

## **Clinical Research Diversity: Engagement and Enrollment Model**

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### **1. Background**

Only two percent of the ten thousand National Cancer Institute (NCI) supported clinical trials have sufficient diversity. Challenges to achieving diversity for early detection trials are different than for treatment trials. Typically, they are not offered in clinical settings, require enrollment of healthy individuals from the general public and in large numbers.

### **2. Goals**

To outline the benefits of a model of intentional integration of community outreach and engagement (COE) with clinical trials teams to increase geographic and racial/ethnic diversity in study enrollment. Using specific examples of how and when to integrate and comparing results from similar studies, one before integration and one after, we demonstrate the power of bringing each group's unique skills and expertise together in collaboration for the benefit of community.

### **3. Solutions and Methods**

Collaboration on two consecutive trials with the same sponsor served to test a new process to increase diversity in enrollment at OHSU Knight Cancer Institute's Early Detection Program (CEDAR). Both studies evaluated a multi-cancer early detection (MCED) test with a blood draw and return of result to participants. OHSU recruited for Trial 1 only at its own hospital site, and while we exceeded enrollment goals, our cohort was not diverse. Prior to Trial 2, the COE Team, in collaboration with longstanding community partners, used novel tools to assess feasibility of running subsites for enrollment. Deployed early in the trial planning phase, the Research in Oregon Communities Review (ROCR) system allows the community to determine Go/NoGo, identify obstacles, and gives opportunity for culturally appropriate adjustments to recruitment and implementation. Importantly, this bi-directional negotiation results in considerable buy-in from stakeholders.

Additionally, the COE Team connected the clinical trials research team to communities within the metro area during educational opportunities. The trials team implemented a variety of strategies within study preparations and operation to overcome barriers to recruitment and encourage participation.

### **4. Outcomes**

In the Trial 2 we are partnering with four remote health systems serving diverse communities, as well as establishing and continuing to cultivate communities in the metro area. Through collaborative problem solving with the community prior to trial initiation, we implemented tailored adaptations and gained community buy-in. These efforts have resulted in dramatic success: increasing our racial diversity more than four-fold (6% to 26%), ethnic more than 20-fold (0.4% to 11%) and nearly quadrupling rural enrollment (10% to 37%). Importantly, as evidence of sustained relationship building, new trials have launched and cancer prevention education is expanding in the subsite communities.

### **5. Learned and Future Directions**

Engaging the community early and collaboratively comes with challenges; be prepared to overcome hurdles, spend extra time and money to achieve partnerships that will be sustainable into the future.

*Category: Community Outreach and Engagement & Health Equity – Completed project*

Early Detection trials are not a passing fad and relying on established relationships will be critical to building representative cohorts.