

Fact or Myth: Black Patients Do Not Want to Participate in Clinical Trials

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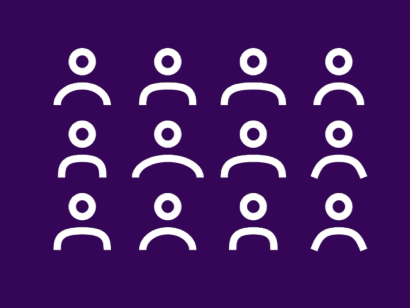
PURPOSE / OBJECTIVES

- Underrepresentation of minority groups, particularly Black individuals, has been a major issue for most clinical trials
- A commonly cited reason is mistrust amongst Black individuals due to historical abuse
- At a Historically Black College and University (HBCU) in a major metropolitan area with predominant Black patient population, we examined the patient participation rate in a clinical trial compared to other study sites with primarily White patient population

MATERIAL & METHODS


- In April 2021, a large prospective, multi-center clinical trial designed to validate a multiomics blood test for early detection of CRC (PREEMPT CRC) was initiated at a HBCU
- To optimize study recruitment:
 - Culturally-sensitive methods, including racially congruent recruitment staff
 - Synchronized timing of consent/study procedures with pre-endoscopy COVID testing and clinic visits
- Evaluated eligible participants screened for a 7-month period
- Enrollment numbers for the HBCU and other study sites compared
- Sociodemographic data collected for the enrolled and not enrolled

Recruitment




45-85 years of age, at average risk for CRC scheduled to undergo a routine screening colonoscopy

Blood Test



Enrolled patients provide a sample through a standard blood draw prior to bowel preparation

Colonoscopy



Enrolled patients undergo standard-of-care screening colonoscopy

Study Endpoints

Sensitivity for CRC

Specificity for advanced colorectal neoplasia

Secondary: Sensitivity for advanced adenoma and negative and positive predictive value for CRC detection
Compared to colonoscopy with histopathology as the reference method

RESULTS

- During the 7-month evaluation period, the number of participants enrolled at the HBCU site (N=229) was significantly higher than the average number enrolled across the other 168 sites (N=90, p<0.0001)
- The HBCU site ranked at the top 11th percentile for participants enrollment across all study sites
- The main difference between the HBCU site and other study sites was race: participants at the HBCU were 86.6% Black and 4.3% White, while at the other sites, the participants were 12.0% Black and 71.5% White (p< 0.0001)
- Comparison of demographic characteristics and socio-demographic data of the enrolled and not-enrolled subjects at the HBCU were similar (Table 1) and did not identify factors that affect participation in clinical trials

RESULTS

Table 1. Baseline Patient Demographic and Sociodemographic Information

	Not Enrolled n=257	Enrolled n=229	p-value
Female	145 (56.4%)	134 (58.5%)	0.64
Age	57.6 ± 7.4	57.5 ± 7.0	0.87
BMI	31.5 ± 8.4	31.8 ± 8.6	0.77
Race			0.75
African American	226 (87.9%)	202 (88.2%)	
Asian	2 (0.8 %)	4 (1.7 %)	
Caucasian	14 (5.4 %)	12 (5.2 %)	
Hispanic	14 (5.4 %)	11 (4.8 %)	
Other/Unk	1 (0.4 %)	0 (0.0 %)	
Marital Status			0.55
Div/Sep/Wid	80 (31.1%)	70 (31.7%)	
Married	42 (16.3%)	45 (20.4%)	
Other/Unk	8 (3.1 %)	4 (1.8 %)	
Single	127 (49.4%)	102 (46.2%)	
Christian	192 (74.7%)	173 (77.9%)	0.41
Insurance Type			0.17
Medicaid	34 (13.3%)	27 (12.2%)	
Medicare	35 (13.7%)	25 (11.3%)	
Medicare/Medicaid	0 (0.0 %)	5 (2.3 %)	
None	117 (45.7%)	101 (45.7%)	
Private(Commercial)	70 (27.3%)	63 (28.5%)	

RESULTS

Figure 1. HBCU enrollment in top 11% of all study sites in PREEMPT CRC

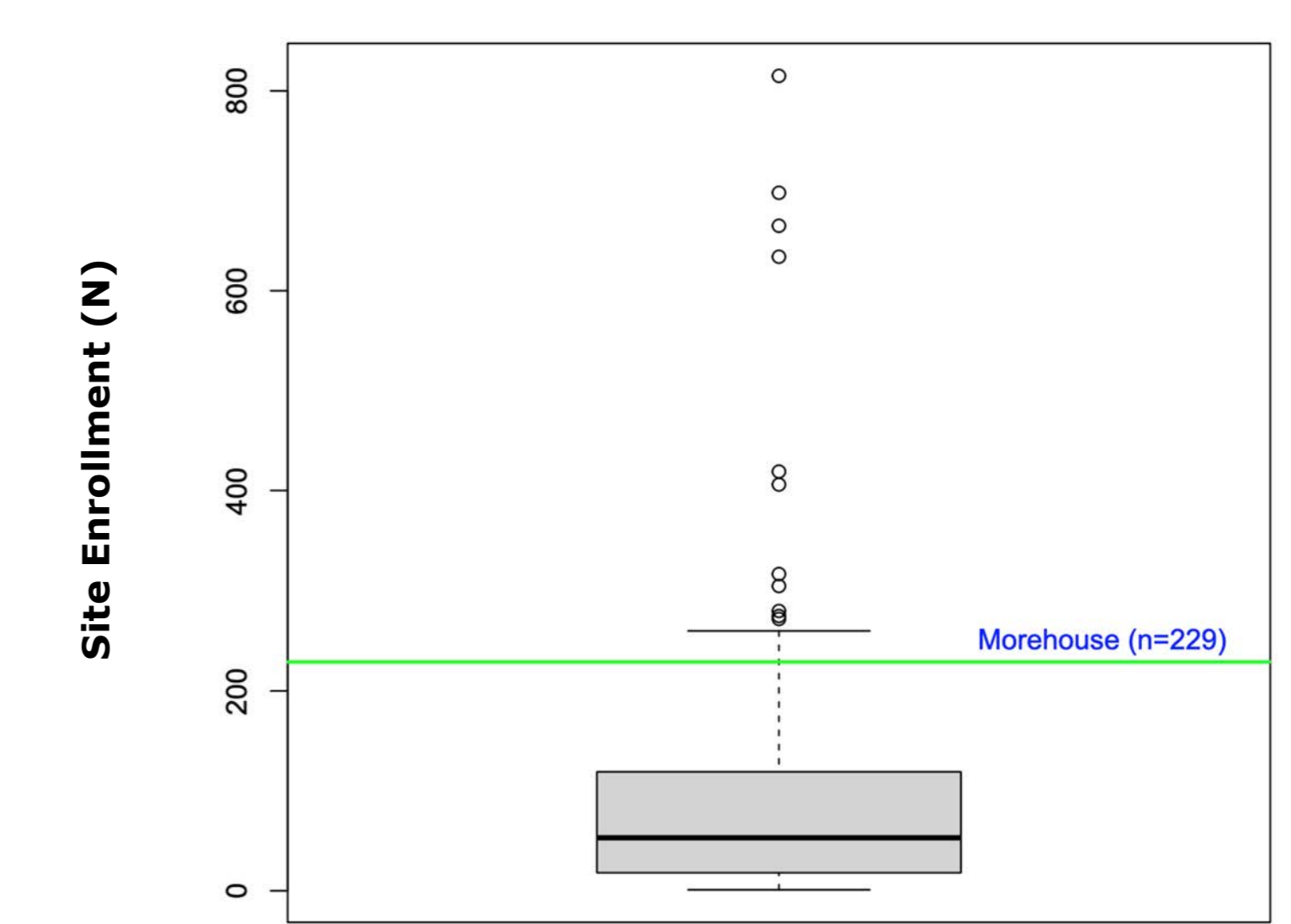
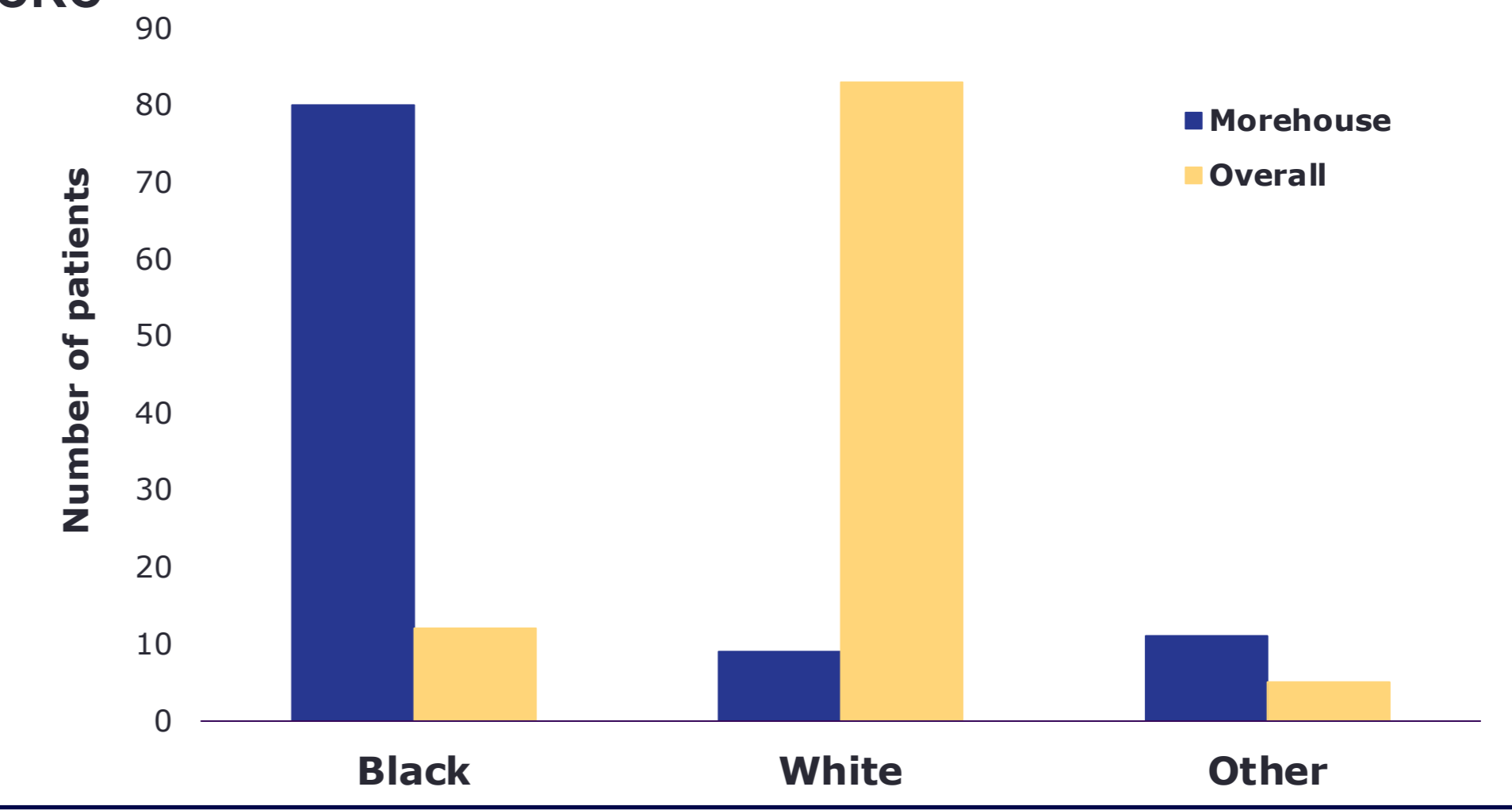


Figure 2. Race comparison of HBCU participants to overall participants enrolling in PREEMPT CRC



SUMMARY / CONCLUSION

- A HBCU site, with predominant Black patient population, was a top enroller among study sites in PREEMPT CRC, a large prospective, multi-center study of a multiomics blood test for average-risk CRC screening
- The finding of our study highlights the importance of providing access to Black individuals to clinical trials to ensure adequate representation in research studies



Scan for Abstract

The authors gratefully acknowledge the participants of PREEMPT CRC as well as Edward Elhauge and Yontao Lu for their data and statistics support.