



ENGAGE : A Collaborative Model for Diverse Clinical Research Empowerment, Navigation, Growth, Access, Guidance, and Equity

Saron Mekonnen, B.S., OHSU, Mireille Martinez, B.S., OHSU, Megan Lonhart, M.A.P.H.B., OHSU, Francis De Asis, M.P.H., OHSU, Danita Tracy Carter, B.S., OHSU, Laura Ferrara, M.A., OHSU, Kathleen Forrester, M.A., OHSU, Nima Nabavizadeh, M.D., OHSU, Olivia Monestime, B.S., OHSU, Diana Potts, M.P.A., OHSU, Derrik Zebroski, B.S., OHSU, Tiffani Howard, Ph.D., OHSU

Background

- Only 2% of the ten thousand NCI supported clinical trials have sufficient diversity.¹
- 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 public and in large numbers.
- Diverse communities are spread across 98,380 square miles of Oregon, making travel and accessibility to OHSU, Oregon's only academic medical cancer center, burdensome.



Figure 1: Map of diverse populations in Oregon Portland State University Population Research Center²

Goals Outline the benefits of a model of intentional integration of the Knight Community Outreach and Engagement (COE) team with research clinical trials team to increase geographic and racial/ethnic diversity in study enrollment. Show how intentional integration between COE and clinical trials increases diversity in trials and compare results from similar studies; one before integration and one after, to demonstrate the power of bringing each group's unique skills and expertise together in collaboration for the benefit of community. • Utilize the community readiness model called Research in Oregon Community Readiness System (ROCRS) to add subsites across the state. Guidance <u>Access</u> Navigation Growth Empowerment <u>Equity</u> Seeking Ensuring low-Building Helping Centering The goal: feedback barrier, participants community communities representation inclusive from trust through decisionunderstand and fairness in enrollment collaboration community making and access research, and opportunities throughout trials on trial teams the research process (ROCRS)

References

Methods

Table 1. Strategies utilized by clinical trial team and COE to increase study diversity. STRATEGY DESCRIPTIONS IMPACT **STUDY PREPARATIONS** Enrollment events within communities represented by staff 1A) Hiring & Training of diverse bilingual staff members led to increased enrollment of a diverse participant population **1B) Community Readiness Model** - Implementation of Added 4 study locations across the state, increasing enrollment in Research in Oregon Community Readiness System rural Oregon (ROCRS)³ 434 visits conducted in 8 non-English languages, 397 of which were 1C) Use of translated study material & interpretation in in Spanish 8 non-English languages Language barriers to enrollment reduced **STUDY OPERATIONS 2A)** Decentralization – offered clinics throughout Oregon 2000 participants eConsented 590 (9.78%) participants enrolled at mobile/nontraditional clinic including weekend, mobile/nontraditional clinic, and hybrid visit using electronic consent (eConsent) Required by community collaborators to enroll at their clinics **2B) Stipends for travel** including one that enrolled 597 participants **2C)** Providers as partners - Utilized grand rounds and Established and continued partnerships between COE, principal community education by PIs and local sub-Is investigators, local providers, and community clinics **COMMUNITY OUTREACH AND ENGAGEMENT** Participants from all areas were able to express interest in the trial **3A)** Community focused Promotion & Media – by calling one main phone number, or by accessing an online Traditional and digital media outlets with community interest form (8500 entries), and both vehicles allowed them to indicate preferred enrollment location specific messages and branding. (Figure 2) 85 educational and enrollment events **3B) Outreach Events & Cancer Screening** Invitation to participate through trusted community partner Education/Awareness alongside community partners increased interest. Lasting connections made in community Example: Oregon Chinese Coalition community champion posted on **3C) Community Champions** Advocates who promoted the study within their own social media, which was followed by a doubling of Asian enrollment in the 3 months after communities Aprobado por la IRB: 9/7/2022 Early Detection *****Galleri When cancers are About Galleri diagnosed early All cells in your body release DNA into the before they have bloodstream. DNA from cancer cells is differ than DNA from healthy cells. The Galleri test had the chance to looks for signals present in the blood that may be associated with cancer at the time of your blo draw. This test does not measure your genet spread, the overall risk of developing cancer in the future. 5-year survival rate is 4 times Important Safety Information higher than when The Galleri test is recommended for use in adult with an elevated risk for cancer, such as those diagnosed in later aged 50 years or older. The Galleri test does not detect all cancers and should be used in additio stages.^{1,2} o routine cancer screening tests recommended healthcare provider. Galleri is intended to detect **AYÚDENOS A DETECTAR MÁS RÁPIDO EL CÁNCER** cancer signals and predict where in the body the cancer signal is located Routine screening tests are recommende Results should be interpreted by a healthcare What is the PATHFINDER 2 Study because they have been proven to save lives provider in the context of medical history, clinical ov detecting some cancers earlier.³ It is time t Too often, cancer goes undetected until EL PROPÓSITO DEL ESTUDIO PATHFINDER 2 ES EVALUAR SI UN ANÁLISIS igns and symptoms. A test result of "Cancer Sign ook at cancer more broadly, in addition to the it is at an advanced stage. Thinking abou lot Detected" does not rule out cancer. A test resu 5 cancers that are routinely screened for tod of "Cancer Signal Detected" requires confirmatory the possibility of having cancer can feel The most important cancer is the one that vo overwhelming, but taking steps to find car agnostic evaluation by medically establishe DE SANGRE SIMPLE LLAMADO GALLERI PERMITE LA DETECCIÓN or your loved one may have - and beating i procedures such as X-Rays or imaging, endoscop early can help you feel more in control of y starts with knowing you have it health. The earlier that cancer is found, th lopsy to confirm cancer. higher the chance of survival. TEMPRANA DE MUCHOS TIPOS DE CÁNCER. If cancer is not confirmed with further testing, The PATHFINDER 2 Study will evaluate the ould mean that cancer is not present or testir Inder Epidemiology, and click resolution (SELTY FOLIAME) REPStati batabase: Incidence - SER1 18 Regis Research Data: Nov 20 persons aged 50 – 79 diagnosed 2006 – 2015. "Early Localized" innol localized tumors that have not spread beyond organ of origin. "Larg-ad" includes invasive cancers that have metastasized beyond the origin the ports of the body. performance of a multi-cancer early detection vas insufficient to detect cancer, including due to he cancer being located in a different part of the test, called Galleri, that can detect many types body, False-positive (a cancer signal detected who cancer through a simple blood draw. This test is ancer is not present) and false-negative (a cance being studied and is not approved or cleared b one AM, Howlader N, Krapcho M, et al. (eds). SEER Cancer Statistics Revie 5–2015, National Cancer Institute, Bethesda, MD, http://seer.cancer.gov/ 1995_2015/, based on November 2017 SEER data submission, posted to t 2 wahete Amril 2019 GRAIL Salem Health Hospitals & Clinics St. Charles ba Bay Area Hospital the Food and Drug Administration (FDA). It is no signal not detected when cancer is present) test CANCER Institute meant to replace the cancer screening tests yo esults do occur ealthcare provider may recommend, such as

Figure 2: Comparison of sponsor provided promotional pamphlet (left) and community focused promotional pamphlet (right) created by study team.

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olonoscopy or mammography



- buy-in.
- subsite communities.

Table 2. Trial and COE integration increases diversity

	OR Pop (2021)	Trial 1	Trial 2
Total enrolled	4.2 M	1735	6175
White	84%	94%	74%
Hispanic/Latino	13%	0.4%	11%
Black/African American	1.9%	0.5%	2%
Asian, Native Hawaiian, Pl	4.8%	1.9%	9%
Native American/Alaska Native	1.2%	0.6%	2%
Female	50%	68%	62%
Rural or Frontier	33%	10%	37%





Results & Outcomes

• In Trial 2, we partnered with 4 remote health systems serving diverse communities and established and continued to cultivate communities in the metro area (Table 2; Figure 3).

• Through intentional integration of COE with clinical trials teams and collaborative problem solving with the community prior to trial initiation, we implemented tailored adaptations and gained community

Importantly, as evidence of sustained relationship building, new trials have launched, and cancer prevention education is expanding in the

Figure 3: Integration of trials and COE in Trial 2 resulted in increased reach across Oregon.