



Social Determinants of Health and Impact on Care Disparities. Pharmacist Role, Patient Education about Trials

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In your opinion, do you believe pharmacists could play a significant role in improving clinical trial enrollment rates?

- Yes, I strongly believe pharmacists have a significant role.
- Yes, I believe pharmacists have some role.
- No, I don't think pharmacists play a significant role.
- I am unsure.

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RESULTS



Learning Objectives



Investigate and discuss patient advocacy case studies as they relate to clinical trial enrollment.



Explain the role of Social Determinants of Health (SDOH) in influencing clinical trial enrollment.



Differentiate between clinician barriers, patient barriers, trial barriers, and institutional barriers to clinical trial enrollment.



Explore evidence-based interventions that enhance oncology clinical trial enrollment that are relevant to pharmacists



Case Study: Zip Code Disparities

Case 1

- Maria, a 52-year-old woman, has lived in zip code 33311 for most of her life. She is **insured through her employer**, which offers comprehensive health coverage. Maria has a primary care physician who emphasizes **regular check-ups** and preventive care. As a result, she has been **proactive** in managing her health and participating in **early cancer screenings**.
- In 2020, Maria was diagnosed with breast cancer after a routine mammogram revealed abnormalities. Her healthcare team identified her as a suitable candidate for a clinical trial testing a novel targeted therapy. Maria eagerly enrolled in the trial, benefiting from cutting-edge treatment options not widely available. Her cancer responded positively to the experimental therapy, and she experienced a higher likelihood of achieving remission and an improved quality of life.



Case Study: Zip Code Disparities

Case 2

- Robert, a 58-year-old man, also calls zip code 33311 home. However, his healthcare journey has been marked by barriers. He works **part-time in a low-wage job** and **lacks health insurance**. Financial constraints have **prevented** him from seeking **regular medical care** and cancer screenings.
- In 2019, Robert began experiencing persistent cough and fatigue. When he finally sought medical attention, he was diagnosed with advanced-stage lung cancer. Due to his late-stage diagnosis and uninsured status, Robert faced limited treatment options. Although a clinical trial for a potentially groundbreaking therapy was available at a nearby research institution, he was unable to enroll due to financial barriers and lack of access to a comprehensive healthcare network.

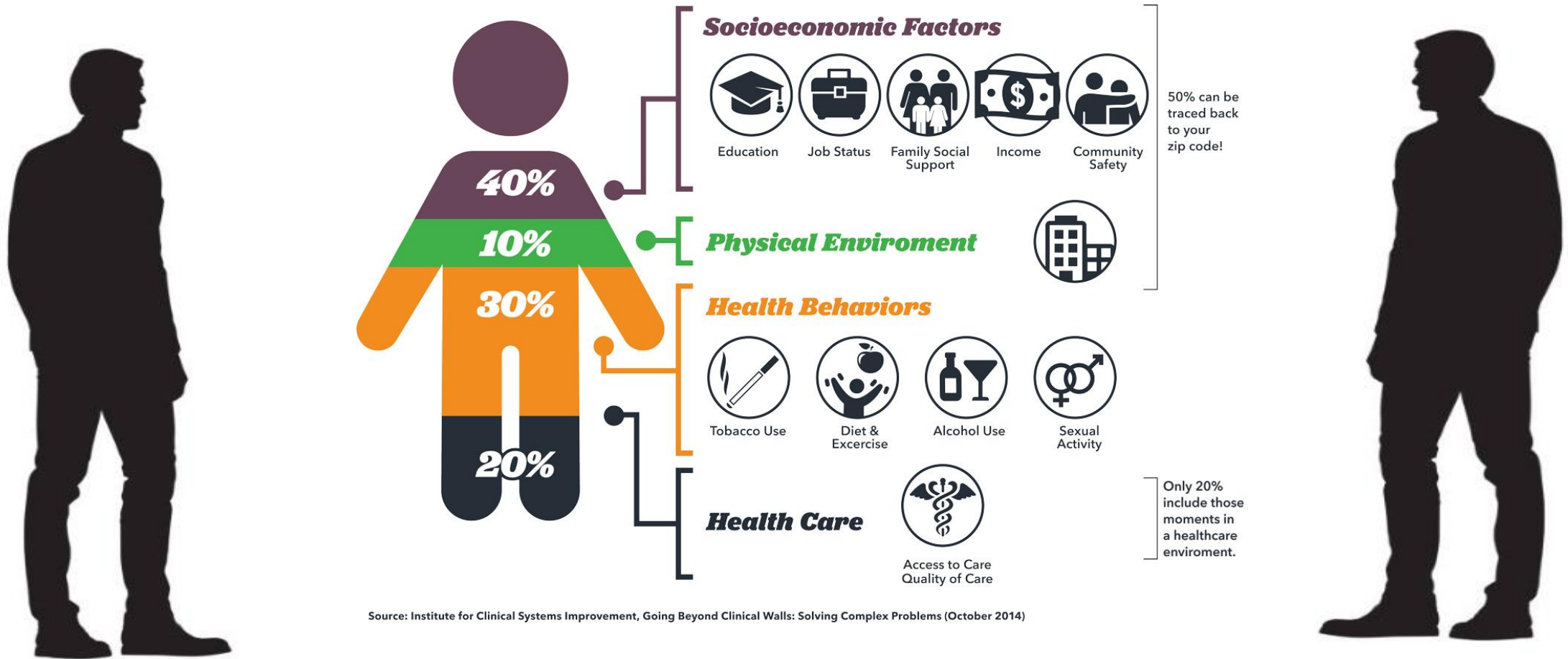


2 People, Same Zip Code, Different Outcomes





2 People, Same Zip Code, Different Outcomes



Source: Institute for Clinical Systems Improvement, Going Beyond Clinical Walls: Solving Complex Problems (October 2014)



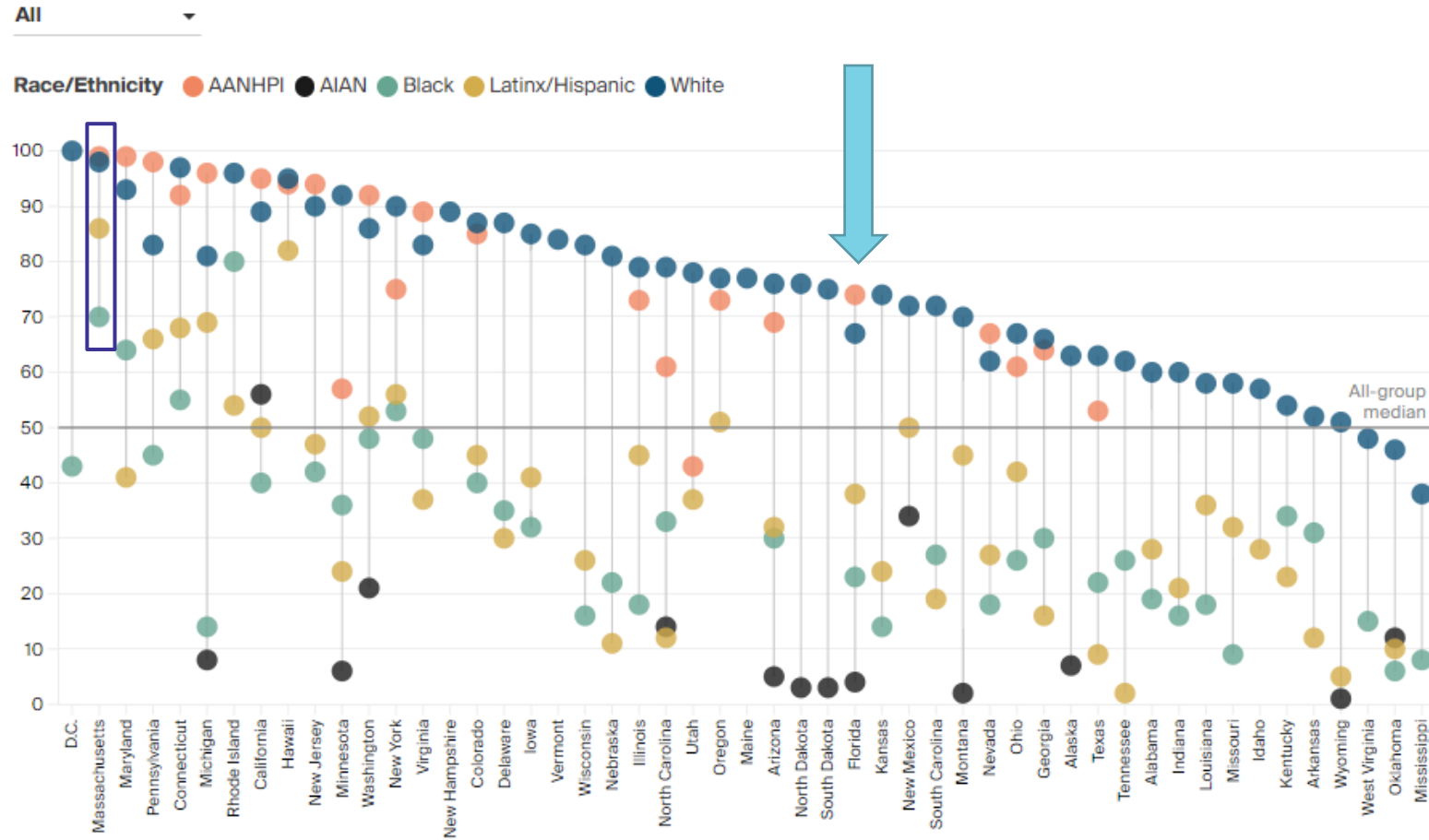
Social Determinants of Health

These circumstances are shaped by the distribution of money, power and resources at global, national and local levels



Profound racial and ethnic inequities in health and health care exist across and within states.

Health system performance scores, by state and race/ethnicity



Notes: Scores are based on the percentile distribution of each group's final composite z-score across all indicators/dimensions; rank-ordered by score of state's highest group. The 50th percentile represents the median health performance score among all the groups measured. Summary performance scores not available for all racial and ethnic groups in all states; missing dots for a particular group indicate that there are insufficient data for that state. AANHPI = Asian American, Native Hawaiian, and Pacific Islander; AIAN = American Indian/Alaska Native.

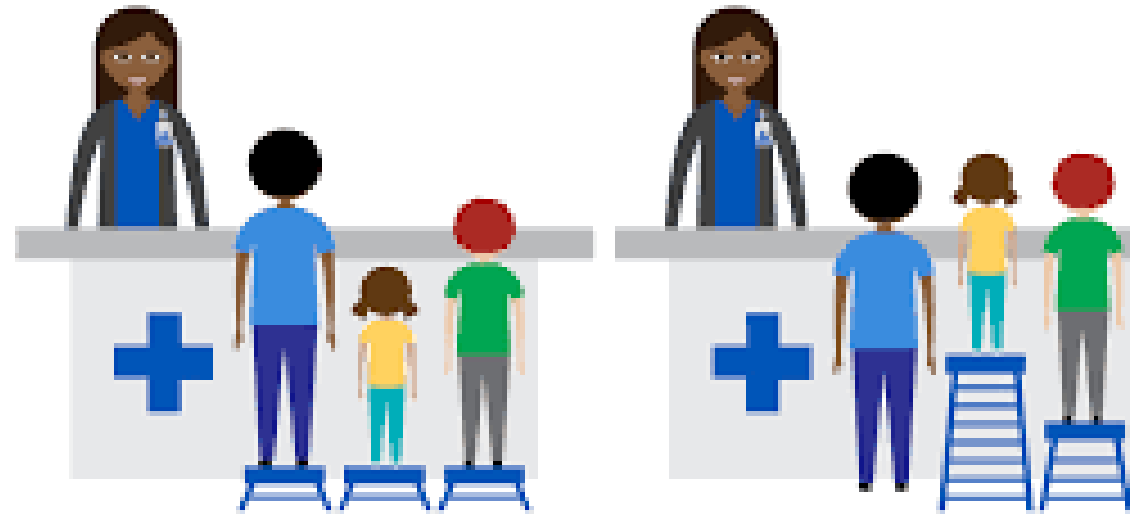
Data: Commonwealth Fund 2021 Health System Performance Scores.


Source: David C. Radley et al., *Achieving Racial and Ethnic Equity in U.S. Health Care: A Scorecard of State Performance* (Commonwealth Fund, Nov. 2021).




How do we Obtain Health Equity?

- Health equity provides everyone with a fair and just opportunity to be as healthy as possible
- Removing obstacles to health such as poverty, discrimination, and their consequences, including powerlessness and lack of access to good jobs with fair pay, quality education and housing, safe environments, and healthcare





“Of all the forms of inequality, injustice in health care is the most shocking and inhuman.”







Oncology Clinical Trial Disparities

- Disparities in cancer mortality and morbidity between BIPOC and NHW populations¹
- Clinical trials = advancement of treatment and outcomes
- <5% of eligible adult cancer survivors participate in cancer trials^{2,3}
- BIPOC = lower enrollment rates³

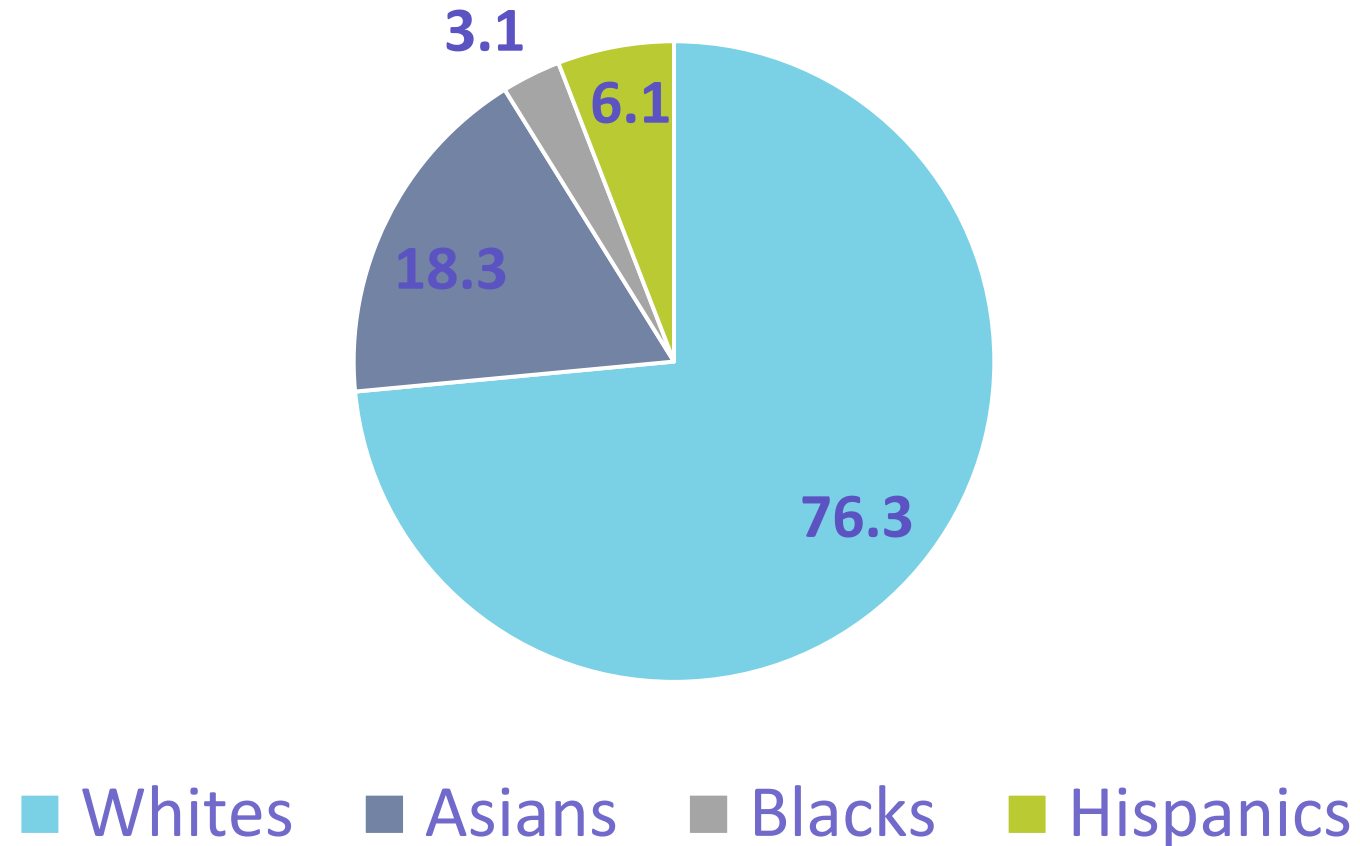
1. National Cancer Institute (2019). Cancer disparities. Retrieved from <https://www.cancer.gov/about - cancer/understanding/disparities>

2. Friedman, M. A., & Cain, D. F. (1990). National Cancer Institute sponsored cooperative clinical trials. *Cancer*, 65(10 Suppl), 2376–2382

3. Murthy, V. H., Krumholz, H. M., & Gross, C. P. (2004). Participation in cancer clinical trials: Race-, sex-, and age- based disparities. *JAMA*, 291(22), 2720–2726.



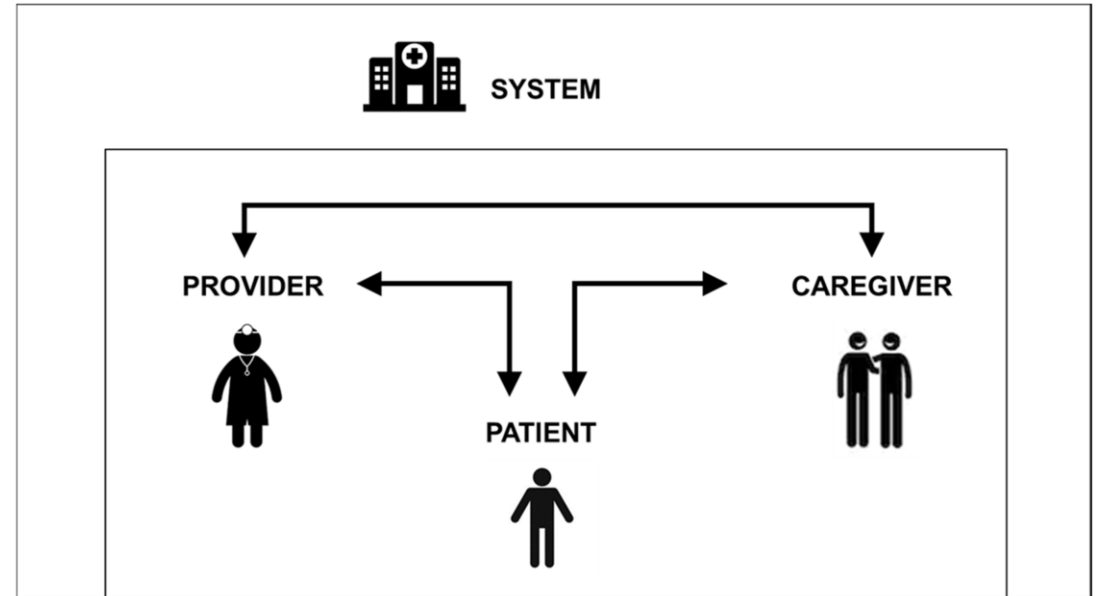
Clinical Trial Participants



1. Loree JM, Anand S, Dasari A, et al. Disparity of Race Reporting and Representation in Clinical Trials Leading to Cancer Drug Approvals From 2008 to 2018. *JAMA Oncol.* 2019;5(10):e191870. doi:10.1001/jamaoncol.2019.1870

Barriers to Clinical Trial¹

- Clinician Barriers
- Patient Barriers
- Trial Barriers
- Institutional Barriers
- Biomarker Testing Uptake Barriers



1. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of Clinical Oncology*. 2022;40(19):2163-71.



Clinician Barriers¹

- Personal bias
- Costs to clinicians
- Limited time
- Support and staff
- Awareness of trials
- Resources to search for trials

1. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of Clinical Oncology*. 2022;40(19):2163-71.



Patients/Caregiver Barriers¹

- Attitudes towards clinical trials
- Knowledge of trials
- Side effects/toxicities
- Burden
- Financial limitations (direct & indirect)
- Location of trials

1. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of Clinical Oncology*. 2022;40(19):2163-71.



Trial Barriers¹

- Overly stringent eligibility criteria
- Onerous participation requirements

1. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of Clinical Oncology*. 2022;40(19):2163-71.



Institutional Barriers¹

- Trial Location
- Availability and diversity of research and support staff
- Lack of access to care
- Limited health insurance uptake

1. Oyer RA, Hurley P, Boehmer L, Bruinooge SS, Levit K, Barrett N, et al. Increasing Racial and Ethnic Diversity in Cancer Clinical Trials: An American Society of Clinical Oncology and Association of Community Cancer Centers Joint Research Statement. *Journal of Clinical Oncology*. 2022;40(19):2163-71.



Biomarker Testing Barriers

- Comprehensive biomarker testing increases clinical trial options¹
- Only 50% of eligible cancer patients in the U.S. receive recommended biomarker tests²
- Older, Black, uninsured patients are less likely to get comprehensive biomarker tests³⁻⁶
- Over 25% of patients skipped biomarker testing due to uncovered costs⁷

1. Survey findings summary: understanding provider utilization of cancer biomarker testing across cancers. American Cancer Society Cancer Action Network. Published December 2021. Accessed December 12, 2021.

2. Chawla A, Peeples M, Li N, Anhorn R, Ryan J, Signorovitch J. Real-world utilization of molecular diagnostic testing and matched drug therapies in the treatment of metastatic cancers. *J Med Econ.* 2018; 21: 543-552.

3. Kehl KL, Lathan CS, Johnson BE, Schrag D. Race, poverty, and initial implementation of precision medicine for lung cancer. *J Natl Cancer Inst.* 2019; 111: 431-434.;

4. Health equity in biomarker testing and targeted therapy. American Cancer Society Cancer Action Network. Published May 2021. Accessed December 3, 2021.

5. Presley C, Soulos P, Chiang A, et al. Disparities in next generation sequencing in a population-based community cohort of patients with advanced non-small cell lung cancer. *J Clin Oncol* 2017; 35(15)(suppl): 6563.;

6. Norris RP, Dew R, Sharp L, et al. Are there socio-economic inequalities in utilization of predictive biomarker tests and biological and precision therapies for cancer? A systematic review and meta-analysis. *BMC Med.* 2020; 18: 282.

7. Improving access to biomarker testing. American Cancer Society Cancer Action Network. Published September 28, 2020. Accessed December 6, 2021.



Global Recommendations to Increase CT Enrollment

The National Cancer Institute and the American Society of Clinical Oncology Clinical Trial Symposium recommend:

- Culturally tailored education tools, including videos and reading materials
- Promoting health literacy and participation among BIPOC through tailored materials

PHARMACISTS, PHARMACISTS, PHARMACISTS!!



Effective Strategies in Treatment Clinical Trial Enrollment Relatable to Pharmacists



Guadagnolo et. al, 2011: Overview

Study characteristics	Participant characteristics	End points	Outcome
Study type: Single arm	N = 332	Primary: (1) Patient navigation utilization	22% recruited (compared with the average in the literature of <1%)
Study setting: Rural cancer institute	Cancer type: Mixed	(2) Potential impacts on clinical care (treatment interruptions and clinical trial enrollment)	
Intervention: Patient navigation	Demographics: 100% Native American		
Length: 5 y	Clinical trial type: Therapeutic and nontherapeutic		

Guadagnolo BA, Boylan A, Sargent M, et al. Patient navigation for American Indians undergoing cancer treatment: utilization and impact on care delivery in a regional healthcare center. *Cancer*. 2011;117(12):2754-2761



Guadagnolo et. al, 2011: Strategies

- Patient navigators helped with coordinating appointments, addressing insurance issues, following up on tests, obtaining medications, arranging transportation and lodging, and offering psychosocial support.
- The program also involved community research representatives who provided cancer education, connected with local health resources, and served as liaisons between the cancer center, patient navigators, and patients or tribal governments.

Guadagnolo BA, Boylan A, Sargent M, et al. Patient navigation for American Indians undergoing cancer treatment: utilization and impact on care delivery in a regional healthcare center. *Cancer*. 2011;117(12):2754-2761



Holmes et. al., 2012: Overview

Study characteristics	Participant characteristics	End points	Outcome
Study type: Single arm	N = 59	Primary: Clinical trials recruitment	86% recruited institutionally.
Study setting: Suburban community physician offices	Cancer type: Breast Demographics: 100% Black		Recruitment rates of Black patients to clinical trials increased from 3% to 7%
Intervention: Nurse navigator	Clinical trial type: Not specified		
Length: 2 y			

Holmes DR, Major J, Lyonga DE, Alleyne RS, Clayton SM. Increasing minority patient participation in cancer clinical trials using oncology nurse navigation. Am J Surg. 2012;203(4):415-422.





Holmes et. al, 2012: Strategies

- Collaborations were established with 6 private practice surgical oncologists, breast surgeons, and medical oncologists practicing
- The nurse navigator:
 - Made weekly visits to each community physician's office to coordinate referrals of newly diagnosed breast cancer patients.
 - Provided counseling and education to patients, assessed their understanding of diagnoses and treatment options, and educated them about available clinical trials.
 - Prospectively evaluated patients for eligibility and clinical trial enrollment.

Holmes DR, Major J, Lyonga DE, Alleyne RS, Clayton SM. Increasing minority patient participation in cancer clinical trials using oncology nurse navigation. Am J Surg. 2012;203(4):415-422.



Robinson et. al., 2017: Overview

Study characteristics	Participant characteristics	End points	Outcome
Study type: Single arm	N = 200	Primary: Clinical trials recruitment	13.5% of sample recruited to trial, 7.5% increase in recruitment from the institution's 2012 baseline of 6%
Study setting: Urban/suburban mix, hospitals, and cancer institutes	Cancer type: Breast Demographics: 100% Black Clinical trial type: Therapeutic	Secondary: Intervention's influence on population's (1) intentions to participate in a clinical trial and (2) attitudes toward clinical trials	
Intervention: 15- min culturally tailored enrollment barriers video			
Length: 1.5 y			

Robinson BN, Newman AF, Tefera E, et al. Video intervention increases participation of Black breast cancer patients in therapeutic trials. NPJ Breast Cancer. 2017;3:36



Robinson et. al, 2017: Strategies

- Eligible participants were identified through electronic clinical schedules, medical records, referrals from healthcare professionals, and support services staff at several hospital sites.
- The study required participants to allocate at least an hour for initial on-site procedures, including completing a demographic survey to assess attitudes and intent to enroll in therapeutic clinical trials before and after a video intervention.
- Patients were followed for 6 months to track consent and enrollment in therapeutic clinical trials.

Robinson BN, Newman AF, Tefera E, et al. Video intervention increases participation of Black breast cancer patients in therapeutic trials. NPJ Breast Cancer. 2017;3:36



Fouad Met. al, 2016: Overview

Study characteristics	Participant characteristics	End points	Outcome
Study type: Single arm	N = 272	Primary: Clinical trials recruitment	Recruitment increased from 9% to 16% between 2007 and 2014
Study setting: Urban NCI Comprehensive Cancer Center	Cancer type: Mixed Demographics: 100% Black		
Intervention: Patient navigation	Clinical trial type: Therapeutic		
Length: 7 y			

Fouad MN, Acemgil A, Bae S, et al. Patient navigation as a model to increase participation of African Americans in cancer clinical trials. J Oncol Practice. 2016;12(6):556-563.





Fouad Met. al, 2016: Strategies

- In-service presentations were conducted for clinical research nurses and principal investigators to introduce them to the patient navigation initiative.
- Patients were identified through clinic schedules, patient charts, and referrals.
- Patient Navigators
 - Contacted patients by phone before scheduled clinic appointments to offer navigation support and obtain informed consent.
 - Offered services including clinical trial education, support for enrollees, needs assessment, assistance with transportation and lodging, appointment reminders, referrals to social workers, peer support, and regular communication with clinic staff.

Fouad MN, Acemgil A, Bae S, et al. Patient navigation as a model to increase participation of African Americans in cancer clinical trials. J Oncol Practice. 2016;12(6):556-563.





Koselke et al. 2022: Overview

Study characteristics	Participant characteristics	End points	Outcome
Study type: Single arm	N = 103	Primary: Monthly clinical trials enrollment rate	367 potentially eligible patients, recommended 325 patients for enrollment, and ultimately consented and enrolled 103 patients (32%).
Study setting: Community cancer network	Cancer type: NSCLC Demographics: XXX		
Intervention: Remote oncology clinical pharmacist	Clinical trial type: Treatment		
Length: 6 months			

Koselke E, Hough S, Howell J, Robert NJ, Neubauer MA, Bullock SA, et al. Impact of oncology clinical pharmacist intervention on clinical trial enrollment in The U.S. Oncology Network's MYLUNG Consortium. Journal of Clinical Oncology. 2022;40(16_suppl):1503-.





Koselke et al. 2022: Strategy

- An oncology-trained clinical pharmacist remotely reviewed chemotherapy regimen orders and a weekly custom recruitment report within six community network practices (n = 149 physicians).
- The ClinReview pharmacist identified, screened, and assisted with recruitment of eligible patients for enrollment in the MYLUNG study.

Koselke E, Hough S, Howell J, Robert NJ, Neubauer MA, Bullock SA, et al. Impact of oncology clinical pharmacist intervention on clinical trial enrollment in The U.S. Oncology Network's MYLUNG Consortium. *Journal of Clinical Oncology*. 2022;40(16_suppl):1503-.





Pharmacists' role in Biomarker Testing for CT Enrollment

Educate

Educate both clinicians and patients about the benefits of comprehensive biomarker testing

Review

Review pharmacogenomic testing results for all patients diagnosed with targetable cancers and refer to clinical trial specialists (i.e., GO2)

Research

Conduct research to explore the reason for the lack of biomarker testing uptake within the population you serve



GO2 for Lung Cancer LungMatch

- Clinical Trial Matching
- Biomarker analysis report
- Education and Awareness



ACCESSING LUNGMATCH IS EASY

- Call us at 1-800-298-2436
- Email your questions to support@go2foundation.org
- Visit www.lungmatch.org

Call our treatment specialists
at 1-800-298-2436 or visit
www.lungmatch.org.



Case Study Closing Remarks

- The cases of Maria and Robert, neighbors in zip code 33311, emphasize the profound impact of healthcare disparities on access to clinical trials and health outcomes.
- Addressing these disparities requires systemic changes in healthcare access, affordability, and outreach, particularly for underserved populations.
- Achieving health equity means ensuring that all individuals, regardless of their zip code or socioeconomic status, have equal opportunities for participation in clinical trials and access to innovative treatments that can improve their lives and chances of survival.



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In your opinion, do you believe pharmacists could play a significant role in improving clinical trial enrollment rates?

- Yes, I strongly believe pharmacists have a significant role.
- Yes, I believe pharmacists have some role.
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RESULTS





Thank you

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