

# Enhancing Diversity and Inclusion in the PREEMPT CRC Study Through Strategic Site Selection and Innovative Recruitment Tools

Aasma Shaukat,<sup>1,2</sup> Karolina Kutnik,<sup>3</sup> Kristen Petersen,<sup>3</sup> Chuanbo Xu,<sup>3</sup> Lilian C. Lee,<sup>3</sup> Lance Baldo,<sup>3,a</sup> Theodore R. Levin<sup>4</sup>

<sup>1</sup>New York University Grossman School of Medicine, New York, NY, US; <sup>2</sup>University of Minnesota Twin Cities, Minneapolis, MN, US; <sup>3</sup>Freenome Holdings Inc., South San Francisco, CA, US; <sup>4</sup>Kaiser Permanente Division of Research, Pleasanton, CA, US

<sup>a</sup>Affiliation at the time the study and/or analyses were conducted

## INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer-related death in the US, with notable disparities existing in incidence and outcomes based on race, ethnicity, and geographic location<sup>1-4</sup>
- CRC screening, which is widely recommended for its potential to significantly reduce CRC-related deaths, remains underutilized<sup>2,5,6</sup>
- A blood test for early CRC detection may offer a more convenient and accessible alternative to CRC screening for individuals who have not screened with traditional methods<sup>7</sup>
- PREEMPT CRC (NCT04369053<sup>8</sup>), a prospective, multicenter, observational study, aimed to recruit a diverse average-risk study population from across the US to support the clinical validation of an investigational CRC early detection blood test

## OBJECTIVE

- To provide additional perspective on the study population and explore the methodology used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC, and willing to undergo a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were utilized to mitigate the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample that was sent to Freenome for processing, storage, and testing
- CS was performed within 120 days of the blood draw
- CS and applicable histopathology reports underwent central review

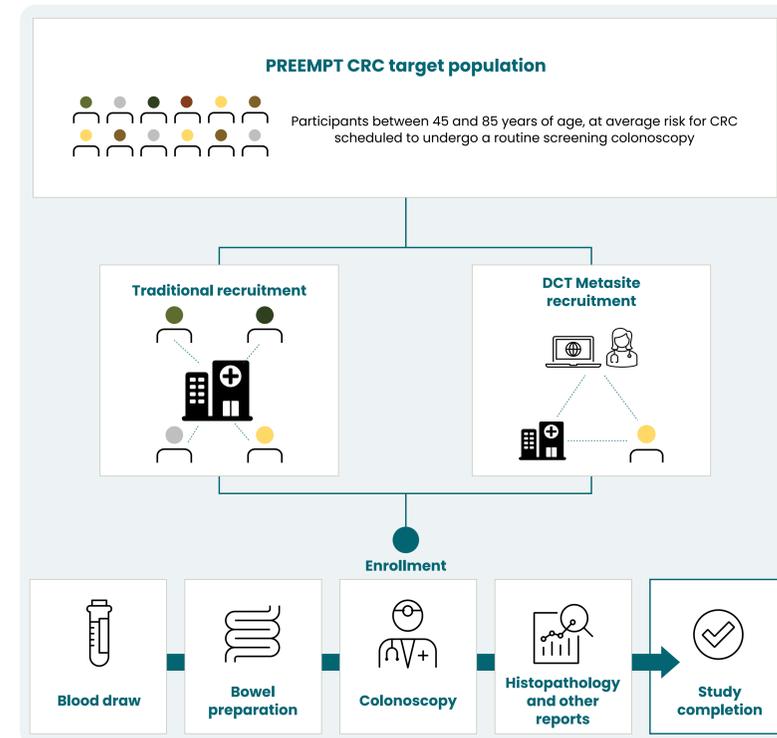
## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a PREEMPT CRC study population that was reflective of the real-world screening demographic in the US
- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened geographical, racial, and ethnic reach
- Facilitating equitable access of all individuals who face barriers to CRC screening is imperative to ensure the communities disproportionately affected by CRC are represented
- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## Study recruitment

- To increase diversity, the study included smaller community clinics and hospitals in addition to larger academic centers and research institutions
- To extend geographical reach, study participants were enrolled into PREEMPT CRC via one of two pathways: traditional in-person enrollment at a designated study site, or enrollment through a single decentralized clinical trial (DCT) "Metasite" (Figure 1)
- Enrollment through the DCT Metasite was enabled by a virtual platform that facilitated all DCT Metasite activities, including eligibility screening, e-consent, medical record review, and patient health questionnaires, with all records and data captured under the unified platform

Figure 1. PREEMPT CRC Study Schema



CRC, colorectal cancer; DCT, decentralized clinical trial.

## RESULTS

### Study site characteristics

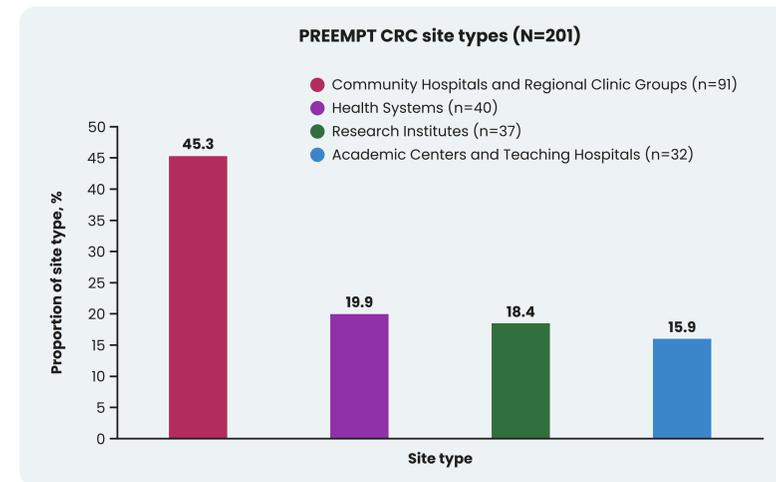
- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (Figure 2)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), 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



The decentralized clinical trial Metasite is not included in the above chart. CRC, colorectal cancer.

### Participant demographics

- Overall, PREEMPT CRC participants had a mean age of 57.9 years and were predominantly female (55.0%) (Table 1)
- The study enrolled a population with a similar ethnic/racial diversity compared with 2023 population estimates based on the 2020 US census for individuals identifying as Black or African American (PREEMPT: 11.2% vs 2023 population estimates: 13.7%), Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>
- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

Table 1. Participant Demographics by Site Type

Characteristic	DCT Model: Science 37 (n=1)	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
<b>Enrollment, n (%)</b>	12,137 (24.8)	3,225 (6.6)	18,283 (37.3)	8,906 (18.2)	6,444 (13.2)	48,995
<b>Age, <sup>a</sup> years</b>						
Mean	57.1	58.1	57.4	58.7	59.6	57.9
<b>Sex, n (%)</b>						
Female	6,772 (55.8)	1,815 (56.3)	9,737 (53.3)	5,159 (57.9)	3,484 (54.1)	26,967 (55.0)
Male	5,348 (44.1)	1,400 (43.4)	8,539 (46.7)	3,729 (41.9)	2,958 (45.9)	21,974 (44.8)
Unknown	17 (0.1)	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
<b>Race, n (%)</b>						
American Indian or Alaskan Native	61 (0.5)	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Asian	247 (2.0)	102 (3.2)	569 (3.1)	2,206 (24.8)	212 (3.3)	3,336 (6.8)
Black or African American	1,164 (9.6)	691 (21.4)	2,208 (12.1)	778 (8.7)	643 (10.0)	5,484 (11.2)
Native Hawaiian or Other Pacific Islander	15 (0.1)	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
White	8,297 (68.4)	2,243 (69.6)	13,327 (72.9)	5,540 (62.2)	4,735 (73.5)	34,142 (69.7)
More than one reported	176 (1.5)	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Other	357 (2.9)	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1,168 (2.4)
Unknown	1,820 (15.0)	83 (2.6)	1,561 (8.5)	131 (1.5)	678 (10.5)	4,273 (8.7)
<b>Ethnicity, n (%)</b>						
Hispanic or Latino	1,015 (8.4)	148 (4.6)	1,841 (10.1)	1,627 (18.3)	867 (13.5)	5,498 (11.2)
Not Hispanic or Latino	8,618 (71.0)	2,901 (90.0)	14,554 (79.6)	7,114 (79.9)	4,934 (76.6)	38,121 (77.8)
Unknown	2,504 (20.6)	176 (5.5)	1,888 (10.3)	165 (1.9)	643 (10.0)	5,376 (11.0)

<sup>a</sup>Age was not available for 54 participants. DCT, decentralized clinical trial.

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## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC and had not had a standard-of-care screening colonoscopy (CS)
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### Study site characteristics

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  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (**Figure 3**)

Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>

- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Demographics by Site Type

Site Type	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
White	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Black or African American	58.1	57.4	58.7	59.6	57.5
Hispanic or Latino	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Asian	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Native Hawaiian or Other Pacific Islander	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
American Indian or Alaskan Native	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Unspecified	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Other	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Unknown	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Total	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
White	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Black or African American	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Hispanic or Latino	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Asian	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Native Hawaiian or Other Pacific Islander	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
American Indian or Alaskan Native	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

Participants

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## OBJECTIVE

- To provide additional perspective on the study population and methodology used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC, and had not had a standard-of-care screening colonoscopy (CS)
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- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
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### Demographics by Site Type

Demographic	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age (years)	58.1	57.4	58.7	59.6	57.7
Sex (%)					
Male	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Female	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Race (%)					
White	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Black or African American	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Hispanic or Latino	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Asian	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Other	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Ethnicity (%)					
Hispanic or Latino	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Non-Hispanic or Latino	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Sex and Race (%)					
Male, White	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Female, White	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Male, Black or African American	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
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## OBJECTIVE

- To provide additional perspective on the study population and recruitment strategies used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC, and willing to undergo a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were utilized to mitigate the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample that was sent to Freenome for processing, storage, and testing
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## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a study population that was reflective of the real-world demographic in the US
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### Study recruitment

- To increase diversity, the study included smaller community clinics and hospitals in addition to larger academic centers and research institutions
- To extend geographical reach, study participants were enrolled into PREEMPT CRC via one of two pathways: traditional in-person enrollment at a designated study site, or enrollment through a single decentralized clinical trial (DCT) “Metasite” (Figure 1)
- Enrollment through the DCT Metasite was enabled by a virtual platform that facilitated all DCT Metasite activities, including eligibility screening, e-consent, medical record review, and patient health questionnaires, with all records and data captured under the unified platform

### Study site characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (Figure 2)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (Figure 3)

Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>

- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Demographics by Site Type

Site Type	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age (years)	58.1 (6.6)	57.4 (37.3)	58.7 (18.2)	59.6 (13.2)	57.5 (13.2)
Sex (%)					
Male	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Female	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Race (%)					
White	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Black or African American	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Hispanic or Latino	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Asian	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Other	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Ethnicity (%)					
Hispanic or Latino	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Non-Hispanic or Latino	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Sex and Race (%)					
Male	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Female	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Race and Ethnicity (%)					
White	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Black or African American	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
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# Enhancing Diversity and Inclusion in the PREEMPT CRC Study Through Strategic Site Selection and Innovative Recruitment Tools

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## INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer in the US, with notable disparities existing in incidence and outcomes by race, ethnicity, and geographic location<sup>1-4</sup>
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized<sup>2,5,6</sup>
- A blood test for early CRC detection may offer a more convenient alternative to CRC screening for individuals who have not screened with traditional colonoscopy<sup>7,8</sup>
- PREEMPT CRC (NCT04369053<sup>9</sup>), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US to evaluate the clinical utility of a blood test for early CRC detection compared to colonoscopy

## OBJECTIVE

- To provide additional perspective on the study population and recruitment strategies used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

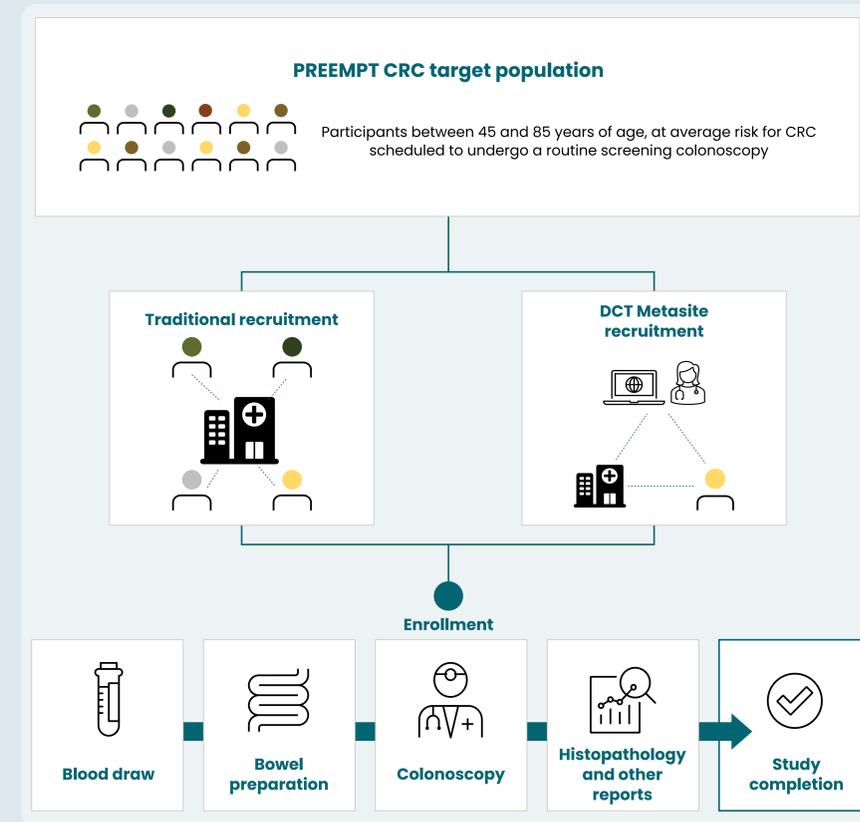
- Participants were aged 45 to 85 years, at average risk for CRC and scheduled to undergo a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to increase study accessibility and reduce the impact of COVID-19
- Prior to bowel preparation for CS, participants provided a blood draw for genetic testing
- CS was performed within 120 days of the blood draw
- CS and applicable histopathology reports underwent central review

## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a study population that was reflective of the real-world demographic in the US
- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened racial, and ethnic reach
- Facilitating equitable access of all individuals with access to CRC screening is imperative to ensure the communities disproportionately affected by CRC are represented
- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## METHODS

**Figure 1. PREEMPT CRC Study Schema**



CRC, colorectal cancer; DCT, decentralized clinical trial.

### Study site characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (**Figure 2**)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (**Figure 3**)

- Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>
- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Site Characteristics by Site Type

Site Type	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Sex	58.1	57.4	58.7	59.6	57.7
Race	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Ethnicity	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Hispanic or Latino	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Asian	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Black or African American	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Hispanic or Latino	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Other	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Education	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
High school or less	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Some college	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
College graduate	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Postgraduate	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Income	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
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### Study design

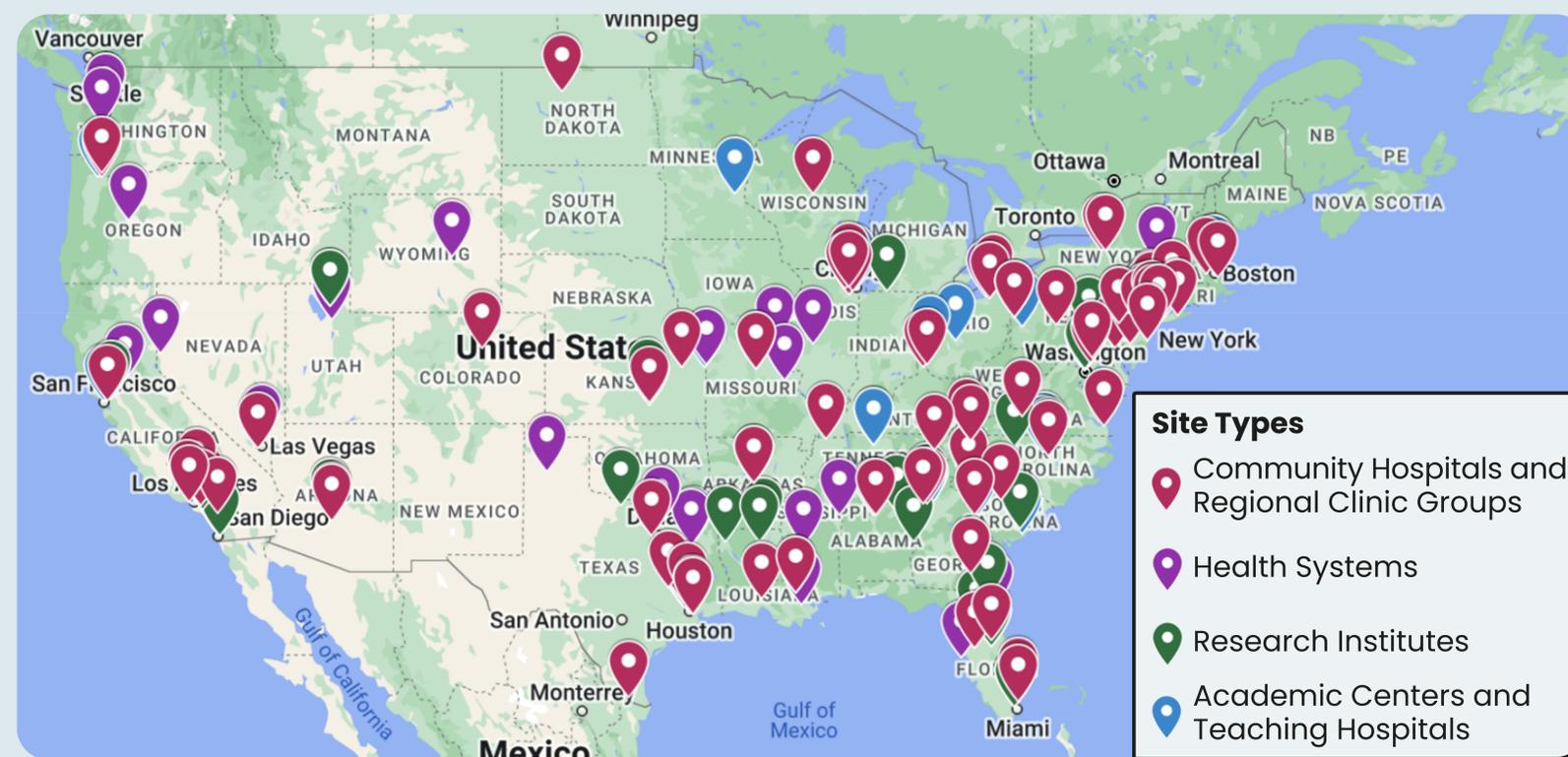
- Participants were aged 45 to 85 years, at average risk for CRC and had not had a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to increase the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample to Freenome for processing, storage, and testing
- CS was performed within 120 days of the blood draw
- CS and applicable histopathology reports underwent central review

## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a study population that was reflective of the real-world demographic in the US
- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened racial, and ethnic reach
- Facilitating equitable access of all individuals who want to participate in CRC screening is imperative to ensure the communities disproportionately affected by CRC are represented
- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## RESULTS

**Figure 2.** Study Site Geographic Distribution by Site Type



Map Data © 2024 Google, INEGI.

### Study Site Characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (Figure 2)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (Figure 3)

- Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>
- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Graphics by Site Type

Site Type	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Sex	58.1	57.4	58.7	59.6	57.5
Race	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Ethnicity	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Education	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Insurance	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Marital Status	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Employment	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Income	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Health Status	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Comorbidities	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Medication	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Healthcare Utilization	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Healthcare Costs	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Healthcare Access	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Healthcare Satisfaction	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

# Enhancing Diversity and Inclusion in the PREEMPT CRC Study Through Strategic Site Selection and Innovative Recruitment Tools

Aasma Shaukat,<sup>1,2</sup> Karolina Kutnik,<sup>3</sup> Kristen Petersen,<sup>3</sup> Chuanbo Xu,<sup>3</sup> Lilian C. Lee,<sup>3</sup> Lance Baldo,<sup>3,a</sup> Theodore R. Levin<sup>4</sup>

<sup>1</sup>New York University Grossman School of Medicine, New York, NY, US; <sup>2</sup>University of Minnesota Twin Cities, Minneapolis, MN, US; <sup>3</sup>Freenome Holdings Inc., South San Francisco, CA, US; <sup>4</sup>Kaiser Permanente Division of Research, Pleasanton, CA, US

<sup>a</sup>Affiliation at the time the study and/or analyses were conducted

## INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer in the US, with notable disparities existing in incidence and outcomes by race, ethnicity, and geographic location<sup>1-4</sup>
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized<sup>2,5,6</sup>
- A blood test for early CRC detection may offer a more convenient alternative to CRC screening for individuals who have not screened with traditional colonoscopy<sup>7,8</sup>
- PREEMPT CRC (NCT04369053<sup>9</sup>), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US to evaluate the clinical utility of an investigational CRC early detection blood test

## OBJECTIVE

- To provide additional perspective on the study population and recruitment strategies used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

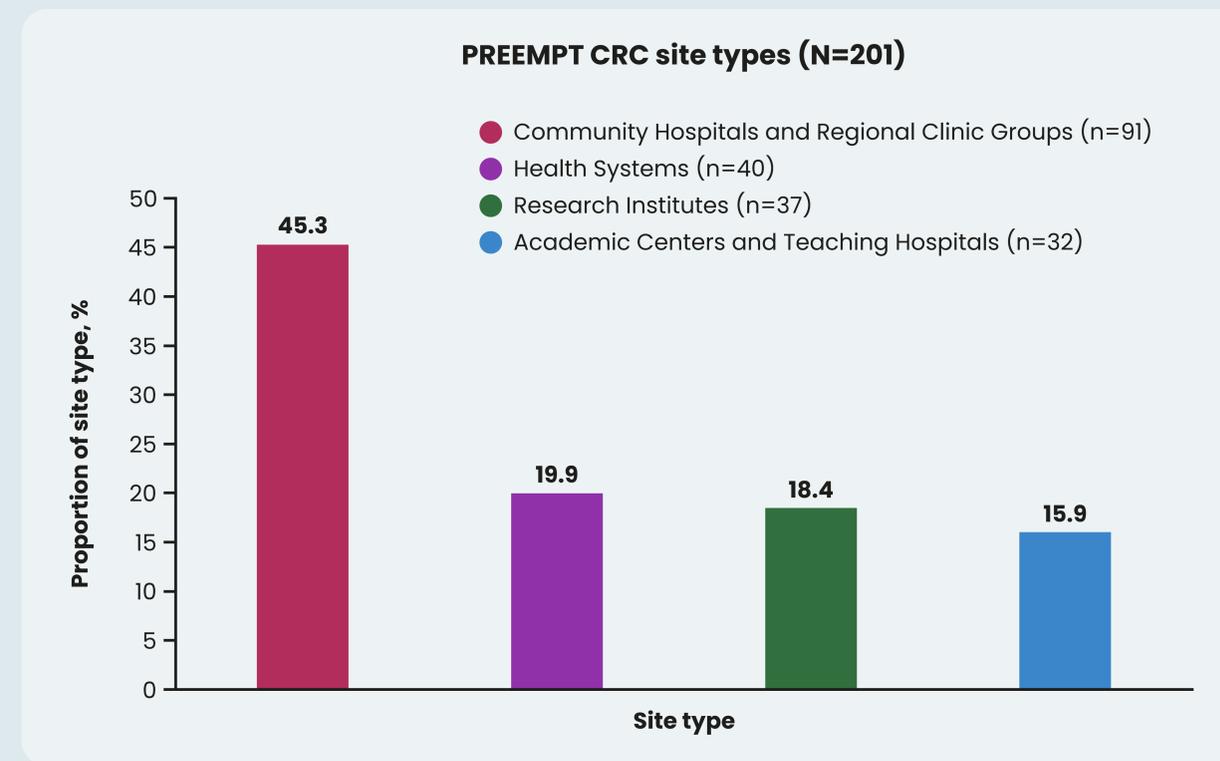
- Participants were aged 45 to 85 years, at average risk for CRC, and had not had a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to address the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample to Freenome for processing, storage, and testing
- CS was performed within 120 days of the blood draw
- CS and applicable histopathology reports underwent central review

## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a study population that was reflective of the real-world demographic in the US
- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened racial, and ethnic reach
- Facilitating equitable access of all individuals with access to CRC screening is imperative to ensure the communities disproportionately affected by CRC are represented
- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## RESULTS

**Figure 3. Study Site Types**



The decentralized clinical trial Metasite is not included in the above chart. CRC, colorectal cancer.

### Study site characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (Figure 2)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (Figure 3)

- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Demographics by Site Type

Characteristic	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age (years)	58.1	57.4	58.7	59.6	57.8
Sex (%)	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Race (%)	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Ethnicity (%)	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Marital status (%)	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Education (%)	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Insurance (%)	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Income (%)	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Health status (%)	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Comorbidities (%)	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Smoking status (%)	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Alcohol use (%)	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Insurance type (%)	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Insurance type (%)	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Insurance type (%)	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

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## INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer in the US, with notable disparities existing in incidence and outcomes by ethnicity, and geographic location<sup>1-4</sup>
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized<sup>2,5,6</sup>
- A blood test for early CRC detection may offer a more convenient alternative to CRC screening for individuals who have not screened with traditional colonoscopy<sup>7,8</sup>
- PREEMPT CRC (NCT04369053<sup>9</sup>), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US for clinical validation of an investigational CRC early detection blood test

## OBJECTIVE

- To provide additional perspective on the study population and recruitment strategies used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC and had not had a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to assess the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample to Freenome for processing, storage, and testing
- CS was performed within 120 days of the blood draw
- CS and applicable histopathology reports underwent central review

## KEY FINDINGS AND CONCLUSIONS

- Deliberate recruitment of diverse participants through a multichannel approach supported enrollment of a study population that was reflective of the real-world CRC demographic in the US
- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened racial, and ethnic reach
- Facilitating equitable access of all individuals with access to CRC screening is imperative to ensure the communities disproportionately affected by CRC are represented
- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## RESULTS

### Participant demographics

- Overall, PREEMPT CRC participants had a mean age of 57.9 years and were predominantly female (55.0%) (**Table 1**)
- The study enrolled a population with a similar ethnic/racial diversity compared with 2023 population estimates based on the 2020 US census for individuals identifying as Black or African American (PREEMPT: 11.2% vs 2023 population estimates: 13.7%), Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>
- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

### Study site characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (**Figure 2**)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (**Figure 3**)

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Table 1. Demographics by Site Type

Site Type	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
Age (mean)	58.1	57.4	58.7	59.6	57.9
Female (%)	58.1	57.4	58.7	59.6	57.9
Black or African American (%)	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Asian (%)	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Hispanic or Latino (%)	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
American Indian or Alaskan Native (%)	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Other (%)	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Unspecified (%)	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Mean age (SD)	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
Female (%)	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Black or African American (%)	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Asian (%)	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Hispanic or Latino (%)	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
American Indian or Alaskan Native (%)	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Other (%)	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Unspecified (%)	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

### Acknowledgments

Medical writing and editorial assistance were provided by Harrison Flynn, PharmD (Healthcare Consultancy Group, US) and were supported by Freenome Holdings, Inc. This study was sponsored by Freenome Holdings, Inc.

### Disclosures

AS: consultant: Freenome Holdings Inc., Iterative Health. KK: employee: Freenome Holdings Inc. KP: employee: Freenome Holdings Inc. CX: employee: Freenome Holdings Inc. LCL: employee: Freenome Holdings Inc. LB: employee: Beacon Therapeutics, former employee: Freenome Holdings Inc. TRL: employee: Kaiser Permanente; participation on a Data Safety Monitoring Board or Advisory Board: CONFIRM trial (NCT01239082); leadership or fiduciary role in other board, society, committee, or advocacy group: California Colorectal Cancer Coalition (unpaid); research funding: PCORI, Universal Diagnostics.

# Enhancing Diversity and Inclusion in the PREEMPT CRC Study Through Strategic Site Selection and Innovative Recruitment Tools

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## INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer in the US, with notable disparities existing in incidence and outcomes by race, ethnicity, and geographic location<sup>1-4</sup>
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized<sup>2,5,6</sup>
- A blood test for early CRC detection may offer a more convenient alternative to CRC screening for individuals who have not screened with traditional colonoscopy<sup>7</sup>
- PREEMPT CRC (NCT04369053<sup>8</sup>), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US to evaluate the clinical utility of a blood test for early CRC detection compared to standard-of-care colonoscopy (CS)

## OBJECTIVE

- To provide additional perspective on the study population and recruitment strategies used to contribute to the diversity of the PREEMPT CRC study population

## METHODS

### Study design

- Participants were aged 45 to 85 years, at average risk for CRC, and had not had a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to increase the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample to Freenome for processing, storage, and testing
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- Future early CRC detection research should consider proactive diversity planning and a multichannel recruitment approach to foster enrollment of a patient population representative of the intended demographic

## RESULTS

**Table 1.** Participant Demographics by Site Type

Characteristic	DCT Model: Science 37 (n=1)	Academic centers and teaching hospitals (n=32)	Community hospitals and regional clinic groups (n=91)	Research institutes (n=37)	Health systems (n=40)	All (N=201)
<b>Enrollment, n (%)</b>	12,137 (24.8)	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
<b>Age,<sup>a</sup> years</b>						
Mean	57.1	58.1	57.4	58.7	59.6	57.9
<b>Sex, n (%)</b>						
Female	6772 (55.8)	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Male	5348 (44.1)	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Unknown	17 (0.1)	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
<b>Race, n (%)</b>						
American Indian or Alaskan Native	61 (0.5)	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Asian	247 (2.0)	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Black or African American	1164 (9.6)	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Native Hawaiian or Other Pacific Islander	15 (0.1)	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
White	8297 (68.4)	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
More than one reported	176 (1.5)	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Other	357 (2.9)	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Unknown	1820 (15.0)	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
<b>Ethnicity, n (%)</b>						
Hispanic or Latino	1015 (8.4)	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Not Hispanic or Latino	8618 (71.0)	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Unknown	2504 (20.6)	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

<sup>a</sup>Age was not available for 54 participants. DCT, decentralized clinical trial.

### Study site characteristics

- PREEMPT CRC participants (N=48,995) were enrolled between May 2020 and April 2022 at over 200 study sites across rural and urban communities largely in the US and one DCT Metasite (**Figure 2**)
  - The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states
  - Traditional study sites enrolled 36,858 participants (75.2%) from 36 states
- The most common site type was community hospitals and regional clinic groups (45.3%), followed by health systems (19.9%), research institutes (18.4%), and academic centers and teaching hospitals (15.9%) (**Figure 3**)

Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)<sup>9</sup>

- Higher proportions of individuals identifying as Black or African American were enrolled through academic centers (21.4%) and community hospitals and regional clinic groups (12.1%) compared to other site types
- Research institutions enrolled the highest proportion of individuals identifying as Asian (24.8%) and Hispanic or Latino (18.3%)
- Higher proportions of individuals identifying as American Indian or Alaskan Native enrolled through academic centers and teaching hospitals (0.5%), health systems (0.5%), and the DCT Metasite (0.5%) compared with other site types

5 of 5

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