

ENGAGE : A Collaborative Model for Diverse Clinical Research

Empowerment, Navigation, Growth, Access, Guidance, and Equity

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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.

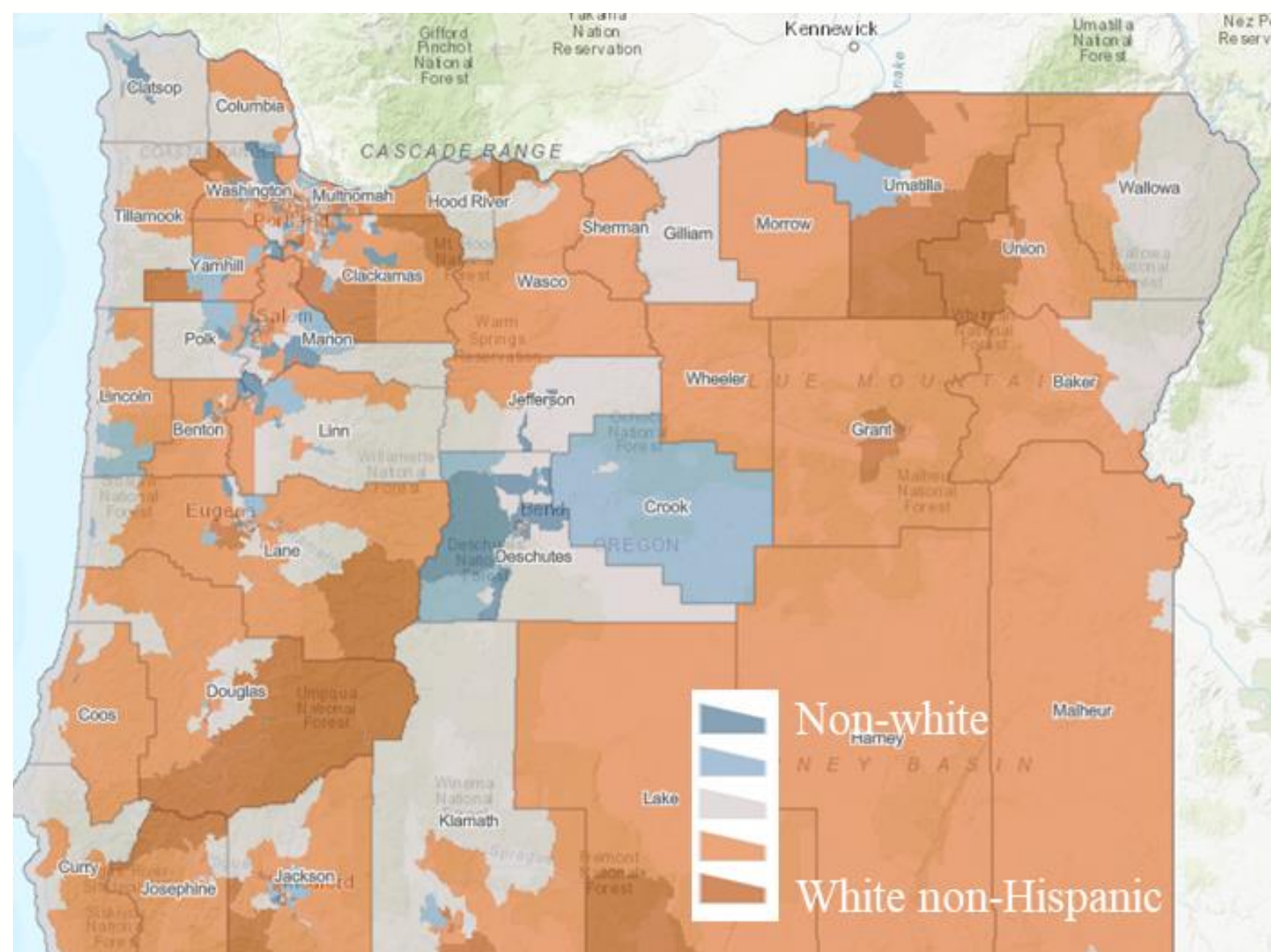


Figure 1: Map of diverse populations in Oregon
Portland State University Population Research Center²

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.

Methods

Table 1. Strategies utilized by clinical trial team and COE to increase study diversity.

STRATEGY DESCRIPTIONS	IMPACT
STUDY PREPARATIONS	
1A) Hiring & Training of diverse bilingual staff	Enrollment events within communities represented by staff members led to increased enrollment of a diverse participant population
1B) Community Readiness Model - Implementation of Research in Oregon Community Readiness System (ROCRS) ³	Added 4 study locations across the state, increasing enrollment in rural Oregon
1C) Use of translated study material & interpretation in 8 non-English languages	434 visits conducted in 8 non-English languages, 397 of which were in Spanish - Language barriers to enrollment reduced
STUDY OPERATIONS	
2A) Decentralization – offered clinics throughout Oregon including weekend, mobile/nontraditional clinic, and hybrid visit using electronic consent (eConsent)	2000 participants eConsented 590 (9.78%) participants enrolled at mobile/nontraditional clinic
2B) Stipends for travel	Required by community collaborators to enroll at their clinics including one that enrolled 597 participants
2C) Providers as partners - Utilized grand rounds and community education by PIs and local sub-Is	Established and continued partnerships between COE, principal investigators, local providers, and community clinics
COMMUNITY OUTREACH AND ENGAGEMENT	
3A) Community focused Promotion & Media – Traditional and digital media outlets with community specific messages and branding. (Figure 2)	Participants from all areas were able to express interest in the trial by calling one main phone number, or by accessing an online interest form (8500 entries), and both vehicles allowed them to indicate preferred enrollment location
3B) Outreach Events & Cancer Screening Education/Awareness alongside community partners	85 educational and enrollment events - Invitation to participate through trusted community partner increased interest. - Lasting connections made in community
3C) Community Champions Advocates who promoted the study within their own communities	Example: Oregon Chinese Coalition community champion posted on social media, which was followed by a doubling of Asian enrollment in the 3 months after

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 buy-in.
- Importantly, as evidence of sustained relationship building, new trials have launched, and cancer prevention education is expanding in the 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, PI	4.8%	1.9%	9%
Native American/Alaska Native	1.2%	0.6%	2%
Female	50%	68%	62%
Rural or Frontier	33%	10%	37%

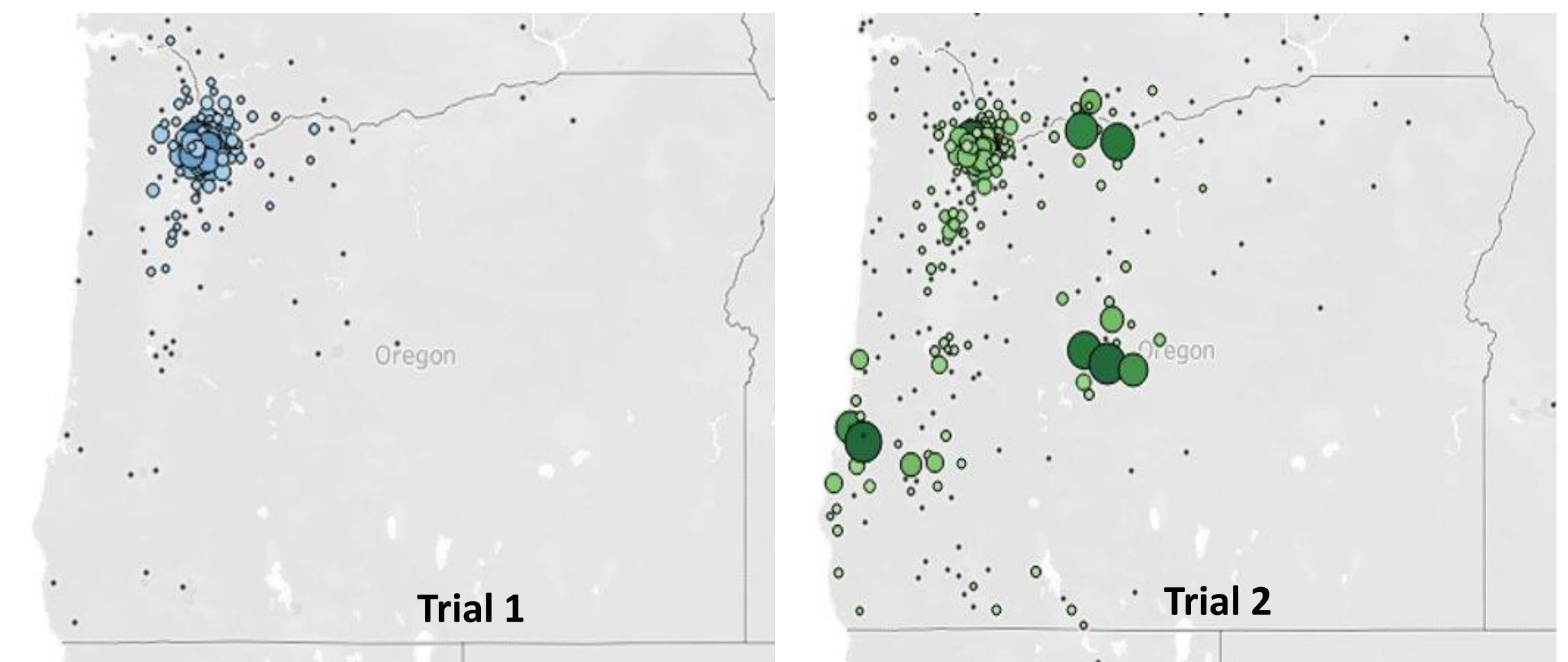


Figure 3: Integration of trials and COE in Trial 2 resulted in increased reach across Oregon.

Future Directions



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

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Empowerment Centering communities in decision-making
Navigation Helping participants understand and access trials
Growth Building community trust through collaboration
Access Ensuring low-barrier, inclusive enrollment opportunities
Guidance Seeking feedback from community throughout the research process (ROCRS)
Equity The goal: representation and fairness in research, and on trial teams

References

- Aristizabal P. (2020). Diverse populations and enrollment in pediatric cancer clinical trials: Challenges and opportunities. Pediatric blood & cancer, 67(11), e28296. <https://doi.org/10.1002/pbc.28296>
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