

# Case Study: Community Engagement and Clinical Trial Success: Outreach to African American Women

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## Abstract

This brief report examines how the use of community engagement principles and approaches enhanced clinical trial recruitment and retention. The Community-Engaged Research Core (CERC), a CTSA-supported resource designed to facilitate community involvement in clinical and translational research, was consulted to provide assistance with the implementation of the clinical trial, and specifically to enhance participation of the target population—African American women. CERC's key recommendations included: (1) convene a Community Engagement Studio, (2) redesign the recruitment advertisement, (3) simplify the language used to explain the scope of the study, and (4) provide transportation for participants. As a result of these interventions, a comprehensive strategy to recruit, enroll, and retain participants was formulated. After implementation of the plan by the study team, enrollment increased 78% and recruitment goals were met 16 months ahead of schedule. Participant retention and study drug adherence was 100%. We conclude that community engagement is essential to the development of an effective multifaceted plan to improve recruitment of underrepresented groups in clinical trials. *Clin Trans Sci* 2015; Volume 8: 388–390

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## Case Presentation

A junior faculty member with research experience in a well-mentored and supportive research environment is the Principal Investigator (PI) for a National Institutes of Health–funded clinical study testing the effect of an FDA-approved drug for insulin sensitivity. The trial targeted African American women with metabolic syndrome and the recruitment goal was to enroll 46 participants. The funding support for the project included 3 years of study activities (active recruiting and investigation with volunteer participation).

## Study Design

The study was a double-blind, randomized, placebo-controlled clinical trial. Volunteers were required to attend seven clinic visits, three of which lasted 6 hours. During these visits, volunteers underwent multiple noninvasive tests, including ultrasound of brachial artery, blood draws, medication infusion, and urine collection.

## Challenges

To meet study goals, the PI developed a recruitment strategy based on her previous experience working with white women volunteers in similar studies.<sup>1</sup> The study was advertised through medical center mass email distribution and a volunteer match Website, with hard copy ads placed in elevators, bathrooms, bulletin boards, and corridors throughout Vanderbilt University Medical Center.

Once enrollment was initiated in April 2011, the email distribution yielded some interest, but the level of response declined over time. By July 2011, the volunteer matching Website returned only 12 potential participants and there was no response from any posted advertisements. To assist research staff, the PI explored other avenues for recruitment.

## Consultation with Community-Engaged Research Core

The investigator then consulted the Meharry–Vanderbilt Community-Engaged Research Core (CERC), a CTSA-funded

institutional resource that facilitates community involvement in clinical and translational research. The Community Engagement Studio (CES) is a forum developed to obtain input from patient, community members, and other nonacademic stakeholders to enhance the design, implementation, and dissemination of research. CERC facilitated a CES giving PI to the opportunity to engage with key community leaders who shared insight and suggestions for strengthening recruitment strategies.

In addition, CERC provided an online searchable database ([www.communityresearchpartners.net](http://www.communityresearchpartners.net)), which allows researchers to find potential community and academic collaborators, who share common interests. Through this database, the investigator found and formed a partnership with a community liaison, formally trained to facilitate dialogue and increase volunteer participation. This person was integrated into the research team and completed IRB-required CITI training on human research principles, IRB regulations and review, and the informed consent process, as well as the full employment process for Vanderbilt University Medical Center. The Community Liaison was responsible for coordination and implementation of all recruitment strategies for the trial.

## Results of Community Engagement

The community experts involved in the CES provided important feedback and workable suggestions. For example, the community experts shared that potential study participants may have a need for transportation assistance and appointment time flexibility. The experts reviewed recruitment materials and made specific suggestions about images and language. The study team redesigned recruitment materials, adding images that participants could identify with and reframed the text, including exclusion/inclusion criteria written in layman terms. Prior recruitment strategies were discussed and the research team developed a strategy tailored to the cultural values of African American women. The strategy was executed through several media and community-based

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approaches. Research showed, and the experts confirmed that a high group value rested on interpersonal relations (family and friends), spirituality, rhythm and imagery, and maintenance of family unity.<sup>2</sup> The research team agreed that it was vital to “meet potential study participants where they are.” A plan was devised to advertise the study in community settings that manifest these values: recreation, event outlets and radio advertisements, places of worship, and social service agencies and utility companies. Approval was granted by the Vanderbilt Institutional Review Board prior to the initiation of these activities.

## Outcomes

Figure 1 represents the accrual rate of volunteers in the study. The recruitment plan was implemented in July 2011 and the recruitment goal was achieved by July 2013, 16 months ahead of the projected schedule. A total of 132 volunteers were enrolled (consented and screened) and 46 volunteers were randomized to study intervention. All participants completed the study; there was no loss of follow-up. About 53% of subjects enrolled in this study were recruited from the community and did not have previous experience participating in clinical research. The retention of participants in this clinical trial was 100%.

## Discussion

Approximately 20 years ago the NIH Revitalization Act of 1993<sup>3</sup> was signed into law requiring women and members of minority groups and their subpopulations to be included in all NIH-funded clinical research. Since the Act's introduction, multiple approaches have been tried to promote the participation of these underrepresented groups in clinical trials<sup>4-6</sup> yet these racial and gender disparities remain a reality,<sup>6</sup> and minority women have

higher rates of chronic diseases such as diabetes mellitus.<sup>7</sup> This case demonstrated that effective community engagement can favorably impact the completion of a challenging clinical trial that targeted underrepresented or hard-to-reach populations to assess the efficacy of a study drug to improve metabolic parameters.

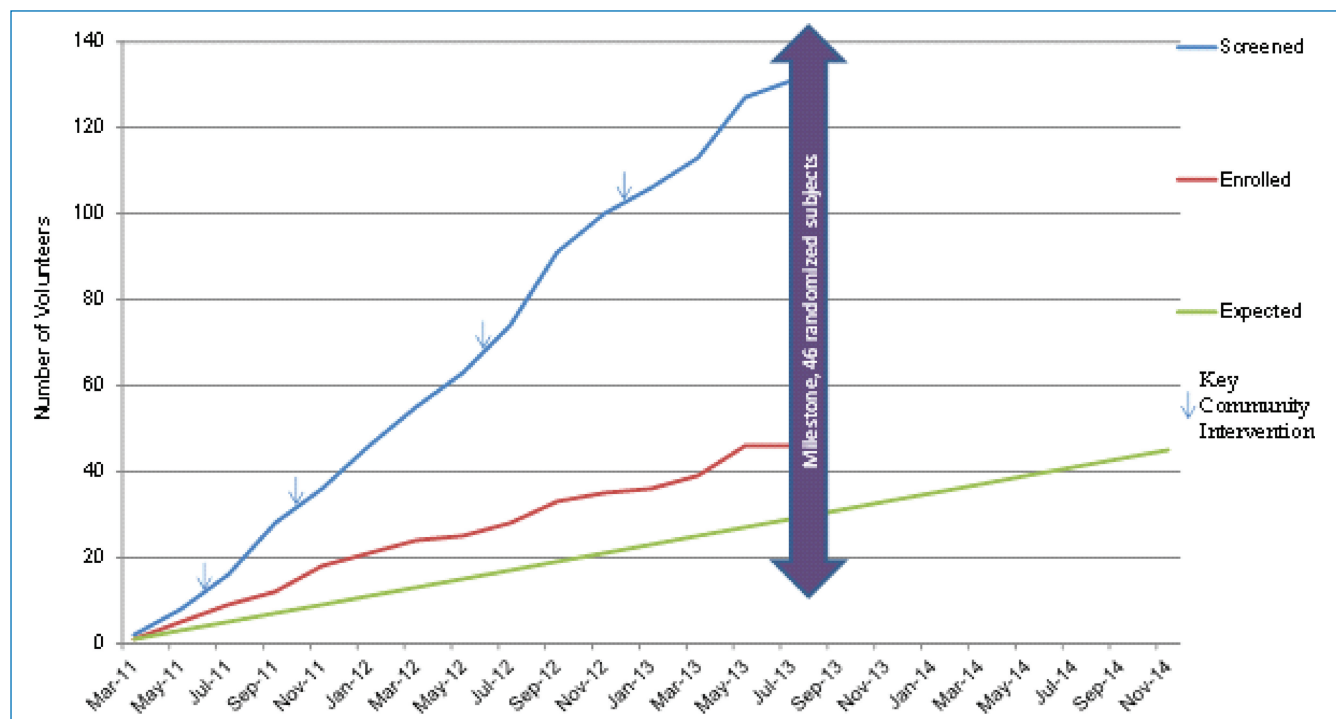
Engaging community members in the research process was pivotal to meeting the recruitment and enrollment goals for this project and CERC was instrumental in facilitating community involvement. CERC addressed key barriers to engaging communities, which many well-trained researchers lack the skills or experience to address.<sup>8,9</sup> The skills typically developed in rigorous research training often do not translate to identifying, recruiting, and convening patient and consumer groups;<sup>10,11</sup> therefore, resources like CERC provide valuable services to support clinical and translational research. With community involvement, the study team developed a tailored strategy to successfully recruit, enroll, and retain 100% of the research participants for the clinical trial.

In conclusion, engaging community members from the study's target population led to improved recruitment and enrollment and lower attrition in a complex, randomized, placebo-controlled clinical trial.

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**Figure 1.** Accrual rate. Green line reflects expected accrual rate. Red line is the actual accrual rate for randomized subjects; Blue line is the actual accrual rate for screened subjects. There is a divergence between the actual randomized and screened participants due to difficulties of the screened participants to meet inclusion criteria. Arrows represent key community interventions.

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