



## GRAIL to Present New Data on Galleri® and its Methylation Platform at American Association for Cancer Research (AACR) Annual Meeting

April 22, 2025

*Real-World Data in 100,000 Patients Further Support the Galleri® Test's Ability to Simultaneously Screen for Multiple Cancers, as Well as its Accuracy of Cancer Signal of Origin Prediction to Support More Efficient Diagnostic Evaluations*

*Data From GRAIL's ctDNA-based Targeted Methylation Assay Highlight Potential to Identify Robust Signals of Promoter Methylation*

MENLO PARK, Calif., April 22, 2025 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, will present new data highlighting the latest real-world evidence with the Galleri® multi-cancer early detection (MCED) test and additional data from GRAIL's circulating tumor DNA (ctDNA)-based targeted methylation platform at the American Association for Cancer Research (AACR) Annual Meeting in Chicago, April 25-30, 2025.



"GRAIL has an extensive evidence program that is setting the standard for multi-cancer early detection development that includes a large real-world dataset demonstrating Galleri test performance and implementation," said Josh Ofman, MD, MSHS, President of GRAIL. "The real-world findings being presented at AACR support those observed in our previous clinical studies, highlighting the test's ability to screen for deadly cancers that do not have recommended screening tests. Additional data presented will underscore the potential of GRAIL's ctDNA-based targeted methylation assay for quantifying abnormal promoter methylation, which is a known hallmark of cancer and has shown potential utility as a biomarker in precision oncology."

### Data Presentations

**Title:** Real-world data and clinical experience from over 100,000 multi-cancer early detection tests

**Abstract Number:** 7202

**Session Title:** Targeted Therapies and Combinations 4

**Date/Time:** April 30, 2025, 9 am-12 pm

**Location:** Poster section 35

- The latest data from a real-world study of more than 100,000 participants with the Galleri test, consistent with previously reported large-scale clinical data, affirming the MCED test can reliably detect a cancer signal across a wide range of cancer types, including cancers without recommended screening, with a high Cancer Signal of Origin prediction accuracy to help guide diagnostic evaluations.

**Title:** Estimated Post-Test Probabilities of Cancers For Individuals Receiving Multi-Cancer Early Detection (MCED) Tests

**Abstract Number:** 7132

**Session Title:** Immune Monitoring / Clinical Correlates

**Date/Time:** April 30, 2025, 9 am-12 pm

**Location:** Poster section 31

- This modeling analysis shows that individuals receiving a no cancer signal detected MCED test result have a reduced risk of cancer diagnosis for one year post-blood draw; this risk increases as screening interval goes beyond one year, highlighting the importance of annual screening with the MCED test.

**Title:** Promoter Methylation as a Cancer Biomarker: Insights From ctDNA-Based Targeted Methylation Data

**Abstract Number:** 1943

**Session Title:** Liquid Biopsy: Circulating Nucleic Acids 5 / Circulating Tumor Cells 2

**Date/Time:** April 28, 2025, 9 am-12 pm

**Location:** Poster section 28

- Leveraging insights from the Circulating Cell-free Genome Atlas (CCGA) study, this early proof-of-concept study underscores the potential of GRAIL's ctDNA-based targeted

# methylation assay for detecting clinically informative promoter methylation signals in a plasma sample.

**Title:** Assessment of Cancer Subtypes Across Multiple Cancer Types Using a Circulating Tumor DNA (ctDNA)-Based Targeted Methylation Assay

**Abstract Number:** 1947

**Session Title:** Liquid Biopsy: Circulating Nucleic Acids 5 / Circulating Tumor Cells 2

**Date/Time:** April 28, 2025, 9 am-12 pm

**Location:** Poster section 28

- Based on this proof-of-concept study, GRAIL's ctDNA-based targeted methylation assay enables subtyping across cancers using a single blood draw, without the need for invasive tissue biopsy.

## About GRAIL

GRAIL is a healthcare company whose mission is to detect cancer early, when it can be cured. GRAIL is focused on alleviating the global burden of cancer by using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art machine learning, software, and automation to detect and identify multiple deadly cancer types in earlier stages. GRAIL's targeted methylation-based platform can support the continuum of care for screening and precision oncology, including multi-cancer early detection in symptomatic patients, risk stratification, minimal residual disease detection, biomarker subtyping, treatment and recurrence monitoring. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom.

For more information, visit [grail.com](https://grail.com).

## About the Galleri® Test

The Galleri multi-cancer early detection test is a proactive tool to screen for cancer. With a simple blood draw, the Galleri test can identify DNA shed by cancer cells, which can act as a unique "fingerprint" of cancer, to help screen for some of the deadliest cancers that don't have recommended screening today, such as pancreatic, esophageal, ovarian, liver, and others.\* The Galleri test can be used to screen for cancer before a person becomes symptomatic, when cancer may be more easily treated and potentially curable. The Galleri test can indicate the origin of the cancer, giving healthcare providers a roadmap of where to explore further. The Galleri test requires a prescription from a licensed healthcare provider and should be used in addition to recommended cancer screenings such as mammography, colonoscopy, prostate-specific antigen (PSA) test, or cervical cancer screening. The Galleri test is recommended for adults with an elevated risk for cancer, such as those aged 50 or older.

For more information, visit [galleri.com](https://galleri.com).

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).

## Important Galleri Safety Information

The Galleri test is recommended for use in adults with an elevated risk for cancer, such as those age 50 or older. The test does not detect all cancers and should be used in addition to routine cancer screening tests recommended by a healthcare provider. The Galleri test is intended to detect cancer signals and predict where in the body the cancer signal is located. Use of the test 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

The GRAIL clinical laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists. 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. The GRAIL clinical laboratory is regulated under CLIA to perform high-complexity testing. The Galleri test is intended for clinical purposes.

## Forward-Looking Statements

This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would," or "will," the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include expectations about or projections of Galleri performance, Galleri clinical impact, proof of concept results that could support future products or product improvements, technology, clinical and real world studies, regulatory compliance, potential market opportunity, anticipated growth strategies, and other topics.

These statements are only predictions based on our current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors and numerous associated risks discussed under the section entitled "Risk Factors" in our Annual Report on Form 10-K for the period ended December 31, 2024 (the "Form 10-K"). Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements we may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Although we believe the expectations and projections expressed or implied by the

forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this press release to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

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