Determinants of Clinical Trial Participation in Prostate Cancer Patients: A Nationwide Medicare Analysis

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BACKGROUND

- Prostate cancer (PCa) is a leading cause of cancer-related death among men in the United States (U.S.), posing a major burden on healthcare systems and communities.
- Despite the importance of clinical trials in advancing PCa treatments, limited evidence exists on the factors influencing trial participation.

OBJECTIVE

This study examined patient- and county-level characteristics associated with clinical trial participation among U.S. men diagnosed with PCa.

METHODS

- This retrospective claims-based analysis utilized the Medicare 5% Standard Analytical Files to identify men aged 65+ with an encounter for PCa between January 1, 2016 and December 31, 2022.
- Clinical trial participation was defined by the presence of International Classification of Diseases, Tenth Revision diagnosis code Z00.6.
- To approximate the total Medicare Fee-for-Service population, patient counts from the 5% sample were extrapolated using a standard multiplier of 20.
- Patient records were then linked to county-level social determinants of health (SDOH) data from the 2020 Agency for Healthcare Research and Quality database.

RESULTS

- Of the 2,368,280 included PCa patients, 4.4% (104,040) participated in a clinical trial (**Figure 1).**
- Clinical trial participants had a mean age of 75.2 years, a mean Charlson Comorbidity Index (CCI) score of 7.06, and were predominantly White **(Table 1)**.
- County-level SDOH factors were significantly associated with trial participation. Participants were more likely to reside in counties with a median home value of ≥ $348,000, a median household income (MHI) of ≥ $85,081, or a metro area designation than non-participants **(Figure 2)**.

Figure 1. Clinical Trial Participation of PCa Medicare Beneficiaries

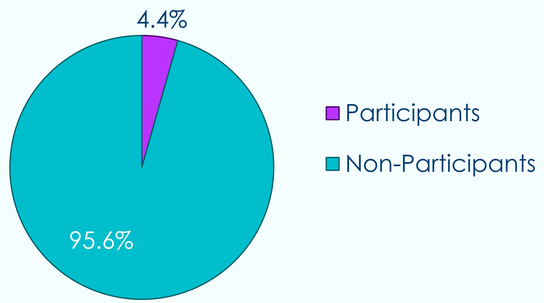
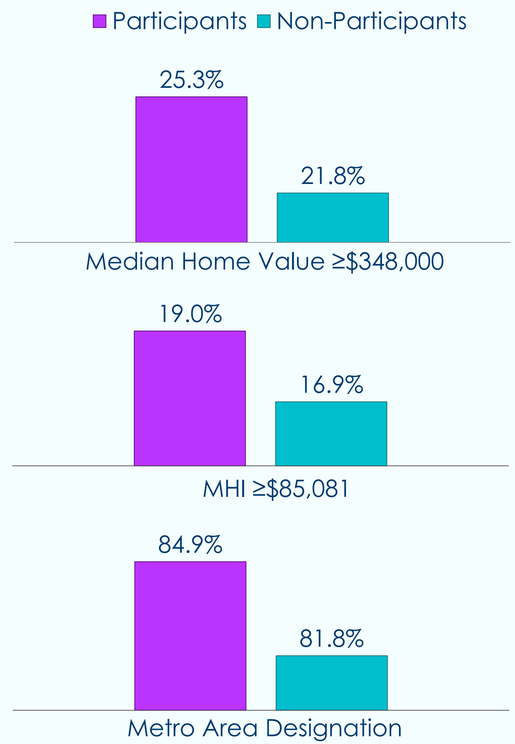


Table 1. Baseline Characteristics by Clinical Trial Participation

	Participants	Non-Participants	p-value
Age, Mean (SD)	75.2 (6.7)	75.1 (7.4)	0.28
Race, %			**<0.01**
Black	5.6%	11.3%	
White	88.9%	81.7%	
Other/Unknown	5.1%	7.1%	
Census Region, %			**<0.01**
Midwest	21.1%	21.5%	
Northeast	18.9%	20.2%	
South	37.4%	38.6%	
West	22.6%	19.7%	
CCI Score, Mean (SD)	7.06 (3.00)	5.50 (3.00)	**<0.01**

Abbreviations: SD = standard deviation; CCI = Charlson Comorbidity Index

Figure 2. County-Level SDOH Characteristics by Clinical Trial Participation



All comparisons are significant at p<0.01.

CONCLUSIONS

- Significant demographic, socioeconomic, and geographic differences exist in clinical trial participation among patients with PCa.
- Incorporating diverse patient populations into clinical trials is critical to promoting equitable access to treatment and improving patient outcomes.
- Further research is needed to understand the drivers of these differences and to inform strategies to improve equitable trial participation.

LIMITATIONS

- Claims data are subject to inherent limitations, including potential coding errors and misclassifications.
- Patient-level SDOH factors are not captured in Medicare data. Therefore, SDOH characteristics were assigned based on the patient's county, which may not reflect individual-level experiences or within-county variability.

DISCLOSURES

This study was funded by Boston Scientific. Alysha M. McGovern and Abimbola O. Williams are full-time employees of, and shareholders in, Boston Scientific. Amy Bolton was a paid intern with Boston Scientific at the time of this research.