GRAIL, Inc. is a healthcare company focused on saving lives and improving health by pioneering new technologies for early cancer detection.

In 2013, researchers evaluating blood from thousands of pregnant women found that 10 had unusual DNA patterns. The babies were healthy, but in each case the mother was ultimately diagnosed with a different type of cancer. This led researchers to believe cancer could be detected in the blood long before symptoms appear.

GRAIL grew out of this discovery, and has since built a team of scientists, engineers, and physicians focused on using the power of next-generation sequencing (NGS), population-scale clinical studies, and state-of-the-art computer and data science to overcome one of healthcare's greatest challenges. In September 2020, GRAIL entered into an agreement to be acquired by Illumina with the goal of accelerating the commercialization and adoption of its transformative multi-cancer early detection technologies. The acquisition is now subject to standard regulatory reviews.

GRAIL is headquartered in Menlo Park, California, with locations in Washington, D.C., North Carolina, and the United Kingdom.

Our mission is to detect cancer early, when it can be cured.

Early Detection Could Save Lives

Cancer is about to become the world's leading cause of death. In the U.S., nearly 1,700 people die of cancer every day.[1]

The majority of cancers are found too late when outcomes are often deadly. Recommended screening tests save lives, but only cover five cancer types and screen for a single cancer at a time. In fact, cancer types responsible for 71% of cancer deaths have no recommended early detection screening.[2]

Earlier cancer detection has the potential to reduce the human and economic toll of cancer by enabling more successful, less costly treatment.

Pioneering New Technologies for Early Cancer Detection

GRAIL's methylation-based technology preferentially targets the most informative regions of the genome and is designed to use its proprietary database and machine-learning algorithms to both detect the presence of cancer and predict the location of the cancer signal in the body.

Our model estimates that by adding GRAIL's multi-cancer early detection test, Galleri™, to existing screening tests, there is the potential to detect nearly 70% of cancers resulting in death within five years at an earlier stage, which would translate to the potential to avert 39% of the deaths expected if not for early detection by Galleri.

[1]Rebecca L. Siegel, Kimberly D. Miller, Ahmedin Jemal DVM, "Cancer statistics, 2020," American Cancer Society Journals, 1/8/20.
[2]Calculated by internal analysis based on the National Cancer Institute (NCI)'s Surveillance, Epidemiology, and End Results (SEER) 18 Regs Research Data, Nov 2017 Submission. Includes persons aged 50-79. Estimated deaths per year in 2020 from American Cancer Society Cancer Facts and Figures 2020.

Overview of Product Pipeline & R&D Initiatives

Using our platform technology and expansive genomic database, we are focused on developing transformative and potentially life-saving products:

Galleri™

Galleri is a multi-cancer early detection test designed to detect many types of cancer, the majority of which have no recommended screening options available today, through a single blood draw. When a cancer signal is detected, Galleri has shown the ability to predict the signal's origin, for example the lungs or the colon, to help guide next steps to diagnosis.

In a clinical study published in the *Annals of Oncology*[3]:
- An earlier version of Galleri detected over 50 types of cancers -- over 45 of which lack recommended screenings today.
- GRAIL's test showed a 67.3% detection rate across stages I-III for a pre-specified set of 12 cancers that together account for approximately 63% of U.S. cancer deaths annually.[4]

The foundational clinical studies for Galleri have collectively enrolled more than 115,000 participants to build what we believe are the largest linked datasets of genomic and clinical data in the genomics field.

Ongoing Development & Launch Plans
- Anticipated U.S. commercial launch of Galleri in 2021 as a laboratory developed test (LDT).
- Plans to pursue U.S. Food and Drug Administration (FDA) approval for Galleri following LDT launch. Previously received Breakthrough Device Designation from FDA.

Diagnostic Aid for Cancer (DAC)

GRAIL's diagnostic aid for cancer (DAC) test is designed to accelerate diagnostic resolution for patients with a clinical suspicion of cancer.

Data presented at the American Association for Cancer Research (AACR) 2020 Annual Meeting showed that our technology was able to detect cancer and identify where it was located in the body with high accuracy, demonstrating the potential for DAC to accelerate diagnosis in individuals with high suspicion of cancer by helping direct the diagnostic workup.

Ongoing Development & Launch Plans
- Anticipated U.S. commercial launch in 2021 as an LDT.

Ongoing R&D and Population-Scale Clinical Research Programs

With one of the world's largest genomic databases with linked longitudinal medical records and blood samples, we have undertaken an ambitious population-scale clinical study program to advance early detection. Our research aims to identify the patterns required to detect and identify many different cancers, and introduce additional products to continue our mission to detect cancer early, and transform the lives of patients.

[3]Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA, Annals of Oncology, Volume 31, Issue 6, 2020, pp. 745-759
[4]Liu MC, et al. Ann Oncol. 2020;31(6):745-759. DOI: 10.1016/j.annonc.2020.02.011

By using Galleri, our multi-cancer early detection blood test, alongside the five existing recommended screenings in the United States, we believe we could avert many deaths through earlier detection of up to 75% of cancers with less than a 50% five-year survival rate.

Partnerships

Together with our partners at leading academic cancer institutions and large community networks, we have taken a rigorous approach to the design and implementation of our clinical programs.

GRAIL's Leadership Team

Hans Bishop,
Chief Executive Officer

Joshua Ofman, MD,
Chief Medical Officer and External Affairs

Gautam Kollu,
Chief Commercial Officer

Matthew Young,
Chief Operating and Financial Officer

Marissa Song,
General Counsel and Corporate Secretary

For more information, please visit: https://grail.com