

Galleri is the first-of-its-kind multi-cancer early detection (MCED) test available. It can detect a signal shared by more than 50 cancer types,<sup>1</sup> and predict the tissue type or organ associated with the signal to help healthcare providers determine next steps.

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older, and is used in addition to recommended single-cancer screening tests.

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

## Current Cancer Screenings

More than 609,000 deaths from cancer are expected in the U.S. each year.<sup>2</sup>

Recommended single-cancer screenings are powerful tools that can help find cancer at an early stage. However, only five cancer types have recommended screenings—breast, cervical, colorectal, lung (smokers considered at risk) and prostate cancers.<sup>3</sup>

While early detection has been proven to significantly improve cancer survival rates and reduce the cost and complexity of treatment for cancers with recommended screenings, most cancers don't have recommended screenings and are detected too late.

## Galleri Facts

**50+**

types of cancer detected by a shared cancer signal<sup>1</sup>

**<1%**

false positive rate (99.5% specificity)<sup>1</sup>

**140+**

clinical study sites contributed to the validation of Galleri

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

**320,000+**  
**participants**

*The Galleri test does not detect a signal for all cancers and not all cancers can be detected in the blood. Galleri should be used in addition to healthcare provider recommended screening tests. False positive and false negative results do occur.*

Cancers without widespread screening recommendations represent:

**71%** of all cancer diagnoses.<sup>4</sup>  
**~70%** of cancer deaths.<sup>5</sup>

The overall survival rate for cancer is

**4x higher** if cancer is detected before it spreads.<sup>6</sup>

Costs associated with treating late-stage cancers are

**2-7x higher** than treating early-stage cancers.<sup>7</sup>

# A New Approach with the Galleri® Test

MCED tests like Galleri are a fundamentally different approach for early cancer detection. When added to recommended cancer screenings, Galleri provides an opportunity to detect more cancers early when additional treatment options may be available.

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:

Can detect a signal shared by **more than 50 types of cancer** as demonstrated in a clinical study. At least 45 of these cancers lack recommended screening tests in the U.S. today.<sup>1</sup>

**Approximately doubled** the number of cancers detected with standard of care cancer screenings.<sup>8</sup>

Detects a cancer signal shared by many types of cancer while maintaining a **low false positive rate**. Single-cancer screenings each have false positive rates of 5-10% and are cumulative.<sup>9</sup>

**Increases asymptomatic cancer screening**, while not overburdening the healthcare system. The Galleri test's **high specificity**—ability to correctly identify people without cancer—combined with a **low false positive rate** helps minimize testing-associated potential risks, including overdiagnosis.<sup>1,8</sup>

Predicts cancer signal origin to help guide next steps to diagnosis when a cancer signal is detected. In a recent study, Galleri predicated cancer signal origin had **88% accuracy**.\*

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*\*Proportion of first or second origins correctly predicted among true positive participants.*

## How the Galleri Test Works

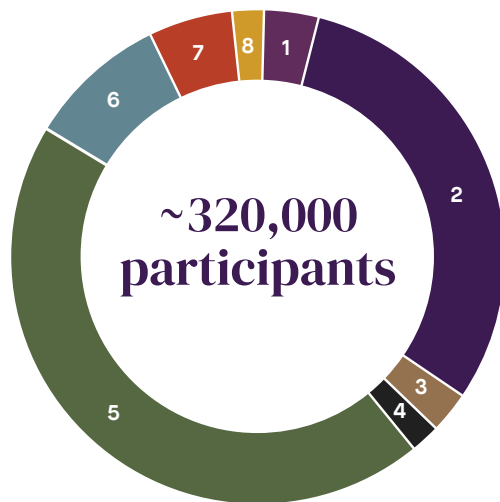
All cells—cancer and healthy ones—shed DNA, which is called cell-free DNA (cfDNA), into the bloodstream. One of the "hallmarks of cancer" is hypo- and hyper-methylation of DNA.

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 cfDNA methylation patterns. The test uses these methylation patterns to determine if a cancer signal is present and, if so, predict the tissue type or organ where the cancer signal originated.

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. The ability of an MCED test to help identify the tissue type or organ associated with the cancer signal is critical for informing appropriate next steps.

# GRAIL Clinical Research Program

The GRAIL clinical development program consists of studies that collectively include more than 320,000 participants—and what is believed to be the largest linked datasets of genomic and clinical data in the cancer field. GRAIL's clinical program includes the foundational Circulating Cell-free Genome Atlas (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 142,321 participants with the primary objective of a reduction in late-stage cancer diagnoses.



- 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=142,321)**  
Assess clinical utility of MCEd for population screening in the UK
- 6 REFLECTION (n~17,000)**  
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~6,242)**  
Assess MCEd test in individuals with signs/symptoms of cancer

*n~ indicates approximate enrollment.*

## Media Contacts

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## 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

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2. American Cancer Society. Cancer Facts & Figures 2023. Accessible at: <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2023/2023-cancer-facts-and-figures.pdf>.
3. U.S. Preventive Services Task Force (USPSTF). Rockville, MD: U.S. Dept. of Health & Human Services, Agency for Healthcare Research and Quality.
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5. Assumes screening is available for all prostate, breast, cervical, and colorectal cancer cases and 43% of lung cancer cases (based on estimated proportion of lung cancers that occur in screen-eligible individuals older than 40 years) Estimated deaths per year in 2022 from American Cancer Society Cancer Facts and Figures 2022. Available at: <http://www.cancer.org/content/dam/cancerorg/research/cancer-factsand-statistics/annual-cancerfacts-andfigures/2022/cancer-factsand-figures-2022.pdf>. Data on file GA-2021-0065.
6. Surveillance, Epidemiology, and End Results (SEER) Program ([www.seer.cancer.gov](http://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. 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.
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9. National Cancer Institute. Cancer Screening Overview (PDQ®)—Health Professional Version. Accessible at <https://www.cancer.gov/about-cancer/screening/hp-screening-overview-pdq>.