Galleri®
Multi-cancer early detection

Study results published in *The Lancet*

GRAIL

PATHFINDER supports using Galleri® for cancer screening

Key Results from the PATHFINDER Study

6,621
participants ≥50 years
of age screened using the MCED blood test

The PATHFINDER Study is an interventional, prospective, multi-center study that evaluated an early version of Galleri, GRAIL's multi-cancer early detection (MCED) blood test.[1] The study marks **the first time the MCED test was used to return results to healthcare providers and participants** to help guide appropriate diagnostic workup.

Adding MCED to standard-of-care screening approximately doubled the number of cancers detected.* These include early-stage cancers and those without existing guideline recommended screening.[1]

35
Additional participants with cancer*
detected by the early version of Galleri vs. 38 cancers detected by standard-of-care and nonstandard screening*

74%
of cancers* detected by the early version of Galleri are not routinely screened for

48%
of cancers* detected by the early version of Galleri were stage I-II

*Cancers detected refer to cancers that were confirmed by diagnostic workup after screening with the early version of Galleri, or standard and non-standard screening. Standard-of-care or standard screening refers to USPSTF (United States Preventive Services Task Force) recommended screening for breast, cervical, colorectal, lung, and prostate cancer. Cancers detected by nonstandard screening refers to those that lack USPSTF screening recommendations such as thyroid and melanoma.

Galleri performance in the PATHFINDER Study supports feasibility of broad screening use[1]

99.5% Specificity
indicating low false positive rate (0.5%)

43.1% PPV
consistent with previously reported results[3]

88% Accuracy
in predicting the top two Cancer Signal Origins among true positive participants, helping guide diagnostic workup

PPV = The proportion of people with "Cancer Signal Detected" results diagnosed with cancer.

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 should be used in addition to guideline recommended cancer screenings such as mammography, colonoscopy, PSA, or cervical cancer screening. The Galleri test does not detect all cancers and all cancers cannot be detected in the blood. False positive results and false negative results do occur.

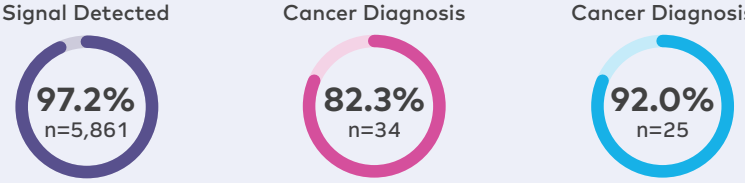
Screening with the early version of Galleri was safely implemented, with high participant satisfaction[2‡]

There were **no adverse events due to diagnostic workup** prompted by receipt of a "signal detected" test result.

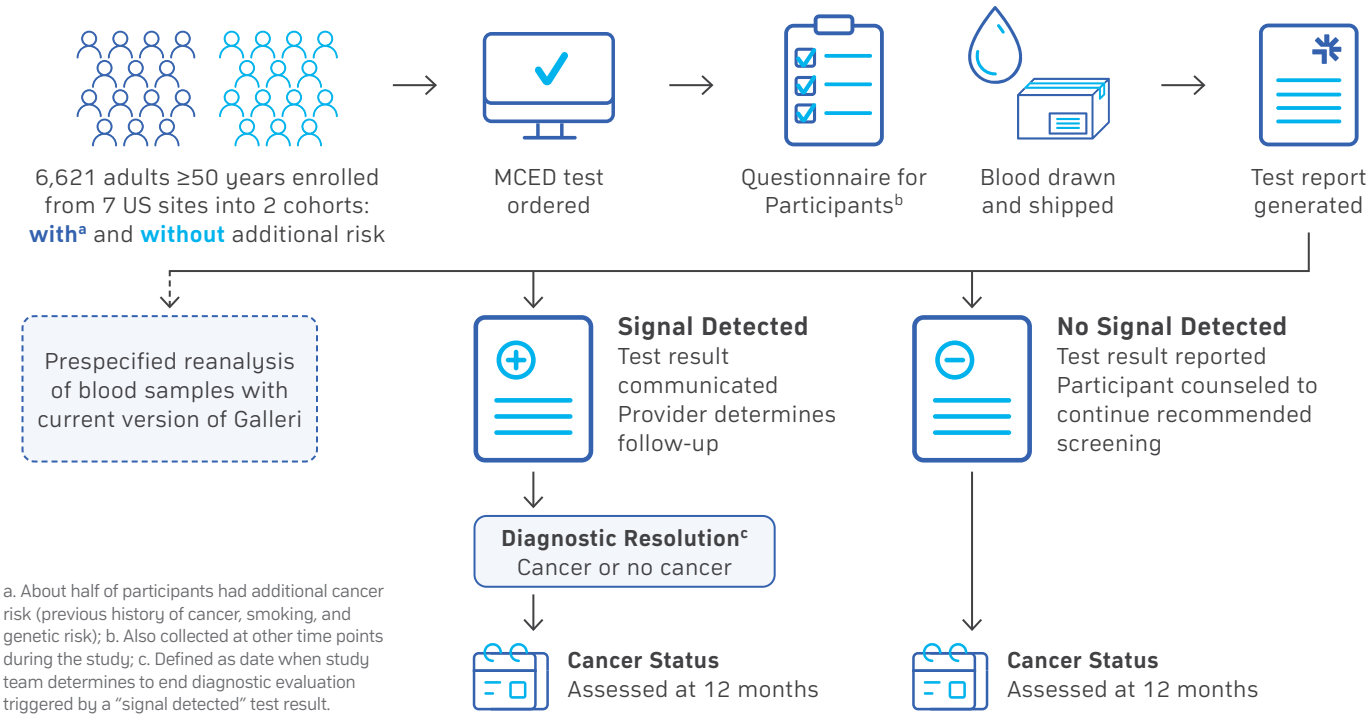
There were **four study-related adverse events** (two related to mild anxiety before the test, one related to mild anxiety about the blood draw, and one related to mild bruising).

High satisfaction rates among PATHFINDER participants[‖] irrespective of test results[‡]

● % OF PARTICIPANTS SATISFIED[¶] WITH THE MCED TEST ●



Study Design



a. About half of participants had additional cancer risk (previous history of cancer, smoking, and genetic risk); b. Also collected at other time points during the study; c. Defined as date when study team determines to end diagnostic evaluation triggered by a "signal detected" test result.

Clinical Study Site Institutions

Intermountain Health
Sutter Health
Cleveland Clinic
The US Oncology Network
OHSU
Dana-Farber Cancer Institute Data Science

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 theCollege 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. Schrag D, Beer TM, McDonnell III CH, et al. Blood-based tests for multicancer early detection (PATHFINDER): a prospective cohort study. Lancet 2023;402:1251–60.
2. Schrag D, et al. Evaluation of Anxiety, Distress and Satisfaction Using a Multi-Cancer Early Detection (MCED) Test. Presentation at European Society for Medical Oncology (ESMO) Congress; September 9-13, 2022.
3. Klein EA, Richards D, Cohn A, et al. Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set. Ann Oncol. 2021;32(9):1167-1177. doi: 10.1016/j.annonc.2021.05.806.

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