## Study design and participant demographics from the PREEMPT CRC study

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### INTRODUCTION

- Colorectal cancer (CRC) is the second leading cause of cancer-related mortality in the US, but a significant portion of these deaths could be avoided through better adherence to guideline-recommended screening<sup>1-3</sup>
- Despite the availability of multiple screening options, approximately 40% of individuals aged ≥45 years are not up to date with CRC screening, in part due to limited access and the inconveniences associated with current screening methods<sup>1,4,5</sup>
- Socioeconomic disparities and systemic inequities further limit CRC screening access and uptake for certain demographic groups, such as non-Hispanic Black individuals and American Indians/Alaskan Natives, that have higher CRC incidence and mortality rates<sup>1,5,6</sup>
- Fostering diversity in clinical studies for new CRC screening tests will further support adequate representation of communities disproportionately affected by CRC
- A blood test for early CRC detection may offer a more accessible and convenient approach to CRC screening
- PREEMPT CRC (NCT04369053), a prospective multicenter observational study, evaluated the clinical validity of a CRC early detection blood test in an average-risk study population representative of the real-world CRC screening population in the US<sup>7</sup>

### **KEY FINDINGS AND CONCLUSIONS**

- The PREEMPT CRC study is one of the largest prospective studies of a blood-based test for CRC in an average-risk population
- The study enrolled a racially, ethnically, and geographically diverse population
- Study participant demographics were reflective of the intended screening population for an accessible CRC screening test with regards to age, sex, ethnicity, and race
- The PREEMPT CRC study provides key data supporting the clinical validation of the CRC early detection blood test and will contribute important insights into the impact of CRC screening in a diverse, average-risk screening population
- Further analyses of PREEMPT CRC will shed light on the screening tendencies of the average-risk study population, including how screening practices differ across various healthcare settings

### **OBJECTIVES**

- Here we provide an overview of the PREEMPT CRC study design and describe the characteristics and demographics of the PREEMPT CRC study population
- Study site characteristics and principal investigator specialties are also described

### METHODS

### Study design

- Participants aged 45–85 years willing to undergo a standard-of-care screening colonoscopy (CS) were eligible
- To mitigate the impact of COVID-19 and increase study accessibility, a virtual enrollment platform and mobile phlebotomy units were utilized
- Prior to bowel preparation for CS, participants provided a blood sample that was sent to Freenome for processing, storage, and future testing
- CS was performed within 120 days of the blood draw (Figure 1)
- The performance of the CRC early detection blood test was assessed using screening CS with histopathology as the reference method

### Figure 1. PREEMPT CRC study schema



### RESULTS

### Participant demographics

- The PREEMPT CRC study enrolled 48,995 participants between May 2020 and April 2022 (Table 1)
- Participants had a mean age of 57.9 years, were predominantly female (55.0%), and had a mean body mass index of 29.6 kg/m<sup>2</sup>
- The study enrolled a diverse population, with 11.2% of participants identifying as Black or African American, 6.8% identifying as Asian, and 11.2% identifying as Hispanic or Latino
- Among the 201 study sites, 65 (32.3%) had at least one participant use mobile phlebotomy for blood collection

Characteristic	All enrolled participants (N=48,995)
Age, <sup>a</sup> years	
Mean (SD)	57.9 (8.0)
Biological sex, n (%)	
Female	26,967 (55.0)
Male	21,974 (44.8)
Unknown	54 (0.1)
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More than one reported	302 (0.6)
Other	1168 (2.4)
Unknown	4273 (8.7)
BMI, <sup>b</sup> kg/m <sup>2</sup>	
Mean (SD)	29.6 (6.5)
Tobacco use, n (%)	
Current	4199 (8.6)
Former	8495 (17.3)
Never	33,851 (69.1)
Unknown	2450 (5.0)
Clinically relevant concomitant medications, n (%)	
Participants using NSAIDs	7506 (15.3%)

<sup>a</sup>Age was not available for 54 participants. <sup>b</sup>Height and/or weight were not available for 2398 participants BMI, body mass index; NSAID, non-steroidal anti-inflammatory drug.

### **Study site characteristics**

- PREEMPT CRC participants were enrolled at 200 study sites across rural and urban communities in the US (**Figure 2**) and 1 site in the United Arab Emirates
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.9%), and academic centers and teaching hospitals (15.9%) (Figure 3)

### Figure 2. Study site geographic distribution by site type



Map Data © 2024 Google, INEGI.



### Figure 3. Study site types



CRC, colorectal cancer.

### Site investigator specialties

- Study oversight was provided by site investigators (N=201) representing 8 specialties, the most common being gastroenterology (n=171, 85.5%)
- Other specialties among site investigators included family medicine (n=8, 4.0%), oncology (n=7, 3.5%), internal medicine (n=7, 3.5%), pathology (n=3, 1.5%), clinical research (n=2, 1.0%), epidemiology (n=1, 0.5%) and proctology (n=1, 0.5%)

### References

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This study was sponsored by Freenome Holdings, Inc. The authors wish to thank the PREEMPT CRC Study Investigators and participants for their contributions to the study.

### Disclosures

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· Fostering diversity in clinical studies for new CRC screening tests will further support adequate representation of communities disproportionately affected by CRC

• A blood test for early CRC detection may offer a more accessible and convenient approach to CRC screening

• PREEMPT CRC (NCT04369053), a prospective multicenter observational study, evaluated the clinical validity of a CRC early detection blood test in an average-risk study population representative of the real-world CRC screening population in the US<sup>7</sup>

- Participants had a mean age of 57.9 years, were predominantly female (55.0%), and had a mean body mass index of 29.6 kg/m<sup>2</sup>
- The study enrolled a diverse population, with 11.2% of participants identifying as Black or African American, 6.8% identifying as Asian, and 11.2% identifying as Hispanic or Latino
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