Multichannel recruitment enabled broad geographical reach in an average-risk population screening study for a blood-based test for the early detection of colorectal cancer

Jonathan Cotliar,[1] Muhammad Shaalan Beg,[1] Gordon Cummins,[1,a] Catherine Schon,[1] Ali Wherry,[1] Karolina Kutnik,[2] Yontao Lu,[2] Chuanbo Xu,[2] Lilian C. Lee,[2] Lance Baldo,[2] Aasma Shaukat,[3,4] Theodore R. Levin[5]

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[a]Current affiliation: Clinetic, Durham, NC, USA

INTRODUCTION

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- Colorectal cancer (CRC) is the second deadliest and third most frequently diagnosed cancer in the US[1]
- CRC incidence and mortality in the US vary racially, ethnically, and geographically, in part due to inequities in access to medical care, including CRC screening[1]
- Promoting equitable access to CRC screening may help alleviate the disproportionate CRC burden faced by medically underserved populations[1]
- Designed to meet patients where they are, decentralized clinical trials (DCTs) allow for all (fully DCT) or some (hybrid DCT) study activities to occur without visiting a designated study site[2]
  - DCT methodology can be integrated into traditional study design, allowing for both in-person and decentralized sites within the same clinical study[2]
- Including DCT sites in CRC studies could increase representation of historically underserved populations with higher CRC morbidity and mortality
- PREEMPT CRC (NCT04369053) is a prospective multicenter observational study evaluating the clinical validity of a CRC early detection blood test in an average-risk population representative of real-world CRC patients[3]
- Participants (N=48,995) were enrolled at over 200 trial sites, including a DCT site, across rural and urban communities

OBJECTIVE

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- Here, we provide an analysis of the recruitment approach utilized by the PREEMPT CRC DCT site and its impact on the study population's diversity and geographical distribution

KEY FINDINGS AND CONCLUSIONS

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- Utilization of the DCT site approach enabled a multichannel recruitment strategy that increased study outreach to historically underrecruited communities, such as those in rural locations,[2] and contributed to the enrollment of a diverse population in the PREEMPT CRC clinical study
  - The direct-to-participant channel expanded the study's geographical reach, enabling enrollment across urban and rural communities nationwide
  - Site-based channels supplemented enrollment, particularly from underrepresented minority groups who may have limited access to CRC screening[2,4]
- Facilitating the access of all individuals who face barriers to CRC screening is imperative to ensure the racial, ethnic, and geographic communities disproportionately affected by CRC are represented[1,4]
- Future early cancer detection studies can ensure adequate representation across diverse patient populations by incorporating DCT methodology that supports tailored recruitment channels

METHODS

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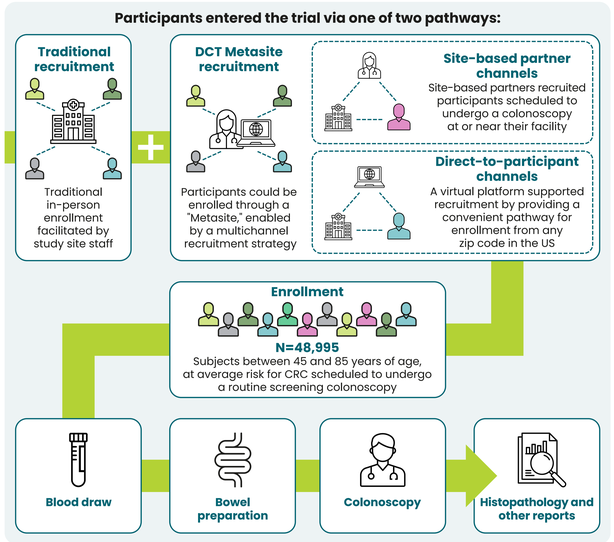
DCT methodology

- The PREEMPT CRC study design and methods have been previously described[3]
- Study participants were enrolled into PREEMPT CRC via one of two pathways (**Figure 1**): traditional in-person enrollment at a designated study site or enrollment through a single DCT "Metasite"[3]
- Enrollment through the DCT Metasite was facilitated by a multichannel recruitment strategy that incorporated:
  - Direct-to-participant digital channels, which provided a virtual platform that supported digital enrollment from any zip code in the US,[3] including rural and urban areas, while maintaining confidentiality and blinding
  - Site-based partners, who supported recruitment by identifying potential participants scheduled to undergo a colonoscopy at or near their facility
- A virtual platform 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
- 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
- Blood samples were obtained prior to participants undergoing bowel preparation for colonoscopy

Figure 1. Entry pathways to study enrollment



CRC, colorectal cancer; DCT, decentralized clinical trial.

RESULTS

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Patient demographics

- The DCT Metasite enrolled a total of 12,137 participants
- Overall, the mean age of participants was 57.1 years, 55.9% were female, 8.4% were Hispanic, and 9.6% were Black or African American (**Table 1**)
- More participants were enrolled through direct-to-participant channels (n=7634) vs site-based partners (n=4503)
- Compared with direct-to-participant digital channels, site-based partners enrolled a higher proportion of Hispanic or Latino (14.6% vs 4.7%), Asian (2.5% vs 1.8%), and Black or African American (11.0% vs 8.8%) participants (**Table 1**)

Table 1. Baseline characteristics of participants enrolled through the DCT Metasite

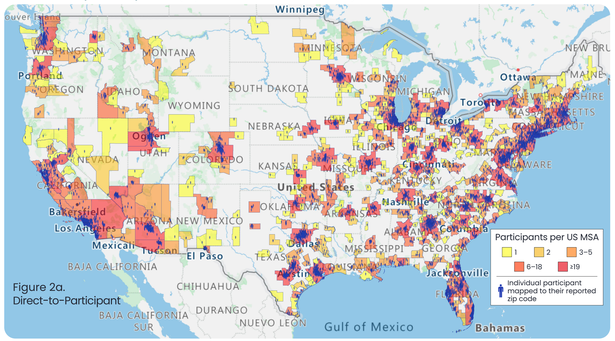
Characteristic	Overall (n=12,137)	Direct-to-participant (n=7634)	Site-based partners (n=4503)
Age, years			
Mean	57.1	56.8	57.6
Biological sex, n (%)			
Female	6752 (55.9)	4231 (55.5)	2541 (56.6)
Male	5348 (44.1)	3397 (44.5)	1951 (43.4)
Ethnicity, n (%)			
Hispanic or Latino	1015 (8.4)	359 (4.7)	656 (14.6)
Not Hispanic or Latino	8618 (71.0)	5031 (65.9)	3587 (79.7)
Unknown	2504 (20.6)	2244 (29.4)	260 (5.8)
Race, n (%)			
American Indian or Alaskan Native	61 (0.5)	46 (0.6)	15 (0.3)
Asian	247 (2.0)	134 (1.8)	113 (2.5)
Black or African American	1164 (9.6)	670 (8.8)	494 (11.0)
Native Hawaiian or Other Pacific Islander	15 (0.12)	6 (0.1)	9 (0.2)
White	8297 (68.4)	4719 (61.8)	3578 (79.5)
More than one reported	176 (1.5)	128 (1.7)	48 (1.1)
Unknown/other	2177 (17.8)	1931 (25.3)	246 (5.5)

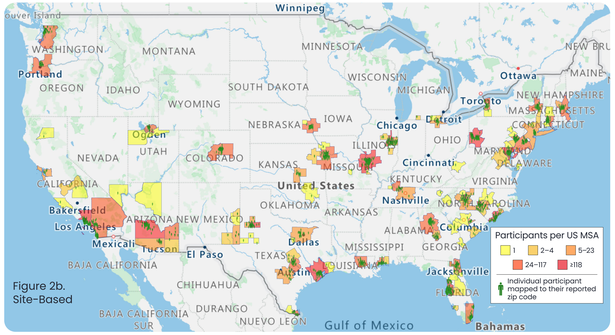
DCT, decentralized clinical trial.

Geographic distribution of DCT Metasite participants

- Direct-to-participant channels enrolled participants from 5134 unique zip codes representing 44% of the US population in 49 states (**Figure 2a**)
- Site-based partners enrolled participants from 1393 zip codes representing 11% of the US population in 34 states (**Figure 2b**)

Figure 2. Zip codes from participants enrolled using DCT Metasite, including direct-to-participant (a) and site-based (b) channels





Individual participants mapped to their reported zip code are shown in blue and green. Shaded areas represent metropolitan/micropolitan statistical areas. Zip code data were available for 12,069 participants (direct-to-participant: n=7582; site-based: n=4487). The remaining 53 participants with missing, incomplete, or invalid zip codes (direct-to-participant: n=39; site-based: n=14) and 15 participants from Alaska (direct-to-participant: n=13; site-based: n=2) are not included in the maps. Maps were generated using eSpatial mapping software.

DCT, decentralized clinical trial; MSA, metropolitan/micropolitan statistical area.

References

1. Siegel RL, et al. *CA Cancer J Clin*. 2023;73(3):233-254.
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Poster Sa1130. Presented at Digestive Disease Week; May 18-21, 2024; Washington, DC, USA.

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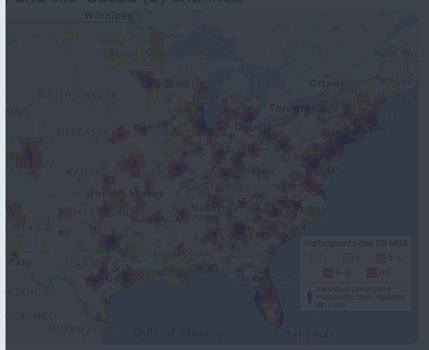

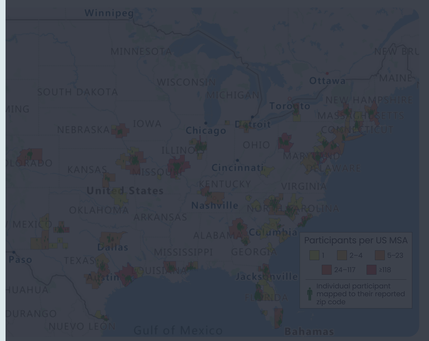

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Poster Sat130. Presented at Digestive Disease Week; May 18-21, 2024; Washington, DC, USA.

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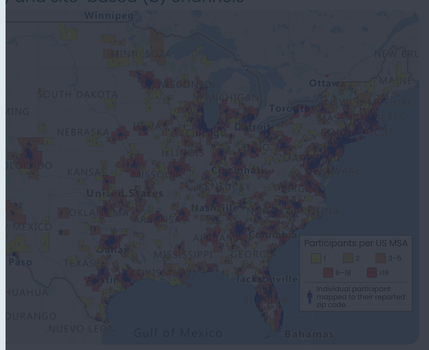

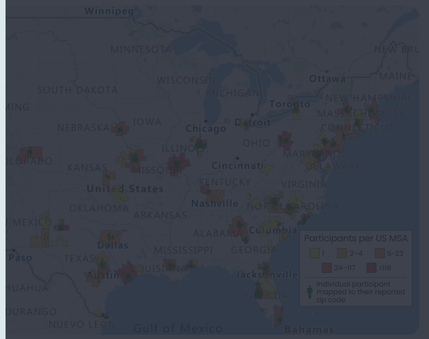

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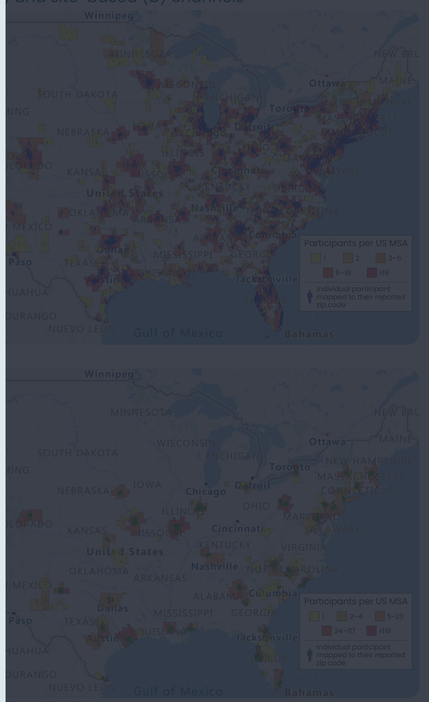

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METHODS

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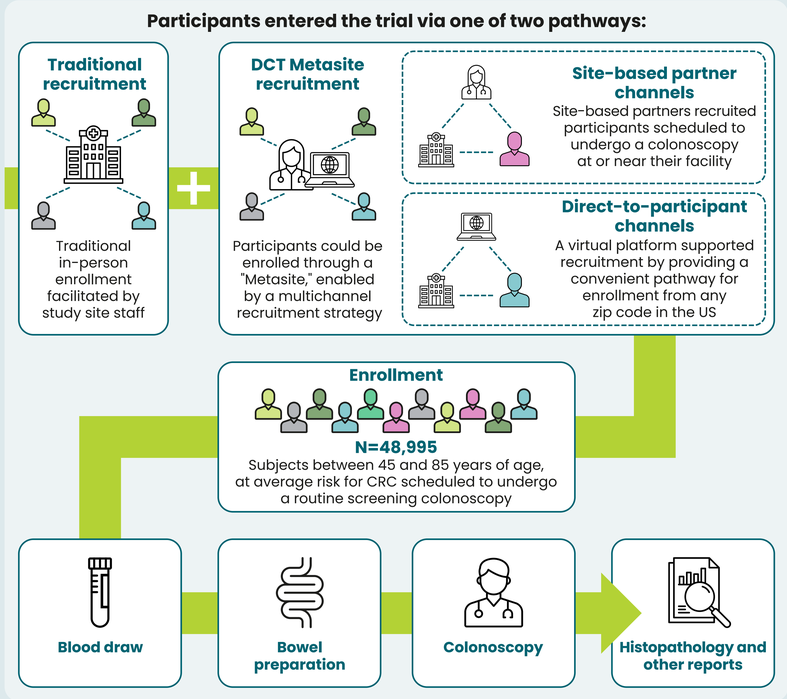

CRC, colorectal cancer; DCT, decentralized clinical trial.

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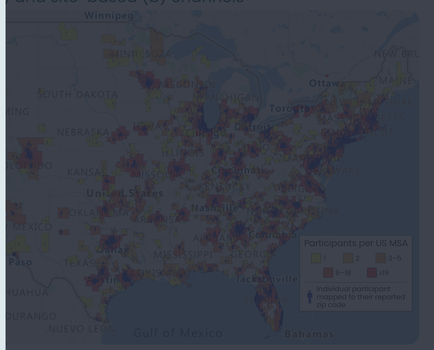

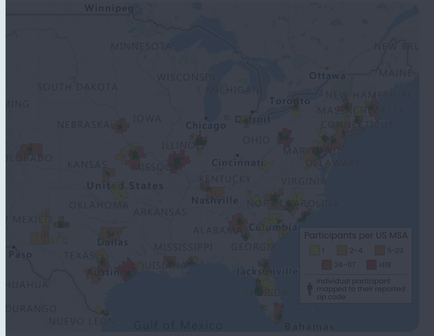

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Unknown/other	2177 (17.8)	1931 (25.3)	246 (5.5)

DCT, decentralized clinical trial.

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- Direct-to-participant channels enrolled participants from 5134 unique zip codes representing 44% of the US population in 49 states (**Figure 2a**)
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Poster Sat130. Presented at Digestive Disease Week; May 18–21, 2024; Washington, DC, USA.

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- Colorectal cancer (CRC) is the second deadliest diagnosed cancer in the US[1]
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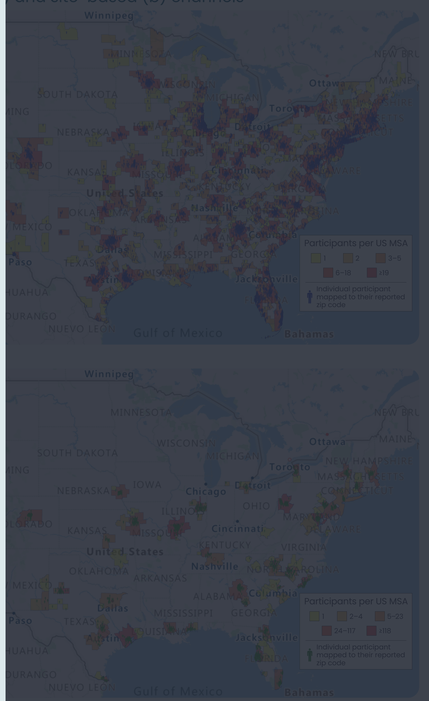

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RESULTS

Patient demographics

- The DCT Metasite enrolled a total of 12,137 participants
- Overall, the mean age of participants was 57.1 years, 55.9% were female, 8.4% were Hispanic, and 9.6% were Black or African American (**Table 1**)
- More participants were enrolled through direct-to-participant channels (n=7634) vs site-based partners (n=4503)
- Compared with direct-to-participant digital channels, site-based partners enrolled a higher proportion of Hispanic or Latino (14.6% vs 4.7%), Asian (2.5% vs 1.8%), and Black or African American (11.0% vs 8.8%) participants (**Table 1**)

Table 1. Baseline characteristics of participants enrolled through the DCT Metasite

Characteristic	Overall (n=12,137)	Direct-to-participant (n=7634)	Site-based partners (n=4503)
Age, years			
Mean	57.1	56.8	57.6
Biological sex, n (%)			
Female	6752 (55.9)	4231 (55.5)	2541 (56.6)
Male	5348 (44.1)	3397 (44.5)	1951 (43.4)
Ethnicity, n (%)			
Hispanic or Latino	1015 (8.4)	359 (4.7)	656 (14.6)
Not Hispanic or Latino	8618 (71.0)	5031 (65.9)	3587 (79.7)
Unknown	2504 (20.6)	2244 (29.4)	260 (5.8)
Race, n (%)			
American Indian or Alaskan Native	61 (0.5)	46 (0.6)	15 (0.3)
Asian	247 (2.0)	134 (1.8)	113 (2.5)
Black or African American	1164 (9.6)	670 (8.8)	494 (11.0)
Native Hawaiian or Other Pacific Islander	15 (0.12)	6 (0.1)	9 (0.2)
White	8297 (68.4)	4719 (61.8)	3578 (79.5)
More than one reported	176 (1.5)	128 (1.7)	48 (1.1)
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Figure 2. Zip codes from participants enrolled using DCT Metasite, including direct-to-participant (a) and site-based (b) channels

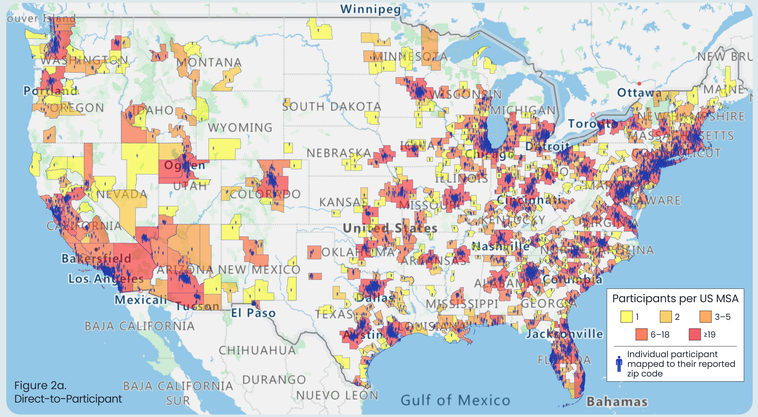

Figure 2a. Direct-to-Participant

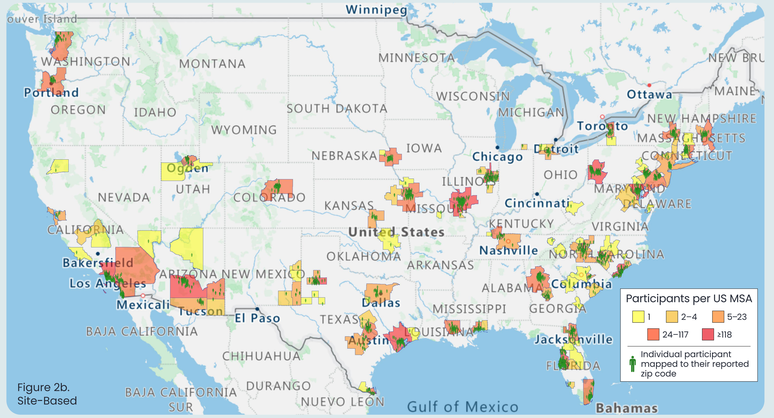

Figure 2b. Site-Based

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Individual participants mapped to their reported zip code are shown in blue and green. Shaded areas represent metropolitan/micropolitan statistical areas. Zip code data were vailable for 12,069 participants (direct-to-participant: n=7582; site-based: n=4487). The remaining 53 participants with missing, incomplete, or invalid zip codes (direct-to-participant: n=39; site-based: n=14) and 15 participants from Alaska (direct-to-participant: n=13; site-based: n=2) are not included in the maps. Maps were generated using eSpatial mapping software.

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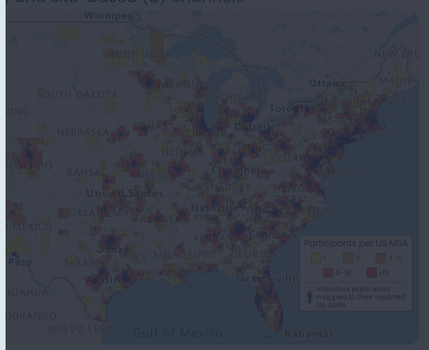

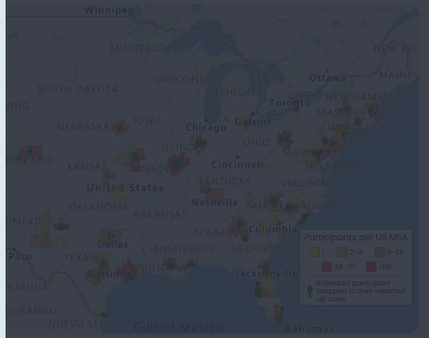

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  - The direct-to-participant channel expanded the study's geographical reach, enabling enrollment across urban and rural communities nationwide
  - Site-based channels supplemented enrollment, particularly from underrepresented minority groups who may have limited access to CRC screening[2,4]
- Facilitating the access of all individuals who face barriers to CRC screening is imperative to ensure the racial, ethnic, and geographic communities disproportionately affected by CRC are represented[1,4]
- Future early cancer detection studies can ensure adequate representation across diverse patient populations by incorporating DCT methodology that supports tailored recruitment channels