GRAIL: Changing Cancer Screening As We Know It

GRAIL's mission is to detect cancer early, when it can be cured. We are working to change the trajectory of cancer mortality and bring stakeholders together to adopt innovative, safe, and effective technology that can transform cancer care. Despite significant advances in therapeutics and guideline-recommended tests that screen for five cancer types, the disease still claims the lives of nearly 1,700 of our loved ones in the U.S. every day.[1]

At GRAIL, we have built a multi-disciplinary organization of scientists, engineers, and physicians and we are using the power of next-generation sequencing (NGS), population-scale clinical studies, and state-of-the-art computer science and data science to overcome one of medicine's greatest challenges.

The disease is poised to become the world's leading cause of death.

Early diagnosis is critical. With it, nearly nine of every 10 cancer patients will live five years or longer.[2] Without it, only 21 percent live for five years after being diagnosed.Id. But many without direct experience are surprised to hear that only five cancers have available screenings: breast, cervical, colorectal, prostate & high-risk lung/ bronchus. That leaves nearly 100 cancers without recommended screenings. Because we have surprisingly few cancer screening tools in the current paradigm, more than 70 percent of cancer deaths in America will come from unscreened cancers.

The most pressing unmet need in early cancer detection is to identify cancers for which there are no existing recommended screening tests. That's why GRAIL has pioneered Galleri, an earlier version of which detected over 50 types of cancer – over 45 of which lack recommended screening today – with a simple blood draw. Together with our partners at leading academic cancer institutions and large community networks, we have taken a rigorous approach to the design of our clinical programs and collection of population-scale clinical data, which we believe to be one of the largest clinical study programs in genomic medicine.

Importantly, when cancer is detected, our test identifies where in the body the cancer is located with high accuracy. This is critical to guide next steps for diagnostics and care. Galleri is a ground-breaking and potentially life-saving advancement – with it, and through earlier cancer detection, we believe we have the potential to reduce the human and economic toll of cancer by enabling more successful, less costly treatment. Right now, we are detecting 206,000 cancers annually via the five recommended single cancer

screenings.3 Adding Galleri to standard of care screenings would roughly triple our rate of cancer detection in the country.

There's a lot of work still to be done to realize the promise of MCED. In addition to continuing our clinical trial program – which is among the largest ever conducted in genomic medicine – and introducing Galleri in the U.S. in June as a laboratory developed test, we are engaged with regulators to ensure timely submission and eventual approval by FDA of our test.

[1] American Cancer Society Cancer Action Network's Cancer Statistics Center.
[2], Id. SEER Cancer Statistics Review, 1975-2015, National Cancer Institute, Bethesda, MD, http://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER website April 2018.

3 The cancer detection rate—a public health approach to early detection, The Cancer Letter