Decentralized trial recruitment methods to facilitate broad coverage across urban and rural counties for a blood-based test in early colorectal cancer detection

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INTRODUCTION

- Projections indicate an average of 418 new cases of colorectal cancer (CRC) and 145 CRC-related deaths will occur daily in the US in 2024¹
- Evidence suggests that CRC incidence and mortality rates are higher in rural areas compared with urban areas²
- Individuals in the US living in rural areas (15% to 20% of the population, depending on the definition of rural used) face health disparities, which may underlie the higher CRC incidence and mortality observed in this demographic²⁻
- Rural populations have also traditionally been underrepresented in clinical trials, partially because the areas
- they reside in can be hours away from study sites^{6,7}
- One way to facilitate research participation among geographically diverse populations is through decentralized clinical trials, which allow for study activities to occur without visiting a designated study site⁷ - Decentralized clinical trial methodology can be integrated into traditional study design, allowing for both in-person and decentralized sites within a single clinical study, providing opportunities for study participation among traditionally overlooked demographics
- PREEMPT CRC (NCT04369053⁸) is a prospective, multicenter observational study designed to validate an investigational CRC early detection blood test intended to provide a convenient and accessible approach to CRC screening
- To bolster enrollment from a wide range of geographic locations, PREEMPT CRC strategically included a decentralized clinical trial site

OBJECTIVE

• To evaluate the demographic characteristics and lifestyle behaviors of participants enrolled through the PREEMPT CRC decentralized clinical trial site based on the areas in which they reside

METHODS

Decentralized clinical trial methodology

- The PREEMPT CRC study design and methods have been previously described⁹
- 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 "Metasite" (Figure 1)
- Enrollment through the decentralized clinical trial Metasite was facilitated by a multichannel recruitment strategy that incorporated:
 - Direct-to-participant (DTP) digital channels, which provided a virtual platform that supported digital enrollment from any ZIP code in the US, including rural and urban areas, while maintaining confidentiality and blinding
 - Site-based (SB) partners, who supported recruitment by identifying potential participants scheduled to undergo a colonoscopy at or near their facility
- Enrolled participants' demographics and lifestyle behaviors, such as tobacco, alcohol, and drug use, were collected at baseline
- A virtual platform facilitated all decentralized clinical trial Metasite activities, including eligibility screening, e-consent, medical record review, and patient health questionnaires, with all records and data captured under the unified platform
- Participants could provide blood samples either at a study site or through mobile phlebotomy services at a location of their preference, such as their home
- After a blood sample was obtained, participants underwent a colonoscopy

KEY FINDINGS AND CONCLUSIONS

- Utilization of a decentralized clinical trial site integrated into traditional study design enabled a multichannel recruitment approach that increased study outreach to populations outside of major metro areas
 - The DTP channel expanded the study's geographical reach, especially to nonmetro areas, which may include traditionally underrepresented rural populations that face an increased disease burden
 - SB partners supported inclusion of non-White racial and ethnic minority groups, enrolling a larger proportion of participants that identify as Hispanic or Latino and Black or African American across all three regions
- The broad coverage across metropolitan and nonmetropolitan counties of the PREEMPT CRC decentralized clinical trial Metasite highlights the effectiveness of targeted outreach strategies
- Future early CRC detection research should consider integrating decentralized clinical trial methodology that supports multiple recruitment methods to ensure communities disproportionately affected by CRC are represented



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Figure 1. PREEMPT CRC study schema



CRC, colorectal cancer.

Regional analysis

- Participant ZIP codes were classified as either major metropolitan (major metro), metropolitan (metro), or nonmetropolitan (nonmetro) based on the United States Department of Agriculture (USDA) 2023 Rural-Urban Continuum Codes (RUCCs)¹⁰
- RUCCs broadly classify counties as metropolitan based on metro area population size, or nonmetropolitan based on their degree of urbanization and adjacency to a metropolitan area (**Figure 2**) - For the purpose of this analysis, the largest metropolitan RUCC corresponding to a population of ≥1 million individuals was separated out from the metro category and assigned to its own category of "major metro"
- This approach was employed due to the lack of a single definition of rural; however, it is worth noting that most counties contain a combination of urban and rural populations, regardless of metropolitan or nonmetropolitan RUCC classification¹¹

Figure 2. USDA Rural-Urban Continuum Codes¹²

Metro counties: Population size on or more^o

Fewer than 250,000

Nonmetro counties: Size of urban population, adjacency^b to metro area

- 20,000 or more, adjacent 20,000 or more, nonadjacent
- 5000 to 20,000, adjacent
- 5000 to 20,000, nonadjacent Fewer than 5000, adjacent
- Fewer than 5000, nonadjacent

Note: Rural-Urban Continuum Codes are also available for the county-equivalents of US territories not shown in the map: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the US Virgin Islands. Adapted from: USDA, Economic Research Service using data from the Office of Management and Budget, and US Department of Commerce, Bureau of the Census.

^aFor the purpose of this analysis, metro counties with a metro area population size of ≥1 million individuals were classified as "major metro" counties. Nonmetropolitan counties are considered adjacent to a metropolitan area if they physically border one or more metropolitan areas and ≥2% of their employed labor force commute to central metropolitan counties." USDA, United States Department of Agriculture.

RESULTS

(Table 1

Participant demographics

- PREEMPT CRC study participants (N=48,995) were enrolled across 201 study sites, with 24.8% (n=12,137) of participants enrolling through the decentralized clinical trial Metasite
- More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, 55.9% identified as female, 8.4% identified as Hispanic, and 9.6% identified as Black or African American
- **Regional comparisons**
- Overall, 60.3% (n=7319) of participants were from major metro areas, 30.2% (n=3669) were from metro areas, and 7.3% (n=880) of participants were from nonmetro areas
- The biological sex and age distribution of participants was similar across all regional classifications
- Apart from American Indians and Alaskan Natives, a larger proportion of participants who identified as non-White racial and ethnic minority groups were enrolled from major metro areas compared with metro and nonmetro areas (**Table 1**)
- No noticeable difference was observed in lifestyle behaviors (tobacco, alcohol and/or drug use) between those living in major metro, metro, and nonmetro areas (data not shown)

Table 2. Baseline characteristics of participants enrolled through the decentralized clinical **Table 1.** Baseline characteristics of participants enrolled through the decentralized clinical trial Metasite overall and by region trial Metasite by region and recruitment channel

Ob averato vietia	Overall ^a	Major metro	Metro	Nonmetro		Direct-to	-participant (I	n=7436)ª	Site	-based (n=44	32)ª
	(n=12,137)	(n=/319)	(n=3669)	(n=880)		Major metro	Metro	Nonmetro	Major metro	Metro	Nonmetro
Age, years					Characteristic	(n=4/58)	(n=2019)	(n=659)	(n=2561)	(n=1650)	(n=221)
Mean	57.1	56.9	57.5	58.3	Age, years ^b						
Biological sex, n (%)					Mean	56.5	57.0	58.1	57.7	57.4	59.0
Female	6772 (55.8)	3997 (54.6)	2121 (57.8)	510 (58.0)	Biological sex, n (%)						
Male	5348 (44.1)	3308 (45.2)	1546 (42.1)	369 (41.9)	Female	2555 (53.7)	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)
Unknown	17 (0.1)	14 (0.2)	2 (0.1)	1 (0.1)	Male	2199 (46.2)	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)
Ethnicity, n (%)					Unknown	4 (0.1)	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
Hispanic or Latino	1015 (8.4)	784 (10.7)	165 (4.5)	45 (5.1)	Ethnicity, n (%)						
Not Hispanic or Latino	8618 (71.0)	5009 (68.4)	2824 (76.9)	591 (67.2)	Hispanic or Latino	260 (5.5)	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
Unknown	2504 (20.6)	1526 (20.8)	680 (18.5)	244 (27.7)	Not Hispanic or	3135 (65.9)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
Race, n (%)					Latino						
American Indian or					Unknown	1363 (28.6)	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
Alaskan Native	61 (0.5)	36 (0.5)	16 (0.4)	8 (0.9)	Race, n (%)						
Asian	247 (2.0)	221 (3.0)	20 (0.6)	3 (0.3)	American Indian or						O(1, 4)
Black or African American	1164 (9.6)	812 (11.1)	283 (7.7)	47 (5.3)	Alaskan Native	30 (0.6)	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
Native Hawaiian or					Asian	118 (2.5)	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
Other Pacific Islander	15 (0.1)	11 (0.2)	4 (0.1)	0 (0.0)	Black or African	523 (11.0)	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
White	8297 (68.4)	4794 (65.5)	2712 (73.9)	599 (68.1)	American						
More than one reported	176 (1.5)	114 (1.6)	44 (1.2)	14 (1.6)	Native Hawaiian or Other Pacific Islander	4 (0.1)	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)
Unknown/other	2177 (17.8)	1331 (18.2)	590 (16.1)	209 (23.8)	White	2830 (59.5)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)
°269 ZIP codes did not map to the list of analysis. ^b Age was not reported for 17 pc	USDA RUCCs. These p articipants.	articipants are included	d in the overall analysis,	but not the regional	More than one reported	84 (1.8)	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
					Unknown/other	1169 (24.6)	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)

Regional comparisons by recruitment channel

- Compared with SB partners, DTP channels enrolled a higher proportion of participants from major metro areas (62.3% vs 56.9%) and nonmetro areas (8.6% vs 4.9%) (**Figure 3**)
- SB partners enrolled a higher proportion of participants from metro regions compared with DTP channels (36.6 % vs 26.4%)

Figure 3. Proportion of decentralized clinical trial Metasite participants enrolled from rural vs urban areas overall and by recruitment channel



• For participants from nonmetro areas who reported their race and/or ethnicity:

- A larger proportion of participants who identified as Black or African American enrolled through SB partners (8.6%) compared with DTP channels (4.2%) (**Table 2**)
- Compared with DTP channels, SB partners enrolled a larger proportion of participants who identified a Hispanic or Latino (14.9% vs 1.8%)
- The proportion of participants who identified as Asian was similar across both channels (SB partners: 0.5% vs DTP channels: 0.3%)
- For participants from metro and major metro areas who reported their race and/or ethnicity: - Compared with DTP channels, SB partners enrolled a larger proportion of participants from metro areas who identified as Black or African American (11.0% vs 5.1%); this trend was not seen for participants from major metro areas (SB: 11.3% vs DTP: 11.0%)
 - A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled through SB partners (5.8%) compared with DTP channels (3.5%); this trend was more pronounced in individuals from major metro regions (SB: 20.5% vs DTP: 5.5%)
 - The proportion of participants from metro areas who identified as Asian was similar across both channels (SB: 0.5% vs DTP: 0.6%); compared with DTP channels, SB partners enrolled a slightly larger proportion of participants from major metro areas who identified as Asian (4.0% vs 2.5%)

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^aThe 269 participants (direct-to-participant: n=198; site-based: n=71) with ZIP codes that did not map to the list of USDA RUCCs were not included in this analysis. ^bAge was not reported for 17 participants.

USDA RUCC, United States Department of Agriculture Rural-Urban Continuum Code.

LIMITATIONS

- Assessing rural populations' participation in clinical research can be complex, partially due to the lack of a standardized definition for "rural"^{4,5}
- Numerous definitions for geographically defined areas that could be considered rural exist, and oftentimes these areas are referred to by other names, such as nonmetropolitan, micropolitan or noncore counties⁵
- Further, locations once considered rural or urban can be reclassified following release of new census data⁵
- For this analysis, the use of RUCCs to group participants based on reported ZIP code means that participants included in the nonmetro classification reside in areas typically considered rural and participants included in the major metro or metro classifications reside in the most urban areas¹¹
- However, an individual considered to live in a rural area per the USDA RUCCs, may reside in a different geographically defined region based on other criteria⁵

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Disclosures

JC: employee: Science 37. GC: employee: Clinetic; former employee: Science 37. MSB: employee: Science 37. KK: employee: Freenome Holdings, Inc. YL: former employee: Freenome Holdings, Inc. CX: employee: Freenome Holdings, Inc. LCL: employee: Freenome Holdings, Inc. LB: employee: Freenome Holdings, Inc. AS: consultant: Freenome Holdings, Inc., Iterative Health. TRL: employee: The Permanente Medical Group, Inc.; 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 (C4; unpaid); research funding: PCORI, Universal Diagnostics, Freenome Holdings, Inc.



INTRODUCTION

Figure 1. PREEMPT CRC study schema

• Projections indicate an average of 418 new cases of colorectal cancer (CRC) and 145 CRC-related deaths will occur daily in the US in 2024¹

• Evidence suggests that CRC incidence and mortality rates are higher in rural areas compared with urban areas² • Individuals in the US living in rural areas (15% to 20% of the population, depending on the definition of rural used) face health disparities, which may underlie the higher CRC incidence and mortality observed in this demographic²⁻⁵ • Rural populations have also traditionally been underrepresented in clinical trials, partially because the areas they reside in can be hours away from study sites^{6,7}

• One way to facilitate research participation among geographically diverse populations is through decentralized clinical trials, which allow for study activities to occur without visiting a designated study site⁷ - Decentralized clinical trial methodology can be integrated into traditional study design, allowing for both in-person and decentralized sites within a single clinical study, providing opportunities for study participation among traditionally overlooked demographics

• PREEMPT CRC (NCT04369053⁸) is a prospective, multicenter observational study designed to validate an investigational CRC early detection blood test intended to provide a convenient and accessible approach to CRC screening • To bolster enrollment from a wide range of geographic locations, PREEMPT CRC strategically included a decentralized clinical trial site

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

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Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

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-to					
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	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
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Decentralized clinical trial methodology

- incorporated:
- baseline

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1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
2 (0.1) 1340 (66 4)	418 (63 A)	1964 (767)	2 (U.I) 1372 (83.2)	181 (81.0)
1340 (00.4)	410 (03.4)	1304 (70.7)	1372 (03.2)	101 (01.9)
27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)

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⁻ A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**







CRC, colorectal cancer.

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

-10							
ro	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)		
	57.0	58.1	57.7	57.4	59.0		
)	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)		
)	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)		
	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)		
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)		
)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)		
)	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)		
	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)		
	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)		
	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)		
	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)		
5)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)		
	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)		
	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)		

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METHODS

Regional analysis

- classification¹¹

Figure 1. PREEMPT CRC study schema

 Participant ZIP codes were classified as either major metropolitan (major metro), metropolitan (metro), or nonmetropolitan (nonmetro) based on the United States Department of Agriculture (USDA) 2023 Rural-Urban Continuum Codes (RUCCs)¹⁰

• RUCCs broadly classify counties as metropolitan based on metro area population size, or nonmetropolitan based on their degree of urbanization and adjacency to a metropolitan area (Figure 2) - For the purpose of this analysis, the largest metropolitan RUCC corresponding to a population of ≥1 million individuals was separated out from the metro category and assigned to its own category of "major metro" • This approach was employed due to the lack of a single definition of rural; however, it is worth noting that most counties contain a combination of urban and rural populations, regardless of metropolitan or nonmetropolitan RUCC

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

on and recruitment channel

-to					
ro	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)
	57.0	58.1	57.7	57.4	59.0
)	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)
)	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)
	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
)	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)
)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)
	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)



⁻ A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**





Figure 2. USDA Rural-Urban Continuum Codes¹²



Note: Rural-Urban Continuum Codes are also available for the county-equivalents of US territories not shown in the map: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the US Virgin Islands.

Adapted from: USDA, Economic Research Service using data from the Office of Management and Budget, and US Department of Commerce, Bureau of the Census.

^aFor the purpose of this analysis, metro counties with a metro area population size of ≥1 million individuals were classified as "major metro" counties. ^bNonmetropolitan counties are considered adjacent to a metropolitan area if they physically border one or more metropolitan areas and ≥2% of their employed labor force commute to central metropolitan counties."

Figure 1. PREEMPT CRC study schema

USDA, United States Department of Agriculture.

• For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Metro counties: Population size of metro areas

> 1 million or more^a 250,000 to 1 million Fewer than 250,000

Nonmetro counties: Size of urban population, adjacency^b to metro area

> 20,000 or more, adjacent 20,000 or more, nonadjacent 5000 to 20,000, adjacent 5000 to 20,000, nonadjacent Fewer than 5000, adjacent Fewer than 5000, nonadjacent

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)
57.0	58.1	57.7	57.4	59.0
1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)
837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)
1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)
1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)
27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)

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RESULTS

Participant demographics

Regional comparisons

Figure 1. PREEMPT CRC study schema



• PREEMPT CRC study participants (N=48,995) were enrolled across 201 study sites, with 24.8% (n=12,137) of participants enrolling through the decentralized clinical trial Metasite - More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, 55.9% identified as female, 8.4% identified as Hispanic, and 9.6% identified as Black or African American (**Table 1**)

• Overall, 60.3% (n=7319) of participants were from major metro areas, 30.2% (n=3669) were from metro areas, and 7.3% (n=880) of participants were from nonmetro areas • The biological sex and age distribution of participants was similar across all regional classifications • Apart from American Indians and Alaskan Natives, a larger proportion of participants who identified as non-White racial and ethnic minority groups were enrolled from major metro areas compared with metro and nonmetro areas (Table 1) • No noticeable difference was observed in lifestyle behaviors (tobacco, alcohol and/or drug use) between those living in major metro, metro, and nonmetro areas (data not shown)

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical on and recruitment channel

-to					
ro	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)
	57.0	58.1	57.7	57.4	59.0
	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)
	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)
	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)
)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)
	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)

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⁻ A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**





Table 1. Baseline characteristics of participants enrolled through the decentralized clinical trial Metasite overall and by region

Characteristic	Overall¤ (n=12,137)	Major metro (n=7319)	Metro (n=3669)	Nonmetro (n=880)
Age, years ^b				
Mean	57.1	56.9	57.5	58.3
Biological sex, n (%)				
Female	6772 (55.8)	3997 (54.6)	2121 (57.8)	510 (58.0)
Male	5348 (44.1)	3308 (45.2)	1546 (42.1)	369 (41.9)
Unknown	17 (0.1)	14 (0.2)	2 (0.1)	1 (0.1)
Ethnicity, n (%)				
Hispanic or Latino	1015 (8.4)	784 (10.7)	165 (4.5)	45 (5.1)
Not Hispanic or Latino	8618 (71.0)	5009 (68.4)	2824 (76.9)	591 (67.2)
Unknown	2504 (20.6)	1526 (20.8)	680 (18.5)	244 (27.7)
Race, n (%)				
American Indian or Alaskan Native	61 (0.5)	36 (0.5)	16 (0.4)	8 (0.9)
Asian	247 (2.0)	221 (3.0)	20 (0.6)	3 (0.3)
Black or African American	1164 (9.6)	812 (11.1)	283 (7.7)	47 (5.3)
Native Hawaiian or Other Pacific Islander	15 (0.1)	11 (0.2)	4 (0.1)	0 (0.0)
White	8297 (68.4)	4794 (65.5)	2712 (73.9)	599 (68.1)
More than one reported	176 (1.5)	114 (1.6)	44 (1.2)	14 (1.6)
Unknown/other	2177 (17.8)	1331 (18.2)	590 (16.1)	209 (23.8)

^a269 ZIP codes did not map to the list of USDA RUCCs. These participants are included in the overall analysis, but not the regional analysis. ^bAge was not reported for 17 participants. USDA RUCC, United States Department of Agriculture Rural-Urban Continuum Code.

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)		
57.0	58.1	57.7	57.4	59.0		
1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)		
837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)		
1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)		
70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)		
1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)		
599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)		
10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)		
12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)		
102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)		
2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)		
1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)		
27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)		
526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)		

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RESULTS

Regional comparisons by recruitment channel

Figure 1. PREEMPT CRC study schema

 Compared with SB partners, DTP channels enrolled a higher proportion of participants from major metro areas (62.3% vs 56.9%) and nonmetro areas (8.6% vs 4.9%) (**Figure 3**)

• SB partners enrolled a higher proportion of participants from metro regions compared with DTP channels (36.6 % vs 26.4%)

Figure 3. Proportion of decentralized clinical trial Metasite participants enrolled from rural vs urban areas overall and by recruitment channel



Overall (n=12,137)

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)





- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

and recruitment channel

-to						
	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)	
	57.0	58.1	57.7	57.4	59.0	
	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)	
	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)	
	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)	
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)	
	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)	
	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)	
	10(0.5)	5(0.8)	6(0.2)	6 (0.4)	3 (1.4)	
	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1(0.5)	
	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)	
	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)	
	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)	
	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)	
	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)	

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RESULTS

Figure 1. PREEMPT CRC study schema

 For participants from nonmetro areas who reported their race and/or ethnicity: - A larger proportion of participants who identified as Black or African American enrolled through SB partners (8.6%) compared with DTP channels (4.2%) (Table 2)

- Compared with DTP channels, SB partners enrolled a larger proportion of participants who identified as Hispanic or Latino (14.9% vs 1.8%)

- The proportion of participants who identified as Asian was similar across both channels (SB partners: 0.5% vs DTP channels: 0.3%)

• For participants from metro and major metro areas who reported their race and/or ethnicity: - Compared with DTP channels, SB partners enrolled a larger proportion of participants from metro areas who identified as Black or African American (11.0% vs 5.1%); this trend was not seen for participants from major metro areas (SB: 11.3% vs DTP: 11.0%)

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled through SB partners (5.8%) compared with DTP channels (3.5%); this trend was more pronounced in individuals from major metro regions (SB: 20.5% vs DTP: 5.5%)

- The proportion of participants from metro areas who identified as Asian was similar across both channels (SB: 0.5% vs DTP: 0.6%); compared with DTP channels, SB partners enrolled a slightly larger proportion of participants from major metro areas who identified as Asian (4.0% vs 2.5%)

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical on and recruitment channel

-to-participant (n=7436)ª							
ro	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)		
	57.0	58.1	57.7	57.4	59.0		
)	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)		
)	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)		
	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)		
	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)		
)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)		
)	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)		
	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)		
	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)		
	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)		
	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)		
)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)		
	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)		
)	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)		



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⁻ A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**





nu metusite by region und recruitment chumier							
	Direct-to-participant (n=7436)ª			Site-based (n=4432)ª			
Characteristic	Major metro (n=4758)	Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)	
Age, years ^b							
Mean	56.5	57.0	58.1	57.7	57.4	59.0	
Biological sex, n (%)							
Female	2555 (53.7)	1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)	
Male	2199 (46.2)	837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)	
Unknown	4 (0.1)	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)	
Ethnicity, n (%)							
Hispanic or Latino	260 (5.5)	70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)	
Not Hispanic or Latino	3135 (65.9)	1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)	
Unknown	1363 (28.6)	599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)	
Race, n (%)							
American Indian or Alaskan Native	30 (0.6)	10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)	
Asian	118 (2.5)	12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)	
Black or African American	523 (11.0)	102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)	
Native Hawaiian or Other Pacific Islander	4 (0.1)	2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)	
White	2830 (59.5)	1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)	
More than one reported	84 (1.8)	27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)	
Unknown/other	1169 (24.6)	526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)	
The 260 participants (direct to participants p=100; site based; p=71) with 710 codes that did not page to the list of UCDA DUCCe ware							

trial Metasite by region and recruitment channel

'The 269 participants (direct-to-participant: n=198; site-based: n=71) with ZIP codes that did not map to the list of USDA RUCCs were not included in this analysis. ^bAge was not reported for 17 participants. USDA RUCC, United States Department of Agriculture Rural-Urban Continuum Code.

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

Table 2. Baseline characteristics of participants enrolled through the decentralized clinical

- A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**

Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)
57.0	58.1	57.7	57.4	59.0
1181 (58.5)	392 (59.5)	1442 (56.3)	940 (57.0)	118 (53.4)
837 (41.5)	266 (40.4)	1109 (43.3)	709 (43.0)	103 (46.6)
1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)
70 (3.5)	12 (1.8)	524 (20.5)	95 (5.8)	33 (14.9)
1350 (66.9)	418 (63.4)	1874 (73.2)	1474 (89.3)	173 (78.3)
599 (29.7)	229 (34.7)	163 (6.4)	81 (4.9)	15 (6.8)
10 (0.5)	5 (0.8)	6 (0.2)	6 (0.4)	3 (1.4)
12 (0.6)	2 (0.3)	103 (4.0)	8 (0.5)	1 (0.5)
102 (5.1)	28 (4.2)	289 (11.3)	181 (11.0)	19 (8.6)
2 (0.1)	0 (0.0)	7 (0.3)	2 (0.1)	0 (0.0)
1340 (66.4)	418 (63.4)	1964 (76.7)	1372 (83.2)	181 (81.9)
27 (1.3)	14 (2.1)	30 (1.2)	17 (1.0)	0 (0.0)
526 (26.1)	192 (29.1)	162 (6.3)	64 (3.9)	17 (7.7)

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LIMITATIONS

Figure 1. PREEMPT CRC study schema

· Assessing rural populations' participation in clinical research can be complex, partially due to the lack of a standardize definition for "rural"^{4,5}

• Numerous definitions for geographically defined areas that could be considered rural exist, and oftentimes these areas are referred to by other names, such as nonmetropolitan, micropolitan or noncore counties⁵

• Further, locations once considered rural or urban can be reclassified following release of new census data⁵

metro classifications reside in the most urban areas¹¹

- However, an individual considered to live in a rural area per the USDA RUCCs, may reside in a different geographically defined region based on other criteria⁵

More participants were enrolled through DTP channels (n=7634) compared with SB partners (n=4503) • For all participants enrolled through the decentralized clinical trial Metasite, the mean age was 57.1 years, (Table 1)

- and nonmetro areas (Table 1)

Table 1. Baseline characteristics of participants enrolled through the decentralized clinical **Table 2.** Baseline characteristics of participants enrolled through the decentralized clinical

- For this analysis, the use of RUCCs to group participants based on reported ZIP code means that participants included in the nonmetro classification reside in areas typically considered rural and participants included in the major metro o

on and recruitment channel

	-to-participant					
	ro Metro (n=2019)	Nonmetro (n=659)	Major metro (n=2561)	Metro (n=1650)	Nonmetro (n=221)	
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	57.0	58.1	57.7	57.4	59.0	
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;U	1 (0.0)	1 (0.2)	10 (0.4)	1 (0.1)	0 (0.0)	
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⁻ A larger proportion of participants from metro areas who identified as Hispanic or Latino were enrolled **Disclosures**