

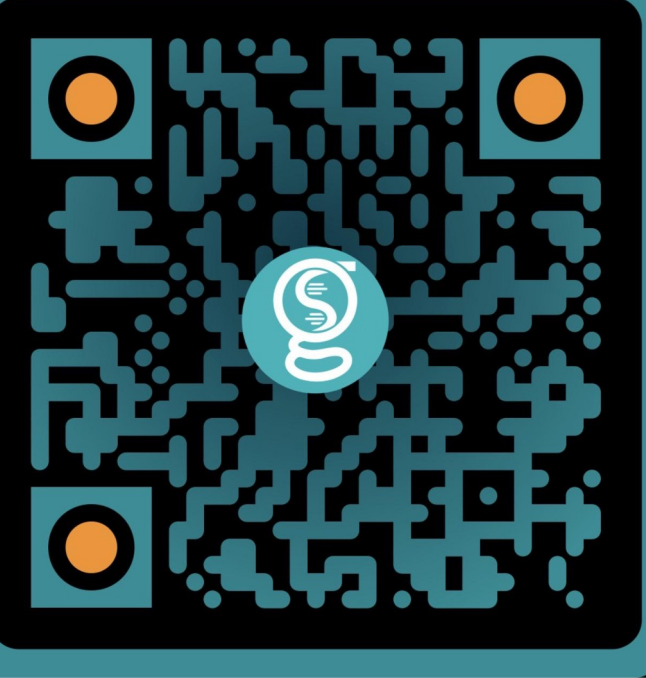
UTILIZING A DECENTRALIZED CLINICAL STUDY APPROACH FOR EXPEDITED AND DIVERSE RECRUITMENT FOR CLINICAL VALIDATION OF A NOVEL NON-INVASIVE MULTI-TARGETED STOOL-BASED RNA TEST

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INTRODUCTION

Traditional clinical trials that utilize fixed sites often fail to recruit and enroll participants that are representative of the intended use population. Participants, particularly those from historically underserved populations, cite geographical constraints, mistrust, miscommunication, and discrimination as barriers to clinical trial participation. A decentralized clinical trial enrollment strategy offers greater study population diversity, lower costs, reduced time requirements, and circumvent barriers associated with the recent pandemic.

METHODS

After the mt-sRNA test system entered design lock, a decentralized clinical trial (CRC-PREVENT) was launched through a digital campaign (<https://www.colonscreeningstudy.com/>; NCT04739722). Online advertisements were published on multiple social media sites, and engagement with materials directed patients to an online screening survey. Participants who completed the screener were eligible for enrollment if they met CRC-PREVENT inclusion and exclusion criteria and were willing to complete all clinical trial components, including providing a stool sample before an optical colonoscopy.

RESULTS

After 12 months of active enrollment:

- 276,400 individuals engaged with digital advertisements and completed pre-screener surveys to determine eligibility for the clinical trial.
- In total, 14,264 individuals consented to participate in the CRC-PREVENT clinical trial.
- Of these individuals, 58% were female (42% were male), and 65% were over 50.
- Regarding race and ethnicity, eligible individuals directly represented the intended use population: 16% were Black or African American, 0.2% were Native Hawaiian, Pacific Islander, American Indian, or Alaskan Native, and 7% were Hispanic or Latinx.
- Regarding socioeconomic status, the decentralized approach permitted access to individuals facing healthcare inequities: 25% of participants had income under \$29,999, 5% of participants were from rural areas (defined as a city center <10,000 people), and 36.7% of participants were on public insurance.
- Individuals were derived from 7,644 unique zip codes across all 48 continental United States.

CONCLUSION

A decentralized recruitment strategy permits highly successful enrollment in the face of screening burdens heightened by the COVID-19 pandemic. This approach also resulted in a significantly more diverse study population and shows promise in mitigating selection bias and attrition bias associated with the cohorts observed in traditional clinical studies.

