Galleri®

Galleri® is the first-of-its-kind multi-cancer early detection (MCED) test available. Cancers growing in the body shed DNA into the bloodstream. Galleri is a blood test that screens for a "fingerprint" of some of the deadliest cancers before people have symptoms.[1]

Galleri is recommended for use in adults with an elevated risk for cancer, such as those aged 50 or older, and should be used in addition to recommended single-cancer screening tests. The Galleri test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider.

GRAIL's sequencing technology was 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

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 (for smokers considered at risk) and prostate cancers.[2] While today doctors test individually for these five specific cancers, nearly 70% of deaths are caused by cancers without recommended screening.[3]**

Although early detection has been proven to significantly improve cancer survival rates[4] and reduce the cost and complexity of treatment[5] for cancers with recommended screenings, most cancers don't have recommended screenings and are detected too late.

Galleri Test Facts

Screens for many of the deadliest cancers, such as pancreatic, esophageal, ovarian and liver.*

<1%
false positive rate (99.5% specificity)[1,8]

140+
clinical study sites contributed to the validation of Galleri

Our robust clinical development program consists of studies that are planned to collectively include

380,000+ 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.[6]

~70% of cancer deaths.[3]**

Data from the National Cancer Institute demonstrated that diagnosing cancer early improves overall 5-year survival rates from

20%–90%[4]***

Costs associated with treating late-stage cancers are

2–7x higher
than treating early-stage cancers.[7]

*Sensitivity in study participants with - Pancreas cancer: 83.7% overall (61.9% stage I, 60.0% stage II, 85.7% stage III, 95.9% stage IV). Esophagus cancer 85.0% overall (12.5% stage I, 64.7% stage II, 94.7% stage III, 100% stage IV). Ovary cancer: 83.1% overall (50.0% stage I, 80.0% stage II, 87.1% stage III, 94.7% stage IV). Liver/bile duct cancer: 93.5% overall (100% stage I, 70.0% stage II, 100% stage III, 100% stage IV).

**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).

***"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.

A New Proactive Tool to Screen for Cancer

MCED tests like Galleri are a fundamentally different approach in early cancer detection. Adding Galleri to recommended screenings gives healthcare providers the chance to screen many of the deadliest cancers that don't have recommended screenings today.[1,2] Cancer identified early, before a person has symptoms, may be more easily treated and potentially curable.[5]

The Galleri Test:

Can help screen for **many of the deadliest cancers** that don't have recommended screening today, such as pancreatic, esophageal, ovarian and liver.

Looks for a unique "fingerprint" shared by many types of cancer while maintaining a **low false positive rate**.[1,8]

Can identify DNA shed by cancer cells while the patient is still asymptomatic with a false positive rate amongst patients/participants without cancer of just 0.5%, and specificity >99%.[1,8] Galleri provides 75% sensitivity rates in cancers responsible for two-thirds of cancer deaths, and this goes over 80% for some of the **most serious cancers**.[1]*

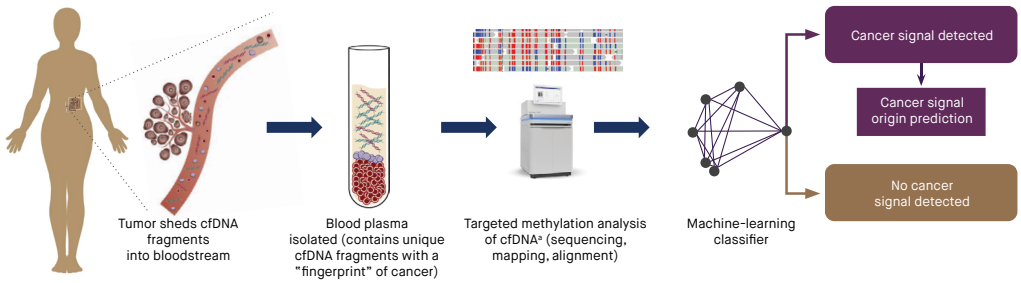
Can **indicate the origin of the cancer with 88% accuracy**,** giving healthcare providers a guide to next steps for diagnosis.[8]

Approximately doubled the number of cancers diagnosed when added to standard of care cancer screenings.[8]

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.

How the Galleri Test Works

Galleri is available by prescription only. If ordered by a physician, a blood sample is analyzed to determine if a cancer signal is present and, if so, predict the origin of the cancer. 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 origin of the cancer is critical for informing appropriate next steps.



cfDNA, cell-free DNA.[a]Bisulfite treatment; targeted probes pull out fragments matching regions of interest. Adapted from Liu MC, et al. Ann Oncol. 2020;31(6):745-759. DOI:10.1016/j.annonc.2020.02.011.

*80%+ sensitivity: Anus, Cervix, Colon/Rectum, Esophagus, Head and Neck, Liver/Bile duct, Neuroendocrine, Ovary, Pancreas, Urothelial Tract
**Proportion of first or second origins correctly predicted among true positive participants.

GRAIL Clinical Research Program

Our robust clinical development program consists of studies that are planned to collectively include more than 380,000 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; the REFLECTION real-world registry; and the REACH/Galleri-Medicare study. The largest of these, the NHS-Galleri trial, has enrolled more than 140,000 participants with the primary objective to assess the clinical utility of an MCED test for population screening in the United Kingdom (UK) when added to standard of care.

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 undergoing mammography screening
3. **SUMMIT (n=13,035)** Observational study in people 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)** Understand the real-world experience of Galleri in clinical settings
7. **PATHFINDER 2 (n~35,000)** Evaluate MCED test performance in eligible screening population
8. **SYMPLIFY (n=6,242)** Assess MCED test in individuals with signs/symptoms of cancer
9. **REACH/Galleri-Medicare (n~50,000)** Understand health equity impact of Galleri in a Medicare population

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 "Cancer Signal Not 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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