

The Galleri test is a multi-cancer early detection (MCED) test that can detect a shared cancer signal across more than 50 types of cancer¹ through a simple blood draw.

Using next-generation genomic sequencing and machine-learning technologies, the Galleri test detects a signal associated with cancer and includes one or two predictions of where in the body the cancer signal originated.

GRAIL's sequencing technology was developed within Illumina and spearheaded by Dr. Richard Klausner, who directed the National Cancer Institute from 1995 to 2001. This research was among the largest unbiased exploration of genomic cancer signals in blood ever undertaken.

Current Cancer Screenings

Cancer is soon to be the world's number one killer. More than 600,000 deaths from cancer are expected in the U.S. each year, according to the American Cancer Society.²

While early detection is known to improve cancer outcomes, most cancers are detected too late, often after the cancer has metastasized and people develop symptoms. Only five cancer types have recommended screenings—breast, cervical, colorectal, lung (smokers considered at risk), and prostate cancers. While critical, single-cancer screenings look for individual cancers, but are not designed to screen broadly for what cancer an individual may have.

Early detection and diagnosis have been proven to significantly improve survival rates and reduce the cost and complexity of treatment for screenable cancers.³

Cancers without widespread screening recommendations represent

85% of all cancer diagnoses⁴

&

~70% of cancer deaths.^{2,5}

The overall survival rate for cancer is

4x higher

if cancer is detected before it spreads.⁶

Costs associated with treating late-stage cancers are

2-7x higher

than treating early-stage cancers.⁷

Fast Facts

50+
types of cancer detected by a shared cancer signal¹

<1%
false positive rate (99.5% specificity)¹

140+
clinical study sites contributed to the development of Galleri

GRAIL clinical development program is one of the largest in genomic medicine with

~335,000 participants

The Galleri test does not detect all cancers, nor does it measure your genetic risk of developing cancer in the future. It should be used in addition to routine screening tests your healthcare provider recommends. False-positive and false-negative test results do occur.

A New Approach with the Galleri Test

New approaches including MCED tests like Galleri represent the best chance to bend the cancer mortality curve.

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those age 50 or older. It is intended to be complementary to, and not a replacement of, U.S. guideline-recommended cancer screenings.

The Galleri Test

Demonstrated the ability in a clinical study to detect a shared cancer signal across more than **50 types of cancer**,¹ at least 45 of which lack recommended screening tests in the U.S. today.

Detects a cancer signal across many types of cancer while maintaining a **low false-positive rate of less than 1%**. Single-cancer screenings each have false-positive rates of 5-10%.⁸

Balances **sensitivity**—a test's ability to correctly identify people with cancer—and **specificity**—a test's ability to correctly identify people without cancer. Through this balance, **Galleri has a low false-positive rate** and is **able to predict cancer signal origin** while minimizing testing-associated potential risks, including overdiagnosis.¹

Can predict where a cancer signal originated with **more than 92%** accuracy in those diagnosed with cancer, helping guide subsequent physician diagnostic evaluations.*

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*The Circulating Cell-free Genome Atlas (CCGA) Study (NCT02889978) is a prospective, case-control, observational study designed to determine whether a screening test could detect a cancer signal and predict signal origin for multiple cancers. CCGA3 was a sub-study that included cancer (n=2823) and non-cancer (n=1254) participants without a history of cancer.

How the Galleri Test Works

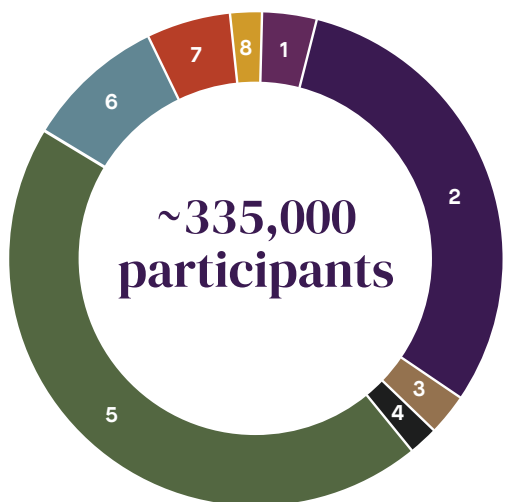
All cells—cancer and healthy ones—shed DNA, which is called cell-free DNA, into the bloodstream. One of the "hallmarks of cancer" is hypo- and hyper-methylation of DNA.

After a blood sample is taken at a healthcare provider's office or at a GRAIL partner laboratory, the Galleri test uses the power of next-generation sequencing and machine-learning algorithms to analyze cell-free DNA methylation patterns. The test algorithm includes two key classifications: one classifier uses features from cell-free DNA to determine whether a cancer signal is present. If a "cancer signal is detected", another classifier predicts the most likely cancer signal origin.

If a cancer signal is detected, a healthcare provider will determine next steps for diagnostic evaluation, which may include personal and family health history, physical examination, and guideline directed evaluation(s) including lab work and imaging.

GRAIL Clinical Research Program

The GRAIL clinical development program consists of studies that collectively include more than 335,000 participants—and what is believed to be the largest linked datasets of genomic and clinical data in the cancer field. GRAIL’s program includes the foundational CCGA development and validation study; the interventional PATHFINDER and PATHFINDER 2 studies; the NHS-Galleri randomized, controlled clinical study; the STRIVE and SUMMIT observational studies; and the REFLECTION real-world registry. The largest of these, the NHS-Galleri trial, has enrolled 140,000 participants with the primary objective of a reduction in late-stage cancer diagnoses, thought to be a necessary prerequisite for a mortality reduction.



- 1 CCGA (n=15,254)**
Develop and validate a cell-free DNA-based MCED test
- 2 STRIVE (n=99,481)**
Evaluate MCED test performance in women to detect invasive cancers
- 3 SUMMIT (n=13,035)**
Clinical validation in individuals at high risk of lung cancer
- 4 PATHFINDER (n=6,662)**
Evaluate clinical implementation and perceptions of MCED test
- 5 NHS-Galleri (n~140,000)**
Assess clinical utility of MCED for population screening in the UK
- 6 REFLECTION (n~35,000)**
Assess experience/clinical outcomes in real-world setting
- 7 PATHFINDER 2 (n~20,000)**
Evaluate MCED test performance in eligible screening population
- 8 SYMPLIFY (n~6,000)**
Assess MCED test in individuals with signs/symptoms of cancer

n~ indicates approximate enrollment. CCGA, Circulating Cell-free Genome Atlas; MCED, multi-cancer early detection; UK, United Kingdom.

Learn more at grail.com
Media contact: pr@grail.com

Important Safety Information:

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older.

The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. Galleri is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of Galleri is not recommended in individuals who are pregnant, 21 years old or younger, or undergoing active cancer treatment.

Results should be interpreted by a healthcare provider in the context of medical history, clinical signs and symptoms.

A test result of "No Cancer Signal Detected" does not rule out cancer. A test result of "Cancer Signal Detected" requires confirmatory diagnostic evaluation by medically established procedures (e.g., imaging) to confirm cancer.

If cancer is not confirmed with further testing, it could mean that cancer is not present or testing was insufficient to detect cancer, including due to the cancer being located in a different part of the body. False-positive (a cancer signal detected when cancer is not present) and false-negative (a cancer signal not detected when cancer is present) test results do occur. Rx only.

Laboratory/Test Information:

GRAIL's clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). The Galleri test was developed, and its performance characteristics were determined by GRAIL. The Galleri test has not been cleared or approved by the Food and Drug Administration. GRAIL's clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

References

1. Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation n-based multi-cancer early detection test using an independent validation set. *Ann Oncol.* 2021;32(9):1167-1177.
2. American Cancer Society. *Cancer Facts & Figures 2022.* Atlanta: American Cancer Society; 2022. Accessible at <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>.
3. U.S. Preventive Services Task Force (USPSTF). Rockville, MD: U.S. Dept. of Health & Human Services, Agency for Healthcare Research and Quality.
4. Hackshaw, A., Cohen, S.S., Reichert, H. et al. Estimating the population health impact of a multi-cancer early detection genomic blood test to complement existing screening in the US and UK. *Br J Cancer.* 2021;125(10):1432-1442.
5. GRAIL data on file GA-2021-0065.
6. Surveillance, Epidemiology, and End Results (SEER) Program (www.seer.cancer.gov) SEER*Stat Database: Incidence - SEER 18 Regs Research Data, Nov 2018 Sub. Includes persons aged 50-79 diagnosed 2006-2015 "Early/Localized" includes invasive localized tumors that have not spread beyond organ of origin, "Late/Metastasized" includes invasive cancers that have metastasized beyond the organ of origin to other parts of the body. Noone AM, Howlader N, Krapcho M, et al. (eds). *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. Data on file GA-2021-004.
7. Reddy SR, Broder MS, Chang E, et al. Cost of cancer management by stage at diagnosis among Medicare beneficiaries. *Curr Med Res Opin.* 2022;38(8):1285-1294.
8. National Cancer Institute. *Cancer Screening Overview (PDQ®)–Health Professional Version.* Accessible at <https://www.cancer.gov/about-cancer/screening/hp-screening-overview-pdq>.