BACKGROUND

- Recent guidelines recommend initiating colorectal cancer (CRC) screening at age 45\(^\text{+1}\), increasing the number of screen-eligible individuals by 70%.
- Only 67% of average-risk individuals over the age of 50 years are up-to-date on CRC screening despite the availability of multiple non-invasive screening options.
- This will likely become even more challenging with the addition of 18-45 year-old children younger individuals have even lower screening rates. and younger patients now comprise a larger proportion of the screening population.
- Further, participation by minorities in clinical trials remains challenging, and this is especially unfortunate since black individuals are at significantly higher risk for CRC. For example, CRC prevalence is 50% higher in Black individuals compared to White individuals.

- Blood tests can help overcome some or all of these barriers even though ease of sample collection and integration into routine clinical care.

- Here, we describe our registrational study for the clinical validation of a blood test for the early detection of CRC using a multiomics approach, which is a combination of DNA and protein assay. We also highlight adaptations to our recruitment processes to increase representation of historically underserved populations and broaden access to our clinical trial.

OBJECTIVES

- To describe our multiomic approach that uses both DNA and protein assays to evaluate tumor- and non-tumor signals to detect CRC and advanced adenomas.
- To describe the recruitment processes used for our clinical validation study: Prevention of Colorectal Cancer Through Multiomics Blood Testing: The PREEMPT CRC Study.
- To describe our multiomic approach that uses both DNA and protein assays. We also highlight adaptations to our recruitment processes to increase representation of historically underserved populations and broaden access to our clinical trial.

CONCLUSIONS

- Our multiomics test combines tumor- and non-tumor signals from DNA and protein biomarkers and uses machine learning to detect complex patterns of disease from blood.
- The test is currently being validated in a large, prospective, multi-center, registrational study called PREEMPT CRC\(^{\circ}\), which will likely be the largest study of a blood-based test in the average-risk CRC screening population.
- The study includes both traditional and virtual recruitment arms to facilitate access and enable enrollment of a diverse and representative clinical trial population, even in the midst of the COVID-19 pandemic.

Additional information:
- clinicaltrials.gov - NCT04369053
- preemptbc.com
- clinicalstudies@freenome.com

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REFERENCES

- Putcha et al., 2018
- Davidson et al., 2018
- Joseph et al., 2020
- Piscetello et al., 2020
- Freenome Holdings Inc.; New York University Grossman School of Medicine; Kaiser Permanente Division of Research
- All inquiries should be sent to authors@freenome.com

Figure 1. Biological signals change as cancer evolves

Figure 2. Our multiomics blood test combines tumor- and non-tumor signals from DNA and proteins and uses machine learning to detect CRC and advanced adenomas.

Figure 3. Our multiomics blood test achieved 94% sensitivity and 91% specificity for early-stage (I/II) CRC in AI-EMERGE.\(^{\circ}\)

Figure 4. Multiomics detected twice as many advanced adenomas as methylation or CEA alone in AI-EMERGE.\(^{\circ}\)

Figure 5. The PREEMPT CRC\(^{\circ}\) study: Prevention of colorectal cancer through multiomics blood testing.

Figure 6. Increasing diversity and accessibility of our clinical study

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