

Study Population Analysis of PREEMPT CRC Using a Multiomics Blood Test for the Early Detection of Colorectal Cancer

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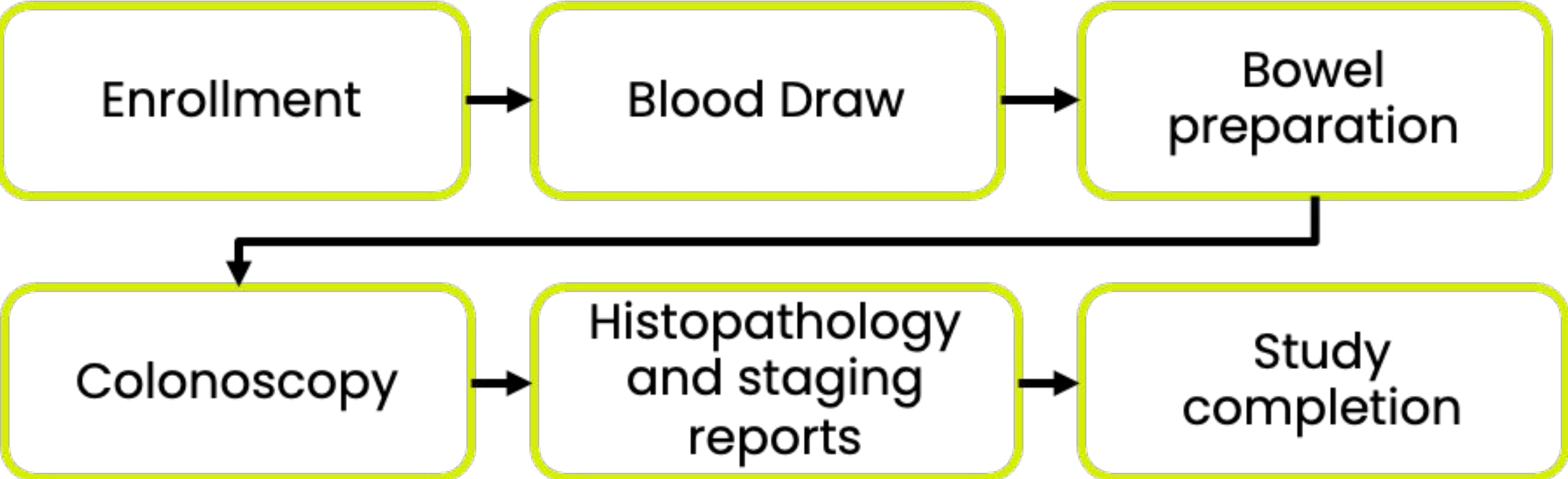
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INTRODUCTION

- Colorectal cancer (CRC) is the second leading cause of cancer death in the U.S.
- Despite evidence that CRC screening reduces mortality and may reduce cancer incidence, screening rates remain below professional society targets.
- There are a number of invasive and non-invasive screening approaches available.
- Freenome is developing a blood based, multiomics test for CRC screening (FMBT-CRC) that is intended to offer an accessible and convenient option for CRC screening.
- Clinical validation of FMBT-CRC is being supported from data and samples collected under the PREEMPT CRC study, a prospective, observational, blinded, multi-center study.
- The aim of this analysis is to study the baseline characteristics of subjects enrolled in the study.

METHODS

- The study enrolled diverse subjects between the ages of 45 and 85, who were at average risk for the development of CRC and underwent CRC standard of care screening colonoscopy (CS), from 192 centers across the U.S. and one site internationally.
- Subjects who met eligibility criteria and provided informed consent were enrolled in the study. Blood collection was completed prior to undergoing bowel preparation for CS.
- De-identified blood specimens were sent to Freenome for processing, storage, and future testing.
- Subjects underwent CS within 90 days (and no more than 120 days) of blood collection and results were collected in a blinding setting.

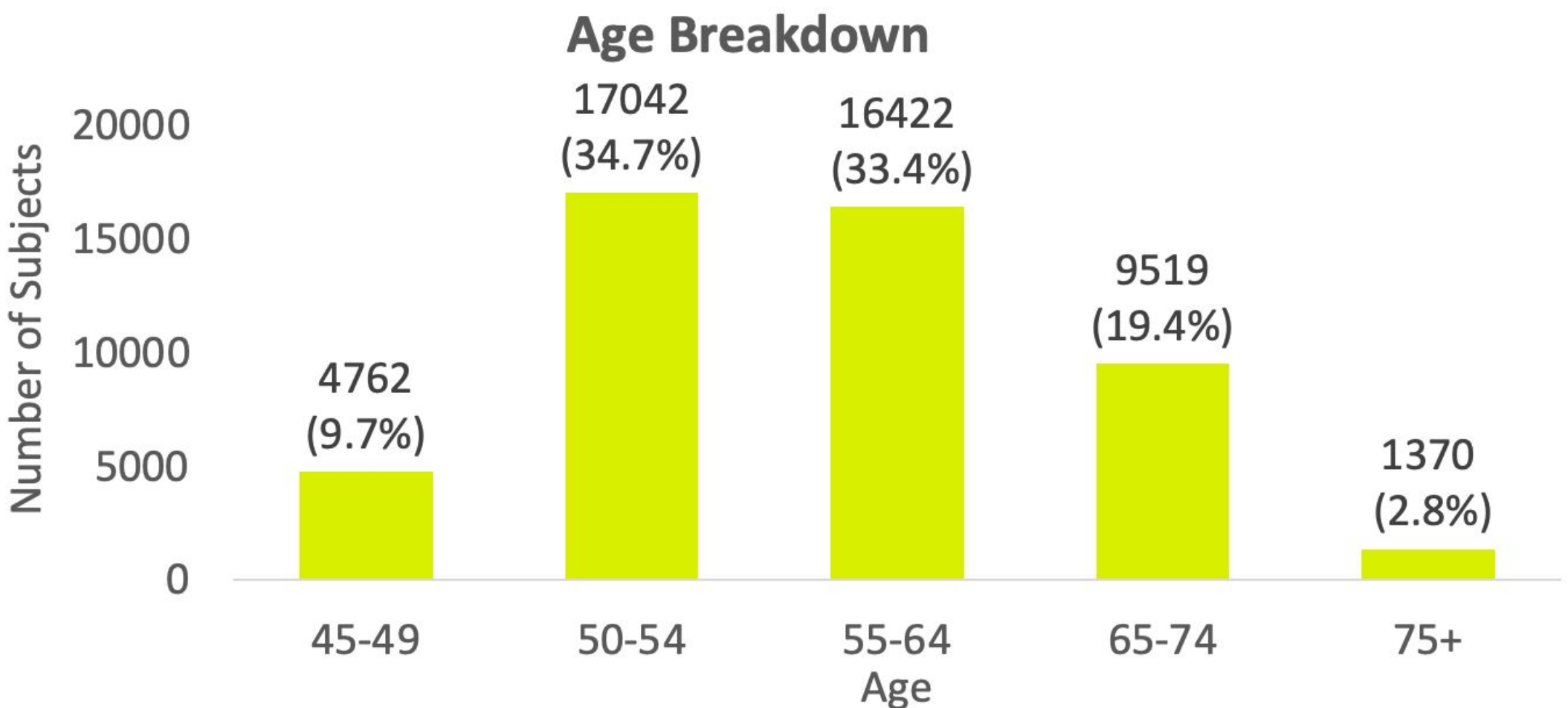


RESULTS

- The PREEMPT CRC study enrolled 49170 subjects between May 2020 and March 2022 (at the time of the Jan 26, 2023 snapshot).
- Subject Demographics and Aspirin Use

All Enrolled Subjects (N=49170)	
Age (Years)	
n	49115
Mean (SD)	57.9 (8.0)
Biological Sex	
Female	27061 (55.1%)
Male	22054 (44.9%)
Ethnicity	
Hispanic or Latino	5513 (11.2%)
BMI	
n	46769
Mean (SD)	29.6 (6.5)
Race	
American Indian or Alaska Native	159 (0.3%)
Asian	3344 (6.8%)
Black or African American	5506 (11.2%)
Native Hawaiian or Other Pacific Islander	131 (0.3%)
White	34246 (69.6%)
Mixed Race	1480 (3.0%)
Refused to Answer	492 (1.0%)
Unknown	3812 (7.8%)
Aspirin Use ¹	
n (%)	7028 (14.3%)

¹Subjects taking aspirin in the 30 days preceding enrollment



Tobacco and Alcohol Use

All Enrolled Subjects (N=49170)	
Tobacco Use	46711
Current	4217 (9.0%)
Former	8532 (18.3%)
Never	33962 (72.7%)
Alcohol Use	46711
Current	26146 (56.0%)
Former	3255 (7.0%)
Never	17310 (37.1%)

- The average time between blood collection and colonoscopy was 20.0 (\pm 21.7) days for subjects who completed the study.
- COVID-19 Mitigations
 - A virtual enrollment platform was used to increase outreach to potential subjects by extending and providing an alternative, virtual pathway for subject engagement. 12167 (24.7%) subjects were enrolled using a virtual platform.
 - Additionally, subjects were provided options to help facilitate participation in remote settings, such as e-consenting and sample collection via mobile phlebotomy. 3499 (7.6%) subjects had blood sample collection via mobile phlebotomy.

CONCLUSION

- The PREEMPT-CRC study is the largest prospective study of a blood-based test in an average-risk CRC population.
- The study enrolled subjects aged 45-85 at average risk for CRC. The overall demographic breakdown of the subject population was reflective of the intended screening population with regards to age, sex, ethnicity and race for an accessible CRC screening test.
- The impact of COVID-19 on the study enrollment was minimized by the mitigations including the engagement of a virtual enrollment platform, e-consenting, and sample collection via mobile phlebotomy.