

# Recruiting and enrolling minority patients to cancer clinical trials

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In an effort to improve minority participation in clinical trials, the United States government passed the National Institutes of Health Revitalization Act of 1993, which mandated the inclusion of women and minorities in clinical research. The National Cancer Institute launched the Minority-Based Community Clinical Oncology Program to increase access to cancer clinical trials among racial and ethnic minorities. Although these initiatives have resulted in some success, minority participation in cancer clinical trials remains low. This article reviews the problem and the reasons why it is important, and offers a number of specific solutions.

**T**he rates of minority participation in cancer clinical trials are disproportionately low<sup>1,2</sup> and have been declining in recent years.<sup>3</sup> While patient barriers to participation are significant (eg, mistrust of medical institutions and language and literacy issues), physician and system-level barriers also perpetuate this situation.

Barriers to physician referral and participation include lack of awareness of active clinical trials; a belief that standard therapy is best; assumptions about patient eligibility, research, and inconvenience of participation; concern about loss of control over patient care; and perceived administrative and financial burdens.<sup>2,4-7</sup>

System-level factors include lack of an adequate

number of protocols in a given area, research design (eg, rigid exclusion criteria), costs related to participation, and the limited numbers of racial and ethnic minority healthcare professionals involved in research.<sup>2,8-12</sup>

Community oncologists are in an excellent position to recruit minority patients into clinical trials. Community-based practices offer minority patients easy access to clinical trials under the supervision of their local oncologist. **The benefits for community oncologists include:**

- Increased visibility within the community through outreach programs, leading to increased patient referrals.
- Increased access to important clinical trials.
- Opportunity to make important contributions to cancer clinical research in efforts to reduce disparities in cancer mortality.
- New or enhanced partnerships between academic centers to accelerate the pace of scientific discovery.

## How to get there from here

Increasing minority participation in cancer clinical trials requires making changes to the doctor/

### KEY POINTS

Despite government efforts, participation of minorities in clinical trials remains low.

There are a number of barriers to physician referral and minority patient participation.

To increase minority participation, a number of changes are needed in the doctor/patient relationship, in the practice itself, and in outreach to the community.

This article offers a series of concrete steps that practitioners can take, as well as a list of resources.

Community oncologists are in an excellent position to recruit minority patients and stand to benefit from doing so.

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## Why is minority participation in cancer clinical trials important?

**THE MORTALITY RATE** for all cancers combined is approximately 33% higher in African-Americans than in Caucasians.<sup>13</sup> Without sufficient minority enrollment in prevention, early detection, and treatment trials, it is difficult to address this disparity.<sup>3,14,15</sup> It's also impossible to distinguish the impact of socioeconomic status from race on responses to treatment and overall outcomes, or to examine minority-group differences.<sup>3,10</sup>

patient relationship and to the practice itself, and improving relationships within the community.

### *Changing the doctor/patient relationship*

**Before discussing trial participation, maximize patients' trust and rapport.** Patients who don't feel comfortable with their current treatment are unlikely to engage in clinical trials. Before broaching the subject of a potential trial, it's important to assess the patient's feelings and attitudes about his or her treatment.

**Learn about your patients' fears and concerns about participation.** Patients might have erroneous perceptions about what a control group is, or they may be wary of receiving a placebo. Patients might also be worried about side effects of a treatment or may be fearful of being "experimented" on. It's important to uncover these issues and address them.

**Talk about any past experience the patient has had with research.** Some patients have misperceptions about research, such as the belief that informed consent serves as a liability waiver for researchers rather than protection for trial par-

ticipants. In your discussions with patients you can acknowledge and dispel these myths.

**Give patients sufficient information about clinical trials.** Patients will be most receptive to participating in trials if they receive comprehensive information, whether conveyed by their physician or clinical staff or through print materials or videos.

**Learn about the patient's concerns about the trial burden.** Patients might struggle with many logistical barriers to trial participation, such as complicated and time-consuming protocols, repeated trips to the healthcare center, and competing work and family demands. If these concerns are accurate, you can suggest needed resources to a patient. If these concerns are unfounded, you can provide reassurance.

**Discuss any potential costs with the patient.** Patients might have inaccurate perceptions about the costs of participation. For example, transportation costs might be a barrier for some patients, so they should be told whether trial participants will be reimbursed. Patients should be made aware of costs they might incur, such as routine care and tests outside the therapeutic agents covered by the grant.

**Involve the patient's family in the dialogue.** Many patients will not make any treatment decisions without first conferring with family members. Involving family members in discussions about clinical trials could help patients feel less burdened about making this decision themselves. This could also provide an opportunity to address any cultural or religious barriers that may exist. Keep in mind that patients might be influenced by family members' negative and positive attitudes regarding clinical trials. If family members are involved in the discussions about taking part in clinical trials, these negative attitudes will be brought out in the open.

### *Changes to the oncologist's clinical practice*

**The entire staff must be committed to the goal of improving minority participation in clinical trials.** Physicians must convey to everyone, from the nurses to the support staff, that improving services for minority patients is an important priority of the practice. The clinical research coordinators need everyone's support to recruit and retain minority patients on clinical trials.

**Educate and train your staff to explain clinical trials to prospective minority patients.** Aside from knowing the protocol requirements and good clinical practice, the staff needs to be sensitive to barriers, myths, beliefs, and norms of minority groups. Written materials about clinical trials should be available in plain language and where possible, be provided in different languages. (See the Resources box at the end of this article.) Staff should also learn effective communication skills in order to improve their ability to assess minority patients' level of acceptance and concerns about treatment in a clinical trial (See the ENACCT Web site listed below.)

**Diversify the staff within your practice.** An ethnically diverse and bilingual staff can improve the credibility of the practice within the minority community.

**Select appropriate clinical trials.** It's important not to be too ambitious about opening clinical trials when considering minority populations. Clinical trials that require extensive follow-up and testing may be difficult for patients who have limited access to your practice.

### *Improving outreach and relationships with the community*

**Foster relationships with community leaders.** Developing relationships with key community leaders, such as clergy, political leaders, business leaders, or esteemed community elders, can help you gain in-

sight into recruitment barriers in that community and the best ways to overcome these barriers.<sup>16</sup>

#### **Network with these leaders.**

They can help you identify community spokespersons and connect you and your staff to other key people and organizations. They can also help you foster community trust by showing support for your practice and clinical trials (especially if they themselves have participated in a trial).<sup>17</sup> These individuals can introduce you and your staff at educational programs and local meetings and can attest to the merits of the study with their families, friends, and neighbors. They can also provide quotes for brochures, newsletters, and inserts into church bulletins.<sup>1,16</sup>

**Form partnerships with local organizations.** Churches, neighborhood associations, libraries, and senior groups/centers are key venues for getting the message out about clinical trials through brochures and newsletters, for example. To the extent possible, involve community leaders in developing recruitment strategies and materials; this demonstrates respect for the value of community partners and increases support and enthusiasm for the research.<sup>18</sup>

**Make educational presentations to the community.** Cancer-related knowledge is poor among most people. Educating your target population—including community leaders and spokespersons—about cancer prevention, early detection, and treatment options is necessary to enhance clinical trial recruitment.<sup>1,17</sup> Presentations about cancer and clinical trials at schools, churches, clinics, and even on local radio shows can help you build respect and trust in a community. Keep in mind that to be effective, presentations should deliver information at the right health literacy level and in a culturally appropriate manner. Presentations should recognize the shortcomings of past research with minority groups and should demonstrate sensitivity to their present needs.

## Resources

### **Education Network to Advance Cancer Clinical Trials (ENACCT)**

- [www.enacct.org](http://www.enacct.org)
- 301-562-2774

### **National Cancer Institute**

For general information:

- [www.cancer.gov](http://www.cancer.gov)

### **The Community Clinical Oncology Program (CCOP)**

For information on the minority-based program of CCOP, a network for conducting cancer prevention and treatment clinical trials by community physicians, go to [www.cancer.gov/Prevention/ccop/mbccop.html](http://www.cancer.gov/Prevention/ccop/mbccop.html).

For educational materials for patients, go to <http://cis.nci.nih.gov/> (or [www.cancer.gov/espanol](http://www.cancer.gov/espanol) for the Spanish version). Most, if not all materials, are translated into other languages, primarily Spanish.

### **Partnership Program**

This program is committed to reaching minority and underserved populations that do not have adequate access to health information and services.

- <http://cis.nci.nih.gov/community/community.html>
- 1-800-422-6237; Spanish-speaking operators are available

### **American Cancer Society**

For educational materials:

- [www.cancer.org](http://www.cancer.org)
- 1-800-ACS-2345

Spanish-speaking operators are available; the hotline also offers translation services in all languages.

### **Society of Cancer Researchers Advocating Therapeutic Excellence for Special Populations**

Contact Mack Roach III, MD, Department of Radiation Oncology, University of California-San Francisco Medical Center

- [mroach@radonc.ucsf.edu](mailto:mroach@radonc.ucsf.edu)
- 1-415-353-7175/7183

**Reach out to primary care physicians in the community.** Making connections with primary care physicians, both in private practice and in clinic settings, can be key to gaining recognition of the importance of clinical trials—and to getting referrals. Hold educational sessions especially

designed for community doctors, nurses, and medical staff. Local doctors' offices and clinics are important places to distribute clinical trial brochures and educational materials. Community doctors may also be interested in being involved as collaborators in the design and implementation of clinical trials.<sup>17</sup>

You can also hire practice liaisons who can serve as contacts for referrals. These liaisons should encourage open communication between oncologists and primary care physicians in the community.

### **Articulate the benefits of clinical trials to enhance accrual rates.**<sup>2,18</sup>

Benefits include identifying potential solutions to health problems of specific populations who are at unusually high risk and, in some instances, free medical tests, physician evaluation, and medication. For prevention or early detection trials, target groups should know that they can potentially decrease their cancer risk or improve their health. Involvement in trials can benefit future generations of racial and ethnic groups.

**Share research findings with the community.** Productive partnerships between community oncology practices and community members should continue beyond the recruitment phase of a specific clinical trial.<sup>19</sup> Ongoing involvement in the community, including sharing findings from clinical trials after they are completed, increases the potential for future enrollment and the likelihood that the community will receive maximum benefit from the research.<sup>18</sup>

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