Strategic Approaches for Enhancing Diversity in a Colorectal Cancer Screening Study Among Black and African American Communities

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INTRODUCTION

Clinical trials face ongoing challenges when it comes to underrepresentation of minority groups. Despite Black and African American individuals constituting 13.6% of the US population, their representation in oncology clinical trials is less than 5%. Addressing this disparity, Freenome is advancing the development of the FMBT-CRC, a blood-based multiomics test aimed at accessible CRC screening. The PREEMPT CRC Study, a prospective multi-center observational study, supports its clinical validation. To bolster diversity, Freenome collaborates with the Institute for Population and Precision Health (IPPH) at the University of Chicago (UOC). This analysis focuses on UOC's enrollment strategies and successes in recruiting Black and African American participants for the PREEMPT CRC study.

METHODS

Initiated in April 2021 at UOC, the PREEMPT CRC Study's procedures are outlined in Figure 1A. Patients were enrolled from May 2021 to March 2022.

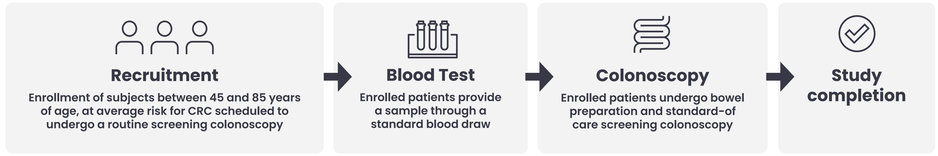
For effective recruitment of Black and African American participants, UOC utilized:

- **Local Collaborations:** Partnerships with diverse local institutions.
- **Mobile Research Units:** Reference Figure 1B.
- **Community-Based Recrutment:** Engaged in local home visits.
- **Clinic-Based Recruitment:** Targeted outpatient and satellite sites of UOC Medical Centers (Ingalls, River East, pending Orland Park)

The enrollment was compared among racial and social groups, and with the US demographic.

Figure 1. Study Procedures A. Procedures needed for study completion. B. Mobile Research Units utilized by UOC during the recruitment and blood collection process.

A.



B.

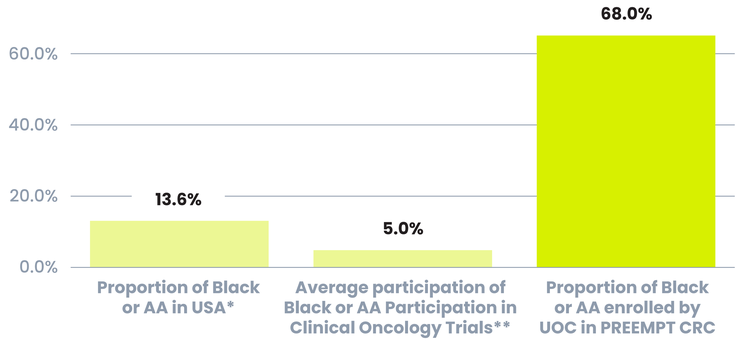
RESULTS

- The UOC screened 1312 prospective participants, identifying 595 participants who met eligibility criteria.
- Ultimately, UOC successfully enrolled a total of 269 participants who are at an average risk for CRC.
- Of 269 participants, 41 (15%) were community-based enrollment.
- Females represented a significant majority, constituting 65.1% of enrollees.
- The mean age at enrollment was 58.8 ± 8.

	All enrolled participants (N=269)
Age (years)	
Mean (SD)	58.8 ± 8.3
BMI	
Mean (SD)	31.4± 7.3
Biological Sex	
Female	175 (65.1%)
Male	94 (34.9%)
Race	
Black or African American	183 (68.0%)
White	67 (24.9%)
Asian	6 (2.2%)
American Indian or Alaska Native	1 (0.4%)
Mixed Race	5 (1.9%)
Other	5 (1.9%)
Unknown	2 (0.7%)
Ethnicity	
Hispanic or Latino	22 (8.2%)
Not Hispanic or Latino	239 (88.8%)
Refuse to answer	3 (1.1%)
Not Reported	1 (0.4%)
Insurance Payers	
Private Payer Insurance	134 (63.2%)
Public Payer Insurance	114 (53.8%)
Unknown	21(9.9%)
Marital Status	
Married	113 (42.0%)
Single	97 (36.1%)
Divorced	25 (9.3%)
Widowed	12 (4.5%)

- Insurance coverage was predominantly from private payers, covering 63.2% of participants, and most identified as either married (42.0%) or single (36.1%).
- Black or AA participants formed the majority at 68.0%, with White participants at 24.9%.
- Notably, the 68.0% representation of Black or AA participants not only surpassed standard oncology trial enrollments but also exceeded their demographic percentage in the US population.

Figure 2. Proportion of Black or AA enrolled by UOC in PREEMPT study in compare to USA population and average participation of those communities in clinical trials for 2020 FDA oncology approval.



CONCLUSIONS

Engagement with clinical sites in historically underserved areas is vital for comprehensive representation in oncology trials. UOC's data exemplifies successful mitigation of healthcare disparities via tailored recruitment techniques. Targeted, community-specific approaches have enabled authentic representation in the PREEMPT CRC study. Strategic involvement of sites in traditionally hard-to-access areas combined with precision in recruitment methodologies is indispensable for inclusivity. The proven efficacy of these strategies highlights their potential in assuring equitable clinical trial access across varied demographics.