Category: Community Outreach and Engagement & Health Equity – Work in Progress

Community Recruitment Process for Cancer Trials: Expanding Access to Underrepresented Populations

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1. Background

Many Clinical Trials (CT) struggle to recruit diverse participants, particularly from communities beyond the institution's established patient population. Expanding outreach to eligible community members benefits the cancer centers and underserved populations. Our Community Clinical Trials Administration team has developed an enrollment process for community participants and successfully implemented it in cancer-related studies and minimal-risk CT. This approach demonstrates promising results for increasing trial diversity and accessibility while maintaining regulatory compliance.

2. Goals

This project aims to create an efficient, scalable process for recruiting community participants in cancer CTs. By partnering with community organizations and using digital platforms, it seeks to boost enrollment, enhance diversity, and streamline the recruitment workflow. The methodology addresses barriers to participation and provides a replicable framework for future recruitment efforts.

3. Solutions and Methods

The recruitment process employed a multi-channel approach utilizing informative flyers shared online via webinars, virtual events, and social media and at community events. QR codes on these materials directed potential participants to an electronic survey in REDCap or Qualtrics tailored with branching logic to assess eligibility. All survey instruments were developed during study pre-submission and included in the institutional review board (IRB) application.

To ensure data privacy and security, all surveys are housed within the Mayo Clinic firewall, allowing external access while restricting project administration to authorized study personnel with valid institutional credentials. This provided comprehensive audit capabilities for monitoring user activity.

For candidates meeting preliminary criteria, survey data was emailed to the study team and entered into PTrax for enrollment management. When additional medical verification was required, Release of Information (ROI) forms were obtained during consent visits to request external medical records.

Once eligibility is established, participants are contacted via phone to provide comprehensive protocol information. If they agree to participate, the consent document is electronically shared. Given sufficient time to review the consent form, a telehealth visit is conducted to verify understanding, address questions, and obtain consent.

4. Outcomes

Preliminary outcomes show that the process has successfully identified and enrolled 127 participants across three studies, all from underrepresented minority groups. Notably, 12 were not local and participated in a fully decentralized CT. The integration of remote consent for minimal risk studies have enhanced accessibility for individuals outside the local area, contributing to a more diverse trial population and expanding the reach of the studies.

5. Learned and Future Directions

Our experience yielded key insights that enhanced recruitment effectiveness. Clear, concise communication in recruitment materials and during community events proved crucial in helping potential participants understand trial criteria, benefits, and the importance of completing the QR-linked survey. This process simultaneously strengthened our enterprise-wide system for creating and maintaining research participant medical records.

Establishing a dedicated study email address, rather than listing specific personnel contact information on recruitment materials, eliminated the need for IRB modifications when staff changes occurred. Implementing electronic ROI forms with digital signatures removed barriers for participants unable to print-and-scan documentation.

Moving forward, we plan to expand this recruitment framework to diverse trial types, cultivate additional community organization partnerships, and optimize survey templates to capture more comprehensive participant information.