13% of the general population in the United States, and the percentage will continue to grow further in the coming years.<sup>4</sup> The death rate from cancer is more common in Black Americans, especially males. The largest difference is for cancers of prostate, stomach, uterine corpus, and multiple myeloma (MM) where Black American death rates are about twice as high when compared with Whites.<sup>4</sup>

Black Americans are under-represented in cancer clinical trials. Taking MM as an example, a cancer in which Black Americans account for about 22% of yearly cases, 32,270 new cases are estimated to occur per year.<sup>5</sup> The age-adjusted incidence rate difference in the period 2011-2015 for development of MM was 8.4 and 7.2 per 100,000 population higher for male and female Black Americans, respectively, when compared with Whites.<sup>5</sup>

In trials submitted in support of MM indications, the median enrollment percentage of Black Americans was 4.5%.<sup>6</sup> Across all studies that resulted in a US FDA cancer drug approval in a 5-year period, Black Americans were under-represented.<sup>7</sup> Participation to prevalence ratio was low in all cancer subtypes with an average Black Americans enrollment percentage of 7%.<sup>7</sup> Reporting race in cancer clinical trials is sub-optimal and needs further improvement.<sup>8</sup>

Improving Black American enrollment in cancer clinical trials is important not only to ensure generalizability of the results but also to provide an opportunity to study cancer biology and response to therapies across different patients' subgroups. This will provide an

opportunity to study therapeutic response across different sociodemographic groups. Differences in biologic responses may result in increased resistance to some medications.<sup>9,10</sup> Improving Black Americans' enrollment in cancer clinical trials is also important to provide high-quality and potentially beneficial care to the participants.

Sampling bias or ascertainment bias is a consequence of poor enrollment of Black Americans in clinical trials. It results from a lower sampling probability of Black Americans as part of the intended study population. In other words, Black Americans are not equally likely to be selected as participants in clinical trials, and this will result in selection bias. This bias will result in a non-random sample (predominately White participants), and the results will not be generalizable to the population with the studied cancer. This is especially significant when the studied cancer is more common in Black Americans.

Here, we discuss some current challenges and proposed solutions to help in increasing the enrollment of Black Americans in cancer clinical trials. We propose the least acceptable race-specific percentage as a new bar that registrational clinical trials need to pass before cancer drugs approval.

## BARRIERS FOR BLACK AMERICANS PARTICIPATION IN CANCER CLINICAL TRIALS

Multiple studies provided potential reasons for lack of appropriate representation of Black Americans in cancer clinical trials. Barriers can be divided into three major categories, which interact and overlap with each other (Table 1).

### Factors Related to Clinical Trials

The design of clinical trials, which includes strict inclusion or exclusion criteria, can render many Black Americans ineligible for participation.<sup>11</sup> A single-institution study of 235 Black Americans cancer patients found that only 20 patients (8.5%) were eligible based on inclusion criteria with most patients excluded for co-existing comorbidities.<sup>12</sup> Even among eligible patients, the enrollment rate was 60%. It is also important to take biologic factors

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into consideration when designing a clinical trial, for example, one prostate cancer trial required serum testosterone levels to be < 50 ng/dL and did not take into consideration that Black Americans have a 15% higher testosterone levels compared with their White counterparts.<sup>13</sup> Other biologic differences should be considered such as glomerular filtration rate and hemoglobin level although the use of race-based cutoffs for hemoglobin and glomerular filtration rate (and other lab tests) is highly controversial. Trials that do not consider racial difference in laboratory values would exclude potentially appropriate participants solely because of normal laboratory differences related to their race.<sup>14</sup>

To conduct a cancer clinical trial, a specific infrastructure that includes trained research staff is needed. Most of the cancer clinical trials are conducted at major academic cancer centers. Many Black Americans may not have access to those centers, which will result in lack of opportunity to participate.<sup>15</sup> Black Americans are disproportionately more likely to receive care in under-resourced hospital systems and to be uninsured.<sup>16-18</sup> Many clinical trials will require patients to use their insurance benefits for follow-up testing and specific treatments, which may not be available for Black Americans. On the other hand, lengthy enrollment and follow-up requirements may result in dissatisfaction and low participation in cancer clinical trials. As a result of many of the above factors, retention rate in Black Americans may be different. One study showed that Black Americans' disengagement from clinical trials is twice that of Whites.<sup>19</sup>

**Factors Related to Patients**

Access to care is a complex process and could limit utilization of clinical trials. For example, the rate of screening colonoscopy is 8% lower in Black Americans.<sup>20</sup> This leads to late diagnosis, which is often associated with poor performance status and worse clinical outcomes. This may result in exclusion of those patients from participation in clinical trials.

Lack of comfort with the process of clinical trial, which includes fear of being treated unequally and of the outcome of experimental drug, has been identified as a barrier to enrollment in clinical trials.<sup>21-23</sup> A systematic review of the factors that influenced participation of Black Americans in cancer clinical trials reported religious beliefs, low clinical trial awareness level, and structural barriers, such as access to health care and transportation, as potential causes for lack of appropriate participation.<sup>24</sup>

Financial constraints are another major barrier. Days off work and childcare cost are usually not covered by clinical trials. Patients in households making less than \$50,000 per year were 27% less likely to participate in clinical trials.<sup>25</sup> The median household income for Black Americans is \$20,000 lower when compared with that for non-Hispanic White Americans.<sup>26</sup> Other financial constraints include the lack of transparency in coverage policy and rising cost of cancer care. This led organizations like ASCO and Lazarex Cancer Foundation to consolidate efforts implementing legislation at the federal and state level.

With sponsorship of Lazarex Cancer Foundation, California was the first state in the United States to legally recognize the financial burdens afflicting patients with cancer seeking treatment in clinical trials. The California law differentiates between inducement and reimbursement with recognition of ancillary costs as a barrier to clinical trial participation.<sup>27</sup> It identifies the allowable expenses that can be reimbursed to patients and encourages industry support of these costs. Lazarex helps patients with advanced-stage cancer and the medically underserved with costs for FDA trial participation, identification of clinical trial options, community outreach, and education. Improving Patient Access to Cancer Clinical Trials, one of the initiatives launched by Lazarex, showed preliminary promising results with approximately 60% participation from minority patients.<sup>28</sup>

Lower level of health literacy may contribute to low participation in cancer clinical trials. Health literacy includes a wide range of skills that people need to make informed choices.<sup>29</sup> Black Americans were reported to have lower health literacy levels when compared with non-Hispanic Whites.<sup>23</sup>

A study looking at attitudes of Black Americans toward medical research found that many participants assumed that the trial consent forms were protecting hospitals and doctors from any legal responsibility.<sup>30</sup> The same study showed that most participants were in favor of medical research if they were not treated as guinea pigs, which reflects a lack of proper clinical trials education.

**Factors Related to Health Systems**

Racism, research misconduct, and low-quality health care have led many Black Americans to be skeptical regarding health care institutions in general and clinical research enrollment specifically.<sup>31-33</sup>

Health care providers play a crucial role in the enrollment of Black Americans patients into clinical trials.<sup>34,35</sup> Patient

**TABLE 1.** Barriers Facing Proper Black Americans Participation in Cancer Clinical Trials

Factors Related to Clinical Trials	Factors Related to Patients	Factors Related to Health System
Clinical trial design	Access to care	Racism
Eligibility criteria	System or provider distrust	Lack of incentives to participating hospitals
Participating centers	Availability awareness	Lack of laws to enforce equal representation
Lengthy enrollment and follow-up requirements	Lack of clinical trials education	

accrual was affected by provider attitude related to patient adherence to the study protocol.<sup>35</sup> A study of Black women to explore factors associated with the decision to participate in cancer screening trial showed that almost all women reported that their doctor had never talked to them about participating in a clinical trial.<sup>36</sup>

Other health system–related factors include lack of incentives to participating hospitals and lack of laws to enforce equal representation. Implicit bias, which includes conscious and unconscious portions, among physicians may lead physicians to believe that Black Americans are less likely to be compliant with the study.<sup>37,38</sup>

## PROPOSED SOLUTIONS

Since the problem is complex, the solution will not be straightforward. Previous efforts to minimize lack of minority representation in clinical trials include the revitalization act of 1993, which requires that clinical trials funded by the National Institutes of Health to include women and participants from minority groups. However, in the field of oncologic clinical trials, many trials are industry-sponsored, which may not adhere to similar regulations. This may result in even lower participation in industry-sponsored clinical trials.<sup>39</sup> In 2003, ASCO established a formal group of cancer health disparities and health equity experts to focus on understanding and eliminating disparities in cancer care. This was followed by the first ASCO policy statement on cancer care disparities, which highlighted the society's commitment to enhancing awareness, support of research on health disparities, and improving cancer care access for minority groups.<sup>40</sup> In 2013, ASCO established a Health Disparities Committee, which later became the Health Equity Committee. This committee is responsible for collaboration within ASCO and with other cancer care stakeholders to improve health equity for patients with cancer. Recently, an updated statement issued by ASCO stressed on the need to move beyond descriptions of differences in cancer outcomes toward cancer health equity.<sup>41,42</sup>

Efforts from National Institutes of Health, FDA, ASCO, and other groups draw a path for a change; however, such efforts will need the appropriate support to succeed. Health equity–promoting agencies should be empowered to set and enforce guidelines for the recruitment of minorities in clinical trials and should require scientific justification for limited or selected study population enrollment.

### Cancer Clinical Trial Design Modification

Biased statistical design can help in diluting the sampling bias. It means to enroll more Black Americans in cancer clinical trials to try to eliminate the sampling bias. The ideal way of doing that is to aim for a proportion of Black American participation that is similar to their proportion in the incident cases.

For example, if we want to match the enrollment proportion of Black Americans with Whites in MM clinical trials, we will

need to enroll 22% of the calculated sample size as Black Americans in a study that will look into patients with newly diagnosed MM in the United States

The lowest acceptable race-specific percentage should be a new bar that clinical trials need to overcome before drug approval. This should be applied initially for registrational trials to ensure that an approved cancer drug will be a suitable option for all patients under the studied cancer. A 10-year implementation goal can be entertained (Fig 1). If such a model is enforced by institutions like the FDA, it will direct the sponsor of the trial to the hospitals or clinics that serve more Black Americans to open sites of enrollment.

Finding the right balance between attempts to recruit a diverse patient population and trial logistics is an inherently difficult and costly endeavor. Attempts to increase diversity may result in trial delays, and this should be balanced with the need to get drugs and therapies approved. It is also known that increasing trial time maybe more expensive, and this could possibly lead to price increase by pharmaceutical companies to offset rising costs.

### Financial Support

Although the impact of incentives on recruitment and retention in practice is still not well-described, attempts to lessen the financial burden associated with participating in clinical trials by covering not only the cost of the drug but also copayments and coinsurance will be helpful. Covering indirect expenses like time off from work, childcare, and transportation would theoretically improve access and participation in clinical trials especially for lower-income patients. The ASCO Health Disparities Committee issued a policy statement with recommendations to overcome financial barriers. Some of the recommendations included the use of a transparent process to estimated out-of-pocket cost of participation in clinical trials and provide financial support to cover those costs.<sup>43</sup> Medicaid, which covers nearly 20% of Americans, is not federally required to cover routine costs of participation in clinical trials, and many states do not explicitly require such coverage. Reduction in co-pays and deductibles for clinical trial participants can be a potential option.

Funding agencies should include ethnicity and race as criteria for assigning priority scores. These scores are currently used to evaluate the expected impact of a particular research and include assessment of significance, innovation, and approach. The final score usually determines the grant funding. By incorporating ethnicity and race, researchers applying for funding will at least be required to actively try to recruit Black Americans. Similar approaches have been taken when evaluating sex or gender inclusion.<sup>44</sup>

### Improving Accessibility and Community Reach Programs

Allowing study centers with easy access to Black Americans to be part of cancer clinical trials will help in recruiting

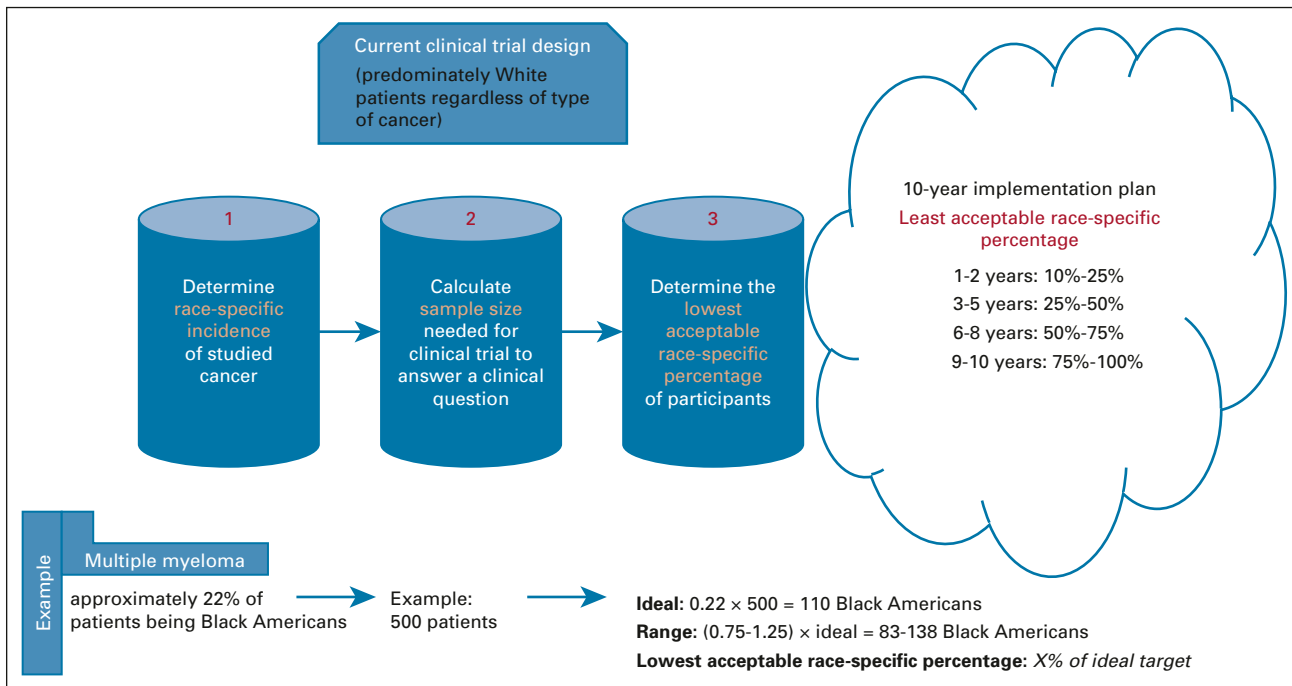


FIG 1. A proposed implementation plan of the least acceptable race-specific percentage.

patients. Black American researchers, research coordinators, patient advocates, and previous trial participants will help in recruiting more Black American patients.<sup>35</sup> The benefits from enrolling in cancer clinical trials can be more attractive for Black Americans given possible higher responses to studied therapies.<sup>45,46</sup> Increasing community involvement, incentivizing collaboration among different groups, and involving community hospitals in the recruitment to clinical trials will not only increase access for minority groups but would likely also result in a quicker enrollment process. National Cancer Institute (NCI)-designated centers have launched an NCI community oncology research program to bring cancer clinical trials and care delivery studies to people in their communities. This is particularly important in the current era of genomics and molecular targeted therapy as the majority of cancer care takes place in the community setting.<sup>47</sup> The increasingly complex requirements of genomic testing, such as next-generation sequencing and tissue biopsy testing, may serve as an extra obstacle for improving community oncology research participation. Some potential solutions include improving coordination between community oncology centers or oncology practices and a nearby NCI-designated cancer center(s) along with backup support system to provide community sites with several linings of support according to their need.

### Patient-Centered Approaches

Targeting enrollment toward specific cultural backgrounds and literacy levels may improve recruitment of under-represented populations.<sup>17</sup> Patient navigation models,

which involve the process of providing educational and facilitative services to the patient, have been proposed to improve the retention of Black Americans in cancer clinical trials with one study showing an increase of participation from 9% to 16%.<sup>48</sup>

Several patient-focused interventions have been developed. In a multicenter, randomized trial of a web-based interactive, education tool in patient with cancer was conducted. Its aim was to increase knowledge, decrease attitudinal barriers, and improve preparation for making decisions about clinical trials. The control group received a standard text-based general information about clinical trials from NCI, whereas the intervention group watched a brief, individually tailored video addressing knowledge and attitudinal barriers to clinical trials participations. Although both groups showed improved knowledge, the intervention group has a significant increase in their preparedness to consider participation in clinical trials.<sup>49</sup>

### Health Care-Centered Approaches

Attempts to reduce the impact of bias in clinical interactions have been made. They include training health care professionals in the use of high-quality patient-centered communication. To successfully enroll Black Americans in clinical trials, health care providers must be culturally sensitive with appropriate communication skills.<sup>50</sup> Specific training curriculum to recognize race and ethnic cultural barriers to participation and understand the structure and function of family units and sex dynamics in different cultures emphasis should be implemented to bridge cultural gaps between participants and research professionals.<sup>51</sup>

To mitigate the lack of clinical trials in under-resourced hospitals servicing Black American patients, several associations have established programs to increase the enrollment among minority groups. The NCI established the Minority-Based Community Clinical Oncology program (MBCCOP), which is a national network of health professionals, investigators, and organizations that conducts cancer-related research across the United States.<sup>50</sup> The network developed outreach programs (eg, minority-targeted media outlet, presentations at minority churches, and distributed fliers at minority health fairs) at institutes that serve large numbers of minorities with cancer. The network enrolled more than 5,500 minority patients with cancer in NCI-sponsored clinical trials, although overall successful it failed to show improved enrollment of premenopausal Black American women in breast cancer trials.<sup>52</sup> Barriers to MBCCOP success include many of the factors we discussed above such as inclusion or exclusion criteria and poor national adoption. We believe that programs such as MBCCOP have the potential to succeed although it will require collaboration between health care microsystems and adopting a systematic series of improvement strategies.

Digital clinical trials, which use digital technologies as part of their design and conduct, can help in enrolling more patients from minority ethnic groups. This becomes particularly helpful for patients who do not live close to a research site or have scheduling constraints. It can also be used to recruit, obtain informed consent, and follow up enrollment milestones. It is still in its infancy stages; however, the use of technology in clinical trials will be the future and will continue to evolve.<sup>53</sup>

In conclusion, the lack of diversity in cancer clinical trials remains a major scientific challenge. The oncology community is obligated to improve participation of Black Americans in cancer clinical trials. With the pace of scientific advancement in the field, reassessment of our current approach to clinical research and recruitment is needed. We introduce the least acceptable race-specific percentage as a statistical method to help end the long-lived disparities that Black Americans are facing. We must strive to fulfill our moral and scientific duty of achieving social justice for under-represented communities when conducting cancer clinical trials.

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