Galleri®
Multi-cancer early detection

GRAIL

PATHFINDER supports broad screening use of Galleri®

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.

Screening with the early version of Galleri more than doubled the number of cancers* detected by standard-of-care† (SoC) screening alone[2‡]

35
Additional participants with cancer*
detected by the early version of Galleri vs. 29 by SoC screening alone

71%
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

Galleri performance in the PATHFINDER Study supports feasibility of broad screening use[2§]

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 = Positive predictive value, the likelihood that a person has cancer when a positive test result is returned

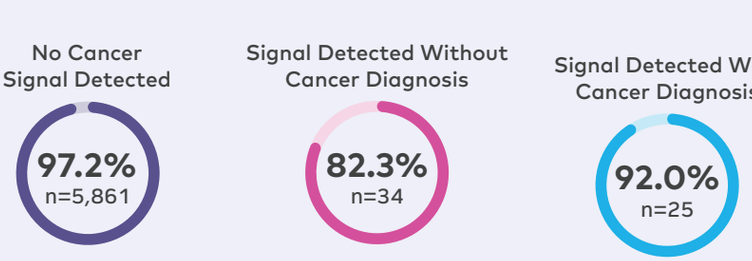
Screening with the early version of Galleri was safely implemented, with high participant satisfaction[2‡]

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).

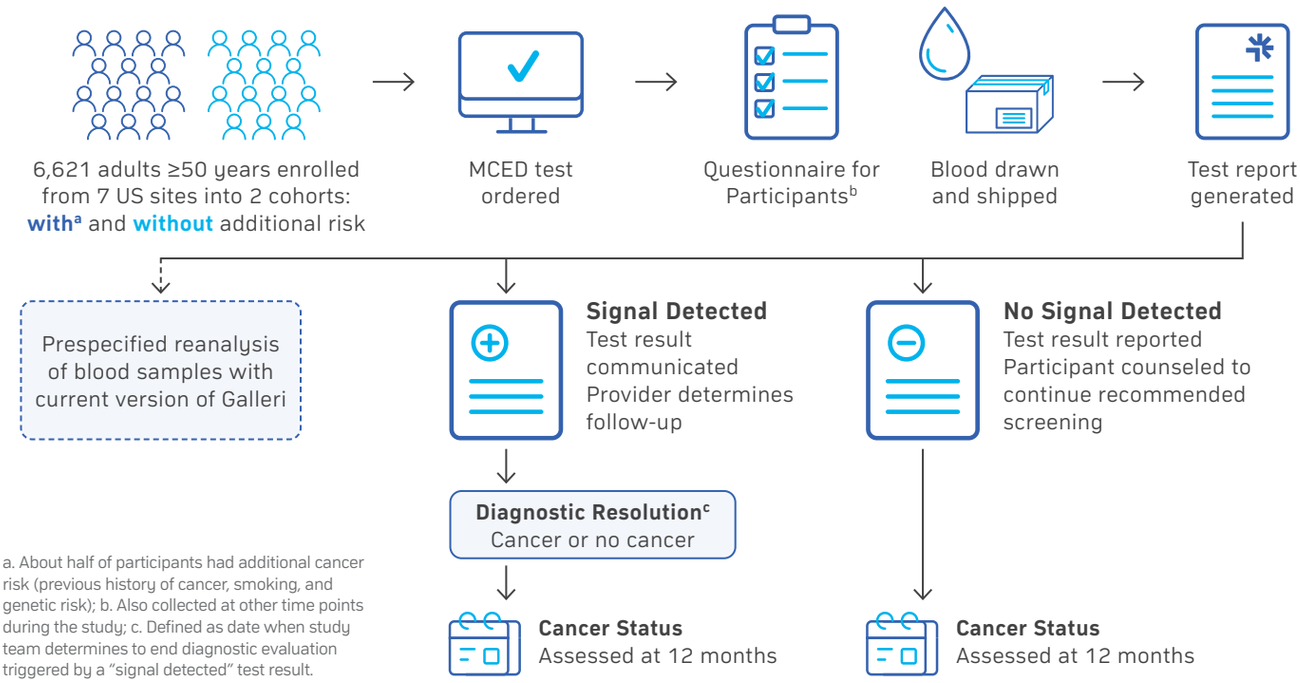
High satisfaction rates among PATHFINDER participants[‖] irrespective of test results‡

% OF PARTICIPANTS SATISFIED[¶] WITH THE MCED TEST



*Cancers detected by the early version of Galleri that were confirmed by diagnostic workup †Standard-of-care screening recommended by USPSTF (United States Preventive Services Task Force) for breast, cervical, colorectal, lung, and prostate cancer. ‡The PATHFINDER study was conducted with an earlier version of Galleri §Blood samples were retrospectively processed with the current version of Galleri to evaluate test performance ‖Refers to participants who completed the questionnaire. ¶Participants responding satisfied, very satisfied, or extremely satisfied to the following question: "Taking all things into account, how satisfied or dissatisfied are you with the multi-cancer early detection 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.

Study Institutions

Intermountain® Healthcare · OHSU Oregon Health & Science University · Cleveland Clinic · Dana-Farber Cancer Institute · The US Oncology Network · Mayo Clinic · Sutter Health

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 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. The PATHFINDER Study: Assessment of the Implementation of an Investigational Multi-Cancer Early Detection Test Into Clinical Practice. https://www.clinicaltrials.gov/ct2/show/NCT04241796
2. Schrag D, et al. 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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