Case Study: Diverse Recruitment at Yale Center for Clinical Investigation
Yale School of Medicine's Integrative Approach to Recruit a Diverse Patient Population for Research

Summary
The Yale Center for Clinical Investigation (YCCI) was established in 2005 as one of the first recipients of NIH’s Clinical and Translational Science Awards (CTSA) and serves as a hub for clinical and translational research at Yale School of Medicine. As an institution, the Yale School of Medicine has been focused on building an integrated approach to clinical research and clinical research participation aimed to create a partnership that included both the University health system and the larger community. Since YCCI was formed in 2005 and Yale’s CTSA grant was awarded in 2006, both Yale School of Medicine (YSM) and the Yale-New Haven Health System (YNHHS) have greatly expanded their clinical practices. Supported by their CTSA, this expansion has made possible a more than 850% growth in industry-sponsored clinical trials, with NIH funding IRB-approved research requiring informed consent growing from less than 25% in 2006 to more than 70% in 2019.

The YCCI utilized a multipronged approach that included: (1) Cultural Ambassador Programs intended to foster a partnership with community leaders, and investigator teams; (2) leveraging patient portal in research by developing innovative ways of utilizing Electronic Health Records (EHRs) to house research activities; and (3) incorporating clinical research recruitment call centers with extended hours to accommodate patients interested in research outside of business hours.

Approach: Cultural ambassador program
One of the key objectives of the YCCI was to diversify clinical trials and research. In 2010 the Center, based on recommendations from a focus group, committed to diversifying clinical trials and research and initiated the Cultural Ambassador Program. The goal of the program is to partner with community leaders to engage community members to participate in research.

Partnerships were formed with the Connecticut African Methodist Episcopal Zion Churches (AME Zion), one of the oldest African American Congregations in the U.S. and Junta, one of the first Latino community-based non-profits in New Haven. Connecticut AME Zion and Junta partners select the Cultural Ambassadors, who then receive about 200 hours in research training. The Ambassador program roles include bidirectional collaboration, expressing community needs, ideas, and interest. They provide assistance in recruitment campaigns. They meet with YCCI investigators and research teams to assess protocols during the design phase, provide input on the recruitment plan, host activities in the community to raise awareness about ongoing research, translate study material and informed consent forms, and participate in community grand rounds that are held monthly.

Through this effort, YCCI has seen an increase in the participation rates of underrepresented populations across the health system each study engaging the Cultural Ambassadors has had participation of underrepresented groups ranging from 22% - 91%, with one exception at 12% underrepresented participation.
Leveraging patient portals for research

In March of 2015, Yale’s “Help Us Discover program” was enhanced through an integration effort with Epic, Yale’s enterprise-wide electronic health record. The integration, created as an opt-out enterprise, helped Yale to focus on many direct to patient innovations using Epic EHR, including the conversion of the “Help Us Discover” volunteer profile from a paper to an electronic profile available from a locally constructed Yale research tab in the MyChart patient portal.

Without any direct advertisements, the MyChart research profiles resulted in more than 3,329 new volunteers for clinical trials, with 2,603 individuals actually referred to and screened for a study. In addition, YCCI rolled out new direct to patient recruitment functionality through MyChart. This functionality allows the EHR to automate high level matching of patients based on study inclusion/exclusion criteria and sends alerts directly to the patient’s MyChart. Yale was the first Epic site in the country to utilize this new functionality in its live environment to aid recruitment. The platform has been used in 40 studies and data from those screened and enrolled showed that: 1) underrepresented minorities made up 35% of the interested respondents; 2) 40% of all responses came after business hours or on weekends; and 3) 57% of the underrepresented minority respondents came after hours as compared with 38% non-underrepresented minorities, suggesting that the digital outreach may enhance underrepresented minority recruitment by being available 24 hours a day.

These combined efforts have enabled Yale to recruit more than 26,000 patients to research studies in FY19, with underrepresented populations making up 31% of all participants in clinical research at Yale. YCCI efforts have improved not only improved broad participation in clinical trials but improved participation by underrepresented minorities by ~29%.

Points to consider

- This case study illustrates that creating long-term community partnerships with local organizations has extensive overarching benefits. The value of this includes building trust among historically underserved communities, improving the biomedical research landscape by incorporating diverse voices into shaping research questions, and increasing recruitment and retention efforts for clinical trials.
- It also highlights the importance of having an integrative multi-pronged methodology that links healthcare to research through patient portals.
- Additionally, having after hour and weekend services for patients interested in research eliminates the burden for patients having to take time off of work to explore their options around participating/volunteering for research.