

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-related death in the US, with notable disparities existing in incidence and outcomes based on race, ethnicity, and geographic location¹⁻⁴
- CRC screening, which is widely recommended for its potential to significantly reduce CRC-related deaths, remains underutilized^{2,5,6}
- 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 methods⁷
- PREEMPT CRC (NCT04369053⁸), 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
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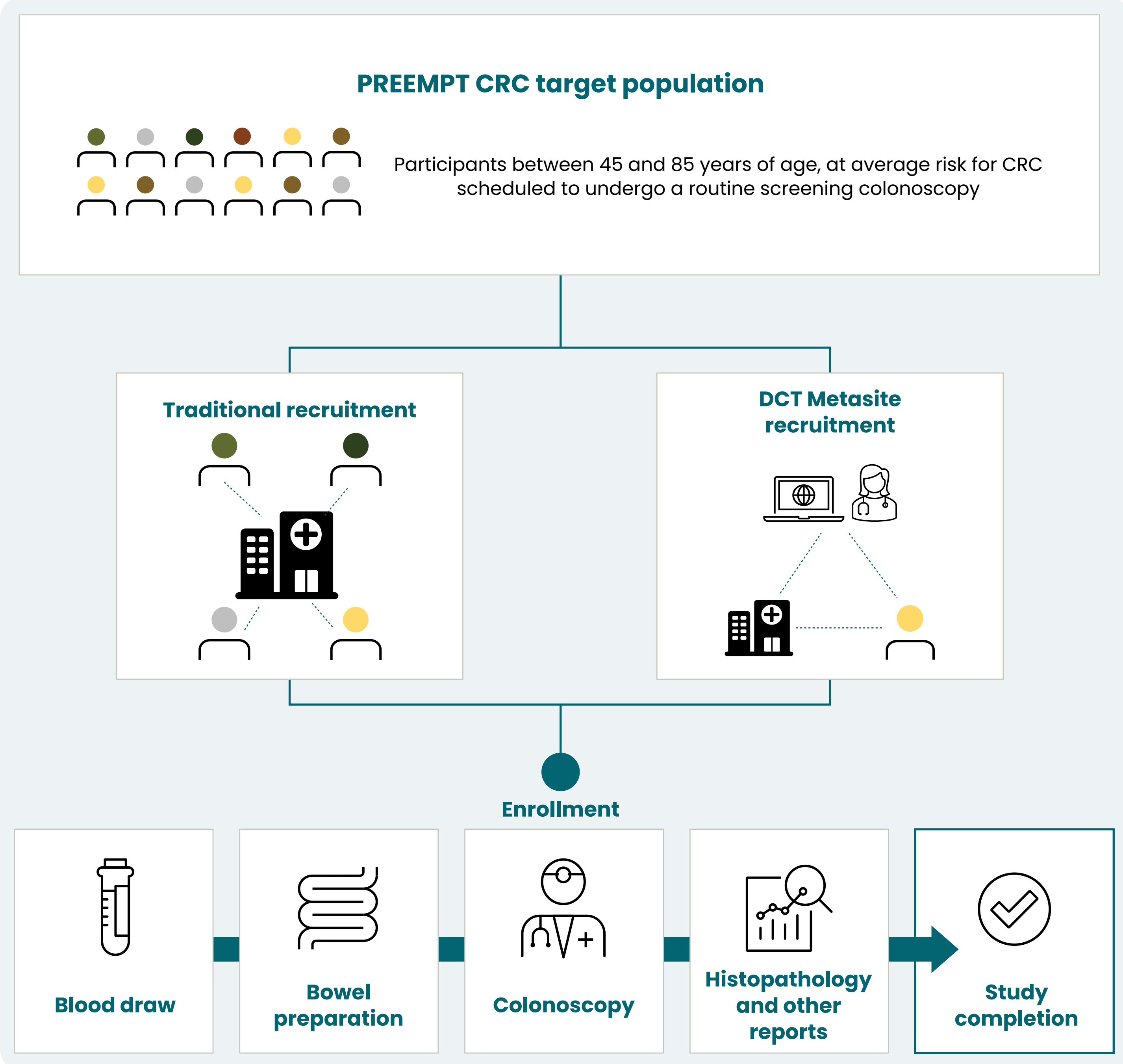
KEY FINDINGS AND CONCLUSIONS

- 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

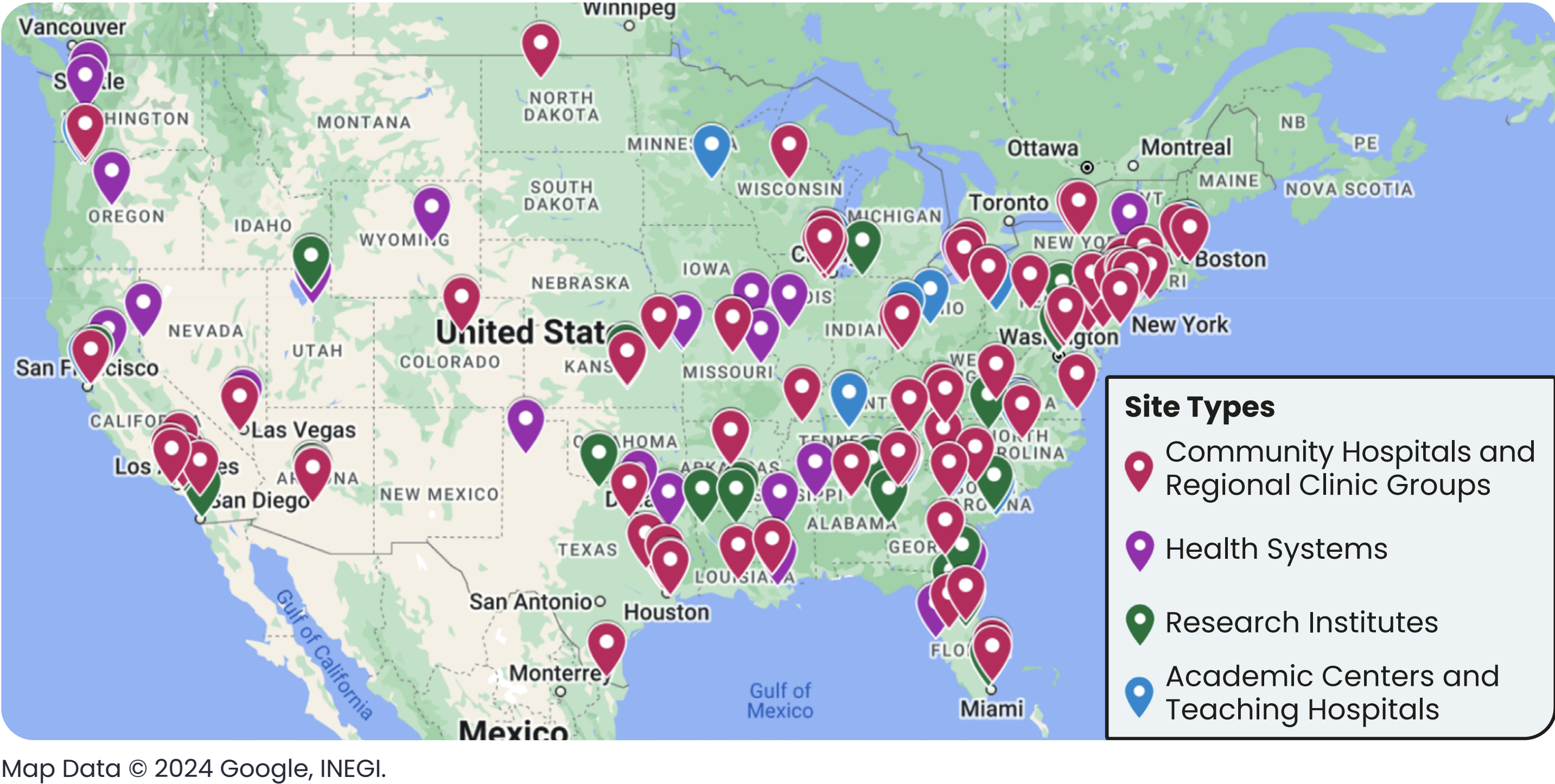
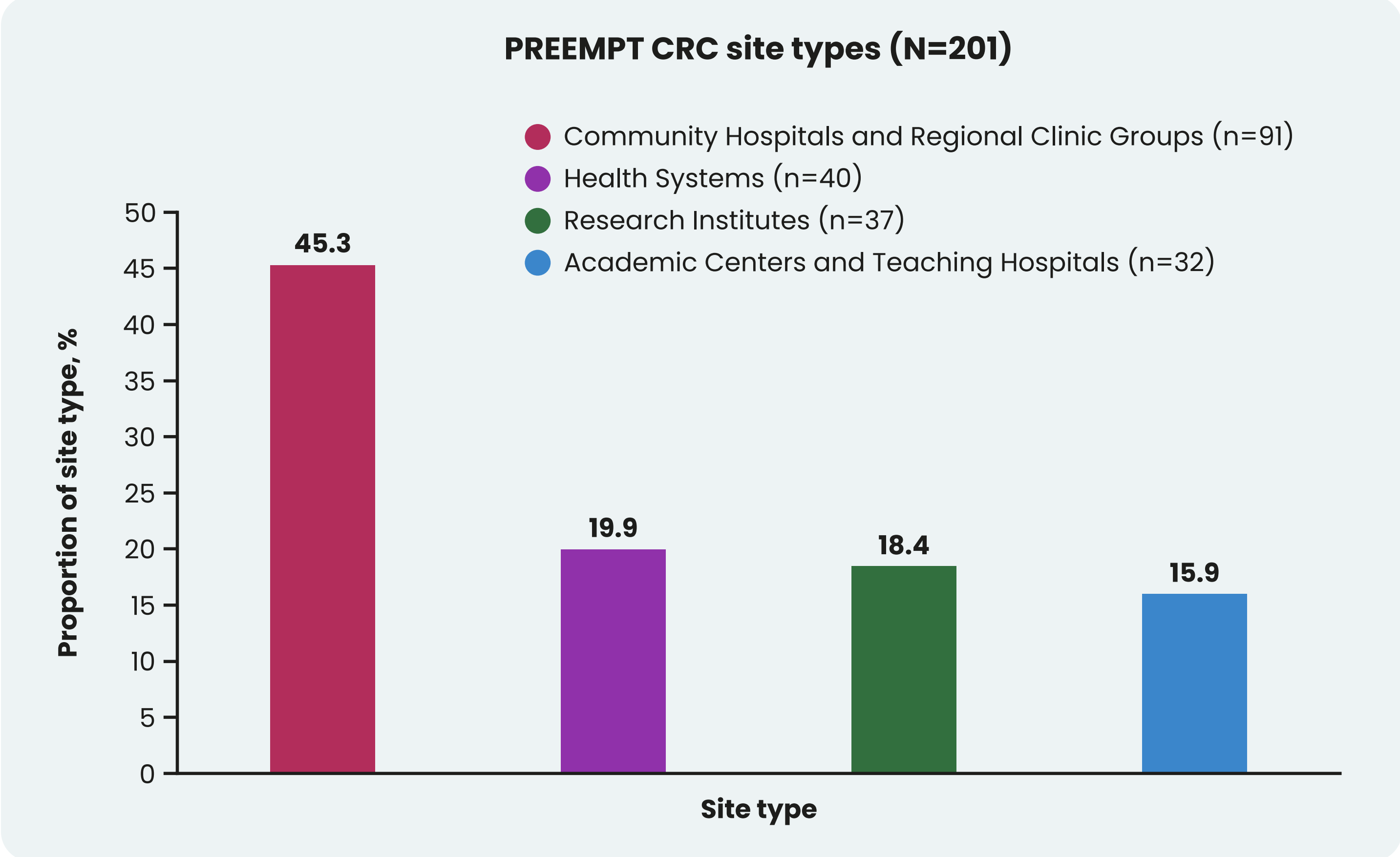


Figure 3. Study Site Types



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%)⁹
- 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

	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)
Characteristic						
Enrollment, n (%)	12,137 (24.8)	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Age, ^a years						
Mean	57.1	58.1	57.4	58.7	59.6	57.9
Sex, n (%)						
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)
Race, n (%)						
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)
Ethnicity, n (%)						
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)

^aAge was not available for 54 participants.
DCT, decentralized clinical trial.

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- 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%)^a
- 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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Enrollment 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)
Enrollment (n)	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Enrollment (%)	58.1	57.4	58.7	59.6	57.9
Enrollment (n)	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
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Enrollment (n)	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Enrollment (%)	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Enrollment (n)	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
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Enrollment (n)	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Enrollment (%)	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
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- 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%)^a

- 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

Figure 3. Site types 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)
Academic centers and teaching hospitals	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Community hospitals and regional clinic groups	58.1	57.4	58.7	59.6	57.9
Research institutes	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Health systems	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
All	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
Academic centers and teaching hospitals	16 (0.5)	25 (0.1)	22 (0.2)	35 (0.5)	159 (0.3)
Community hospitals and regional clinic groups	102 (3.2)	569 (3.1)	2206 (24.8)	212 (3.3)	3336 (6.8)
Research institutes	691 (21.4)	2208 (12.1)	778 (8.7)	643 (10.0)	5484 (11.2)
Health systems	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
All	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Academic centers and teaching hospitals	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Community hospitals and regional clinic groups	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Research institutes	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Health systems	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
All	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

Aasma Shaukat,^{1,2} Karolina Kutnik,³ Kristen Petersen,³ Chuanbo Xu,³ Lilian C. Lee,³ Lance Baldo,^{3,a} Theodore R. Levin⁴

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

^aAffiliation at the time the study and/or analyses were conducted

INTRODUCTION

- Colorectal cancer (CRC) is the second-leading cause of cancer death in the US, with notable disparities existing in incidence and outcomes by race, ethnicity, and geographic location¹⁻⁴
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized^{2,5,6}
- A blood test for early CRC detection may offer a more convenient alternative to CRC screening for individuals who have not screened with traditional methods^{7,8}
- PREEMPT CRC (NCT04369053⁹), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US to evaluate the utility of a blood test for early CRC detection before 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

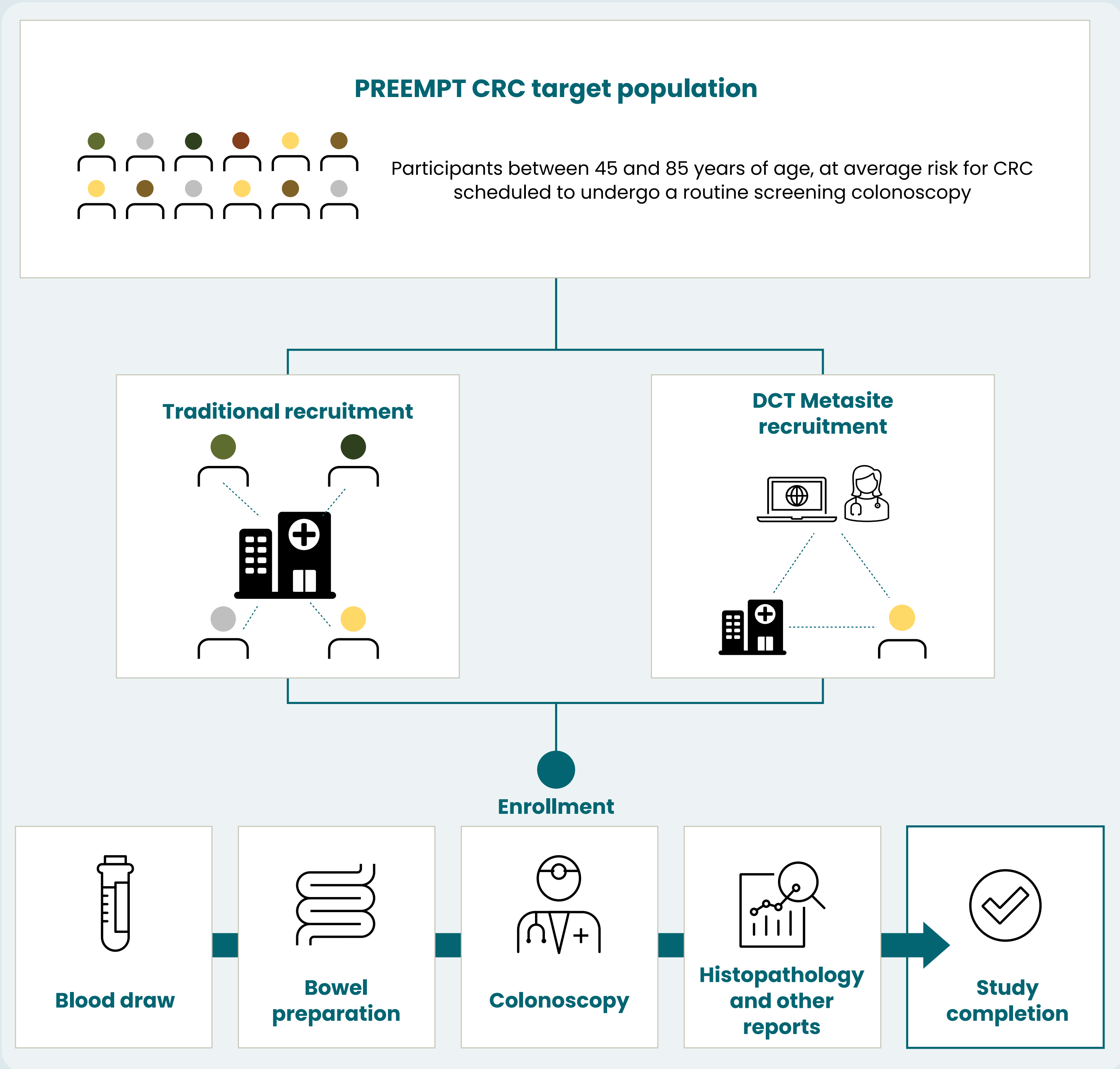
- Participants were aged 45 to 85 years, at average risk for CRC, and were not scheduled to undergo a standard-of-care screening colonoscopy (CS)
- A virtual enrollment platform and mobile phlebotomy units were used to increase study accessibility and enrollment during the impact of COVID-19 and increase study accessibility
- Prior to bowel preparation for CS, participants provided a blood sample, which 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 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 are eligible 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.

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Enrollment by Site Type

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KEY FINDINGS AND CONCLUSIONS

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- The incorporation of a DCT Metasite alongside traditional study sites near harder-to-reach populations broadened the study's 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
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RESULTS

Study site characteristics

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Figure 3: Site types by Site Type

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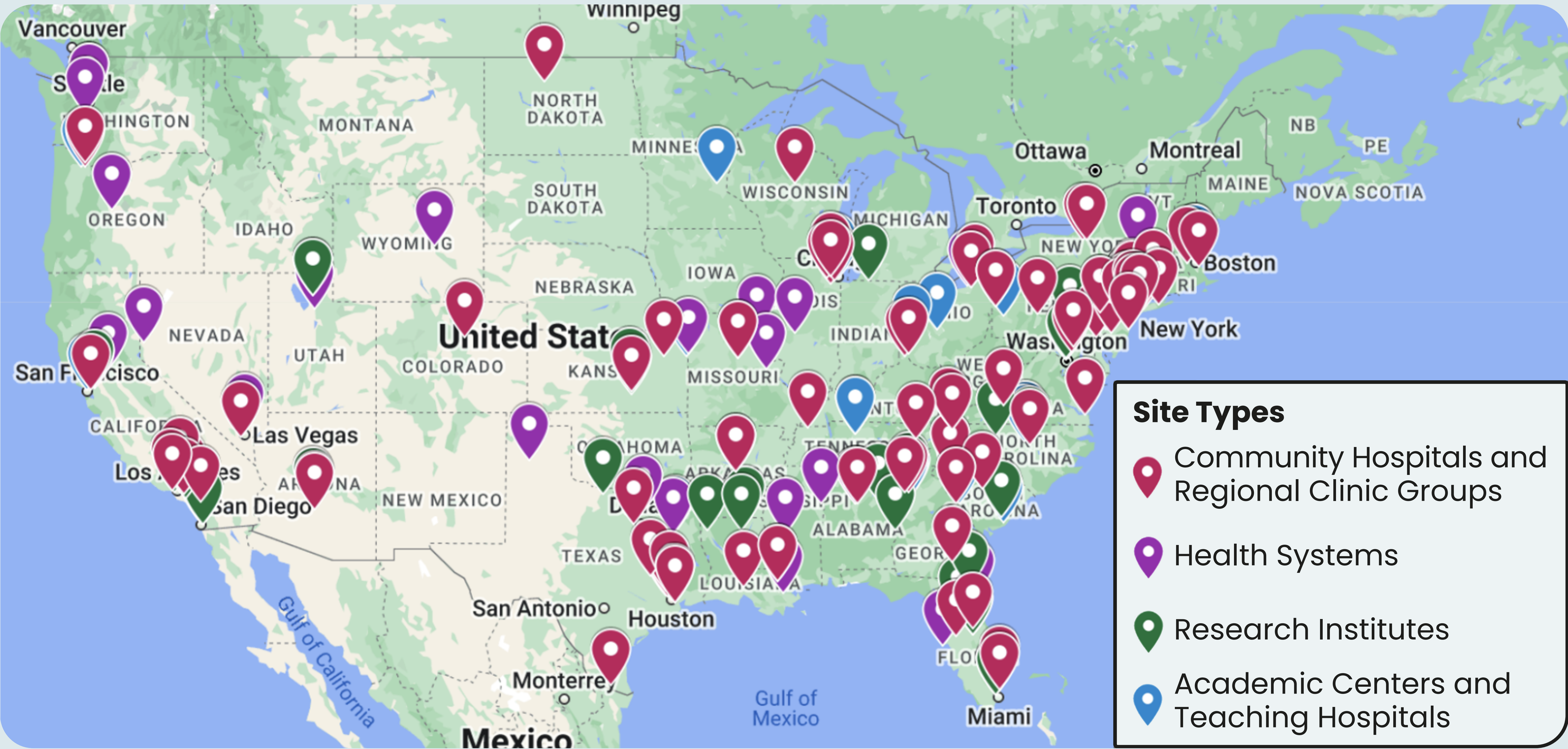
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RESULTS

Figure 2. Study Site Geographic Distribution by Site Type



Map Data © 2024 Google, INEGI.

Study site characteristics

2 of 5

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METHODS

Study design

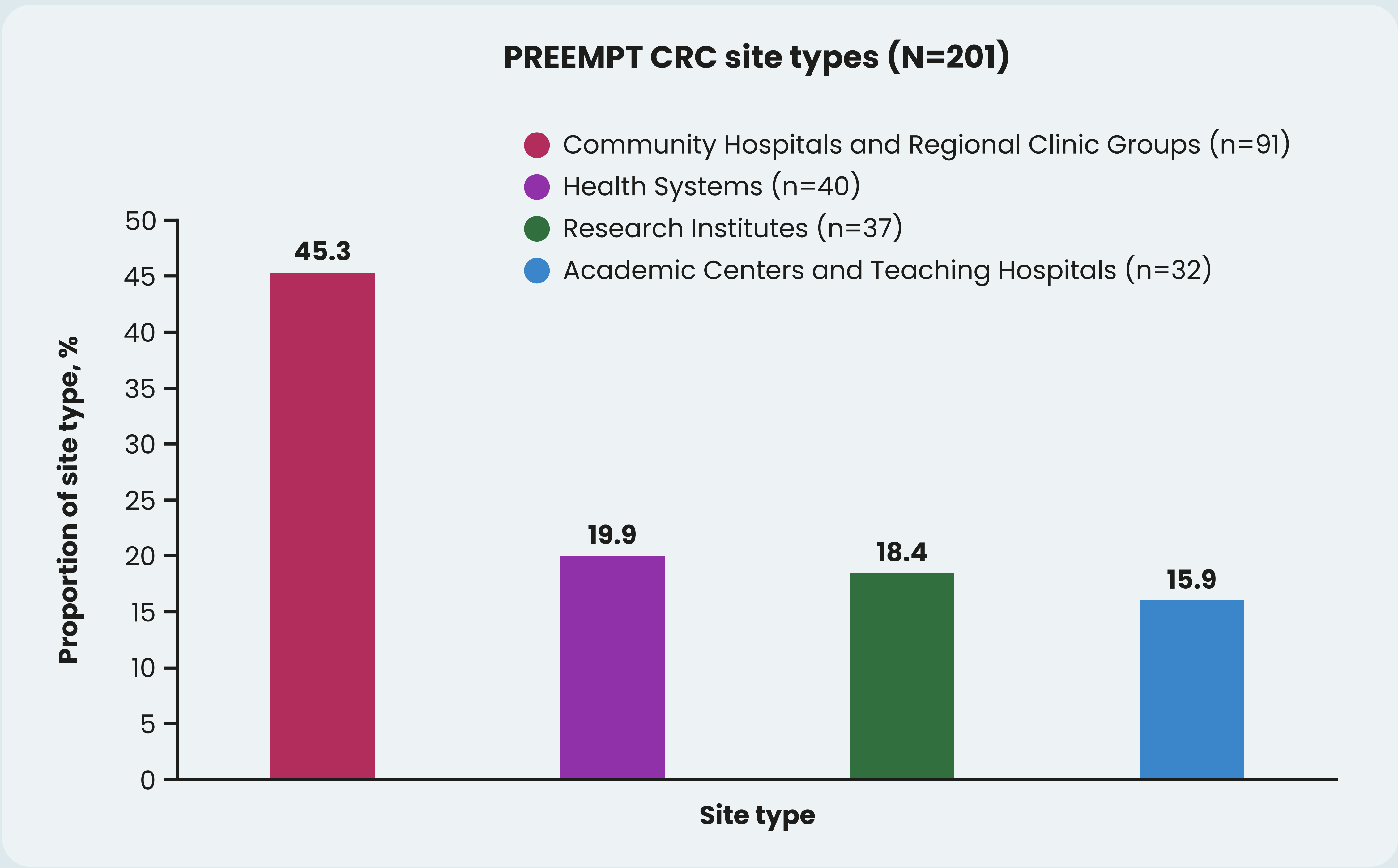
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The decentralized clinical trial Metasite is not included in the above chart. Metasite, colorectal cancer.

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Demographics by 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, range)	58.1 (45-85)	57.4 (45-85)	58.7 (45-85)	59.6 (45-85)	57.9 (45-85)
Sex (n, %)					
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 (n, %)					
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)
Native Hawaiian or Other Pacific Islander	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
American Indian or Alaskan Native	4 (0.01)	22 (0.01)	11 (0.03)	11 (0.03)	48 (0.01)
Other	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Ethnicity (n, %)					
Hispanic or Latino	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Non-Hispanic or Latino	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Other	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
Marital status (n, %)					
Married	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Unmarried	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Other	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

Participants 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. The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states and 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%).

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. The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states and 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%).

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. The DCT Metasite enrolled 12,137 participants (24.8%) across 49 states and 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%).

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 death in the US, with notable disparities existing in incidence and outcomes by race, ethnicity, and geographic location¹⁻⁴
- CRC screening, which is widely recommended for its potential to reduce CRC-related deaths, remains underutilized^{2,5,6}
- A blood test for early CRC detection may offer a more convenient and accessible option for individuals who have not screened with traditional methods^{7,8}
- PREEMPT CRC (NCT04369053⁹), a prospective, multicenter, observational study, aims to recruit a diverse average-risk study population from across the US to evaluate the 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, which 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 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%)⁹
- 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**)

- Asian (6.8% vs 6.4%), and Native Hawaiian or Other Pacific Islander (0.3% vs 0.3%)⁹
- 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 (mean)	58.1	57.4	58.7	59.6	57.9
Gender (%)					
Female	1815 (56.3)	9737 (53.3)	5159 (57.9)	3484 (54.1)	26,967 (55.0)
Male	1400 (43.4)	8539 (46.7)	3729 (41.9)	2958 (45.9)	21,974 (44.8)
Ethnicity (%)					
Black or African American	10 (0.3)	7 (<0.1)	18 (0.2)	2 (<0.1)	54 (0.1)
White	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)
Native Hawaiian or Other Pacific Islander	6 (0.2)	48 (0.3)	16 (0.2)	46 (0.7)	131 (0.3)
American Indian or Alaskan Native	2243 (69.6)	13,327 (72.9)	5540 (62.2)	4735 (73.5)	34,142 (69.7)
Other	28 (0.9)	46 (0.3)	31 (0.3)	21 (0.3)	302 (0.6)
Education (%)					
High school or less	56 (1.7)	499 (2.7)	182 (2.0)	74 (1.1)	1168 (2.4)
Some college	83 (2.6)	1561 (8.5)	131 (1.5)	678 (10.5)	4273 (8.7)
College graduate	148 (4.6)	1841 (10.1)	1627 (18.3)	867 (13.5)	5498 (11.2)
Postgraduate	2901 (90.0)	14,554 (79.6)	7114 (79.9)	4934 (76.6)	38,121 (77.8)
Unknown	176 (5.5)	1888 (10.3)	165 (1.9)	643 (10.0)	5376 (11.0)

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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)
Enrollment, n (%)	12,137 (24.8)	3225 (6.6)	18,283 (37.3)	8906 (18.2)	6444 (13.2)	48,995
Age, ^a years						
Mean	57.1	58.1	57.4	58.7	59.6	57.9
Sex, n (%)						
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)
Race, n (%)						
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)
Ethnicity, n (%)						
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)

Age was not available for 54 participants.
DCT, decentralized clinical trial.

Study site characteristics

5 of 5