

Jordyn Simpson<sup>1</sup>, Claudia Leonardi PhD<sup>2</sup>, Eileen Mederos RN<sup>3</sup>, Holli Bologna RN<sup>3</sup>, Augusto Ochoa MD<sup>3</sup>, Denise Danos PhD<sup>2</sup>  
Fisk University<sup>1</sup>, LSU Health Sciences Center, New Orleans, Behavioral and Community Health Sciences<sup>2</sup>, Gulf South Clinical Trials Network<sup>3</sup>



## Introduction

- Cancer clinical trials are designed to answer specific questions in clinical research.
- Clinical trials are important to advancing strategies for prevention, detection, and improved treatment of cancer.
- There is a need to recognize the macro-level conditions that impact representation of minorities in clinical trials to improve health and wellness.
- The objective of this study was to explore patterns and types of barriers experienced by patients screened for cancer clinical trials in the Gulf South Clinical Trials Network (GS CTN).

## Methods

- Patients screened for a clinical trial from August 1, 2018, to July 31, 2020.
- Primary outcomes were defined to identify barriers in clinical trial enrollment belonging to barrier domains
  - ineligible for the trial,
  - trial not offered by physician,
  - patient declined enrollment into the trial, or
  - patient enrolled in the trial.
- Patient zip code was used to link patients to area-based estimates of income from the US Census American Community Survey.
- The distribution of patient enrollment status was compared via chi-square tests. All statistical analyses were performed in SAS version 9.4.



Figure 1. Site affiliates in the Gulf South Clinical Trials Network, a network of community-based oncology providers, is minority and underserved site in the National Cancer Institute's (NCI) Community Oncology Research Program (NCORP).

Table 1. Reasons for failure to enroll were classified by each domain, based on data gathered in the GS CTN database.

Domain	Category
Patient Ineligible	Patient Status
	Time Lapse
	Clinical/Pathological
	Other
Physician Not Offered	Structural
	Treatment Preference
	Patient Status
Patient Declined	Other
	Trust
	Structural
	Treatment Preference
	No Desire
	Other

## Results: Cancer Treatment Trials

Table 2: Patient characteristics for cancer treatment trials.

	All		Female		Male		p-value
	N	%	N	%	N	%	
All	4,656	100.0	3,108	100.0	1,548	100.0	
Age							<.0001
Less than 50	712	15.3	591	19.0	121	7.8	
50-64	1,942	41.7	1,340	43.1	602	38.9	
65 and older	2,002	43.0	1,177	37.9	825	53.3	
Race							<.0001
White	2,346	50.4	1,451	46.7	895	57.8	
Black or African American	1,847	39.7	1,302	41.9	545	35.2	
Other	463	9.9	355	11.4	108	7.0	
Low Income							0.3561
No	4,150	89.1	2,761	88.8	1,389	89.7	
Yes	506	10.9	347	11.2	159	10.3	
Primary Site							<.0001
Breast	1,963	42.2	1,963	63.2	0	0.0	
Gastrointestinal	474	10.2	191	6.1	283	18.3	
Genitourinary	707	15.2	75	2.4	632	40.8	
Gynecological	121	2.6	121	3.9	0	0.0	
Head and neck	100	2.1	21	0.7	79	5.1	
Hematology	57	1.2	32	1.0	25	1.6	
Lung	456	9.8	218	7.0	238	15.4	
Neurology	155	3.3	61	2.0	94	6.1	
Other	623	13.4	426	13.7	197	12.7	

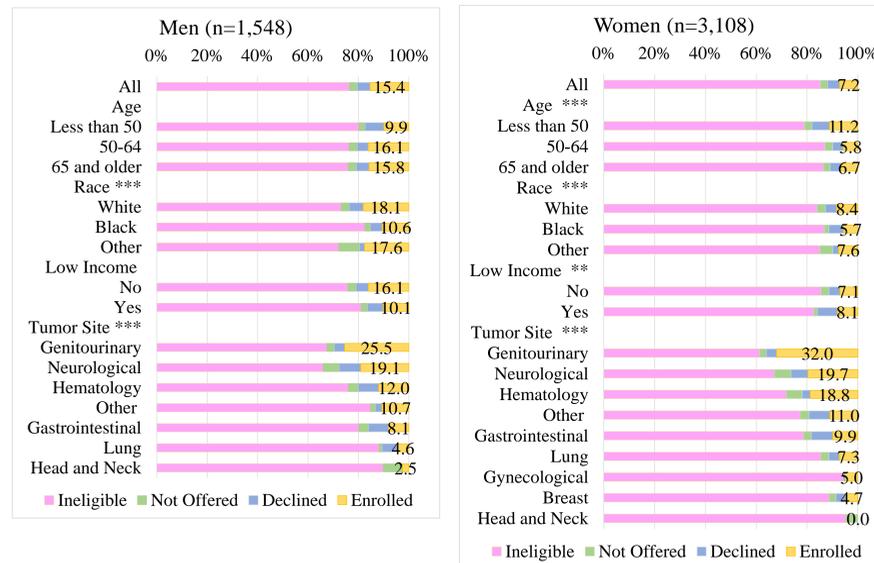


Figure 2: Clinical cancer treatment trial enrollment status among a) men and b) women.

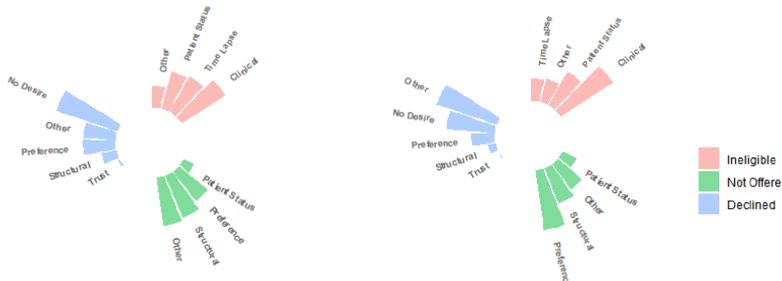


Figure 3: Reasons for failed enrollment in cancer clinical trials among a) men and b) women.

## Results: Female Breast Cancer

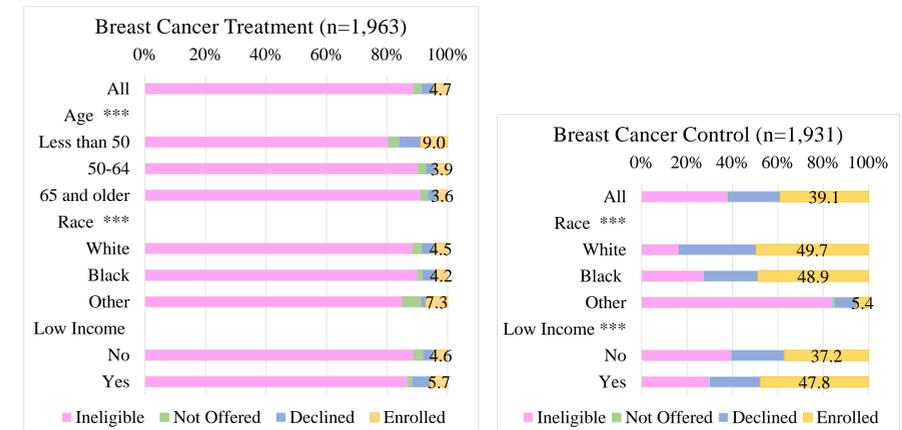


Figure 4: Breast cancer clinical trial enrollment status for a) treatment and b) control trials.

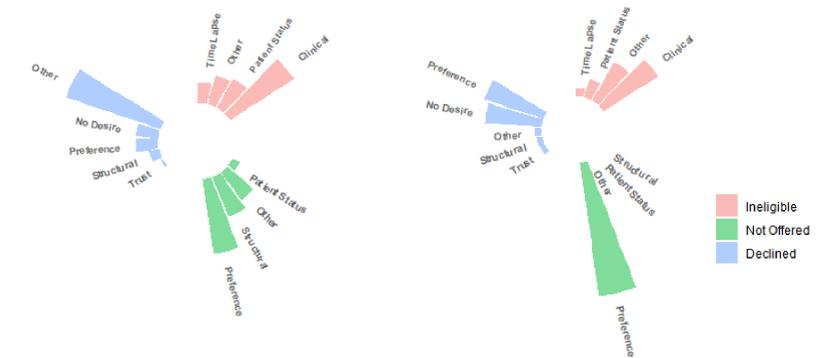


Figure 5: Reasons for failed enrollment in breast cancer clinical trials among a) treatment and b) control trials.

## Conclusions

- Rate of enrollment in treatment trials was lower among women and Black patients.
- Primary barrier to cancer treatment clinical trial enrollment has been ineligibility.
- We observed strict eligibility for head and neck, breast and gynecological cancers.
- NCI, the American Society of Clinical Oncology and the Federal Drug Administration have all prioritized expanding eligibility for clinical trials.
- More inclusive trial eligibility is vital to ensure adequate representation in clinical research and move towards health equity.

## References

Thetford, K., Gillespie, T. W., Kim, Y. II, Hansen, B., & Scarinci, I. C. (2021). Willingness of latinx and African Americans to participate in nontherapeutic trials: It depends on who runs the research. *Ethnicity and Disease, 31*(2), 263–272. <https://doi.org/10.18865/ED.31.2.263>

Unger, J. M., Cook, E., Tai, E., & Bleyer, A. (2016). The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies. *American Society of Clinical Oncology Educational Book, 35*(36), 185–198. [https://doi.org/10.1200/edbk\\_156686](https://doi.org/10.1200/edbk_156686)

Unger, J. M., Hershman, D. L., Till, C., Minasian, L. M., Osarogiabon, R. U., Fleury, M. E., & Vaidya, R. (2021). "When Offered to Participate": A Systematic Review and Meta-Analysis of Patient Agreement to Participate in Cancer Clinical Trials. *Journal of the National Cancer Institute, 113*(3), 244–257. <https://doi.org/10.1093/jnci/djaa155>