PATHFINDER 2 Fact Sheet

Primary analysis as presented at the 2026 ASCO® Annual Meeting

PATHFINDER 2 (NCT05155605) is the largest interventional Multi-Cancer Early Detection (MCED) study conducted in North America to date.[1] The study provides further validation of the Galleri® MCED test and its safety and performance in a prospective trial in the intended use population: adults aged 50 years and over with no clinical suspicion of cancer.[2]

PATHFINDER 2 Study Participants[1,2]

35,878 enrolled participants
across a broad population aged ≥50 years, conducted at 32 clinical sites across North America

32,007 participants analyzable for MCED performance
with 12-month follow-up

35,335 participants analyzable for safety

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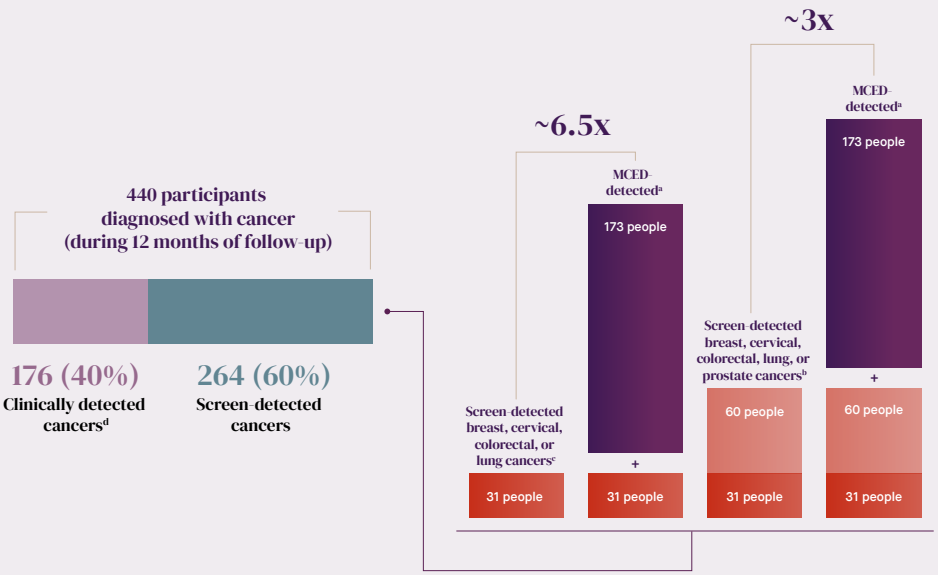
Primary Results from PATHFINDER 2 Study[1]

The Galleri test **increased the number of cancers detected more than six and a half-fold** when added to USPSTF A and B guideline-recommended screening tests for breast, cervical, colorectal, and lung cancer.

Galleri **nearly tripled the number of cancers detected** when added to USPSTF A, B, and C guideline-recommended screening tests, which include prostate cancer, in addition to breast, cervical, colorectal, and lung screening.



[a]MCED-detected refers to cancers diagnosed within 12 months following a positive MCED test result.

[b]Screen-detected refers to cancers diagnosed following USPSTF grade A/B/C recommendations, which include screening for breast, cervical, colorectal, lung, and prostate cancers.

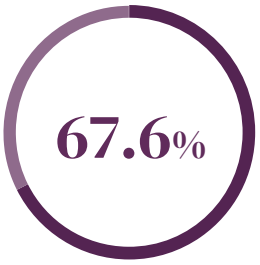
[c]Screen-detected refers to cancers diagnosed following USPSTF grade A/B recommendations, which include screening for breast, cervical, colorectal, and lung cancers.

[d]Clinical detection includes: cancers detected based on participant-reported signs or symptoms, incidental findings on imaging, physical exam, laboratory tests, surgical procedures, or through surveillance for prior imaging findings or post-treatment recurrence.

Galleri detected most cancers at an early stage, when they can be easier to treat and are potentially curable.[1]

of the new primary cancers diagnosed were Stage I and II.

of the new primary cancers diagnosed were Stage I–III.



of cancers detected were types without USPSTF grade A/B/C screening recommendations. [1,†]

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Galleri Test Performance by the Numbers[1]

Results from PATHFINDER 2 were consistent with previous studies of the Galleri test in the intended use population.[3,4]

Positive predictive value was 60.3%

Positive predictive value reports how likely it is that a person with a positive test result actually has cancer.

Cancer detection rate was 0.54%
(173 True Positives/32,007 participants)

Cancer detection rate is the number of cancers identified in the screened population, which can be expressed as a percentage.

Episode sensitivity was 69.8% for the group of 12 cancers that cause 2/3 of cancer deaths,†† and was 39.3% overall

Episode sensitivity refers to the proportion of cancers detected by the initial screening test, out of all cancers diagnosed in individuals during a pre-defined follow-up period (in this case, 1 year).†††

Specificity was 99.6%, reflecting a false positive rate of less than 0.4%

Specificity indicates how likely the test is to return a negative result in individuals without cancer. False positives are when the test indicates a cancer signal, but cancer is absent.

Cancer signal origin (CSO) prediction accuracy†††† was 91.3%, giving doctors the actionable information to guide rapid diagnosis following a positive MCED test result (median time to diagnostic resolution: 48 days)

CSO is the prediction of where the cancer signal originated in the body. CSO prediction accuracy is the proportion of participants with a correct CSO prediction (i.e., CSO prediction matching clinical CSO) among participants with true positive MCED test results.

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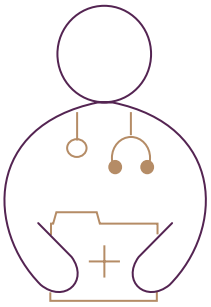
No serious study-related adverse events were reported during the diagnostic workup.[1,*]

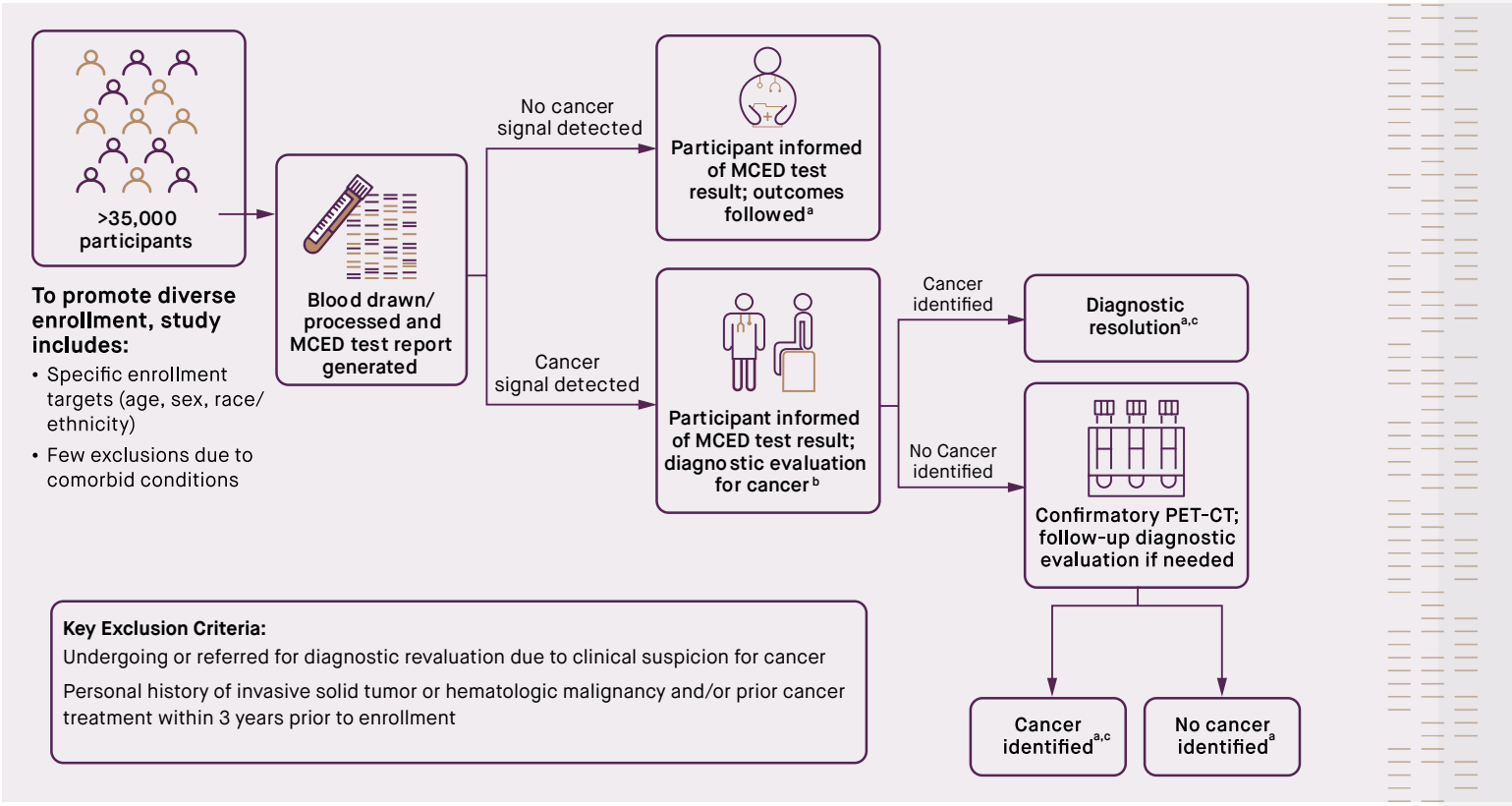


0.6% of all 35,335 safety analyzable participants had an invasive procedure, such as a biopsy, to evaluate a positive MCED result. A total of 90.5% of invasive procedures were nonsurgical.[1]

Participant-reported anxiety temporarily increased with a positive MCED test and cancer diagnosed, but returned to pre-study levels by the end of the study.

* One serious adverse event related to the diagnostic work-up was identified after the data lock. Follow-up is ongoing; this and any other findings after data lock will be reported in full in the next interim analysis.

PATHFINDER 2 Study Design[1,2]



[a]All participants will be actively followed by enrolled institutions for 3 years to assess cancer status and utilization of guideline-recommended cancer screening.
[b]Diagnostic evaluations based on CSO are recommended in the protocol.
[c]Clinical information including, but not limited to, cancer type, histology, and staging information will be captured.

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†USPSTF grade A/B/C recommendations include screening for breast, cervical, colorectal, lung, and prostate cancers.

††Anus, Bladder/urothelial tract, Colon/rectum, Esophagus, Head & neck, Liver/intrahepatic bile duct, Lung, Lymphoid lineage, Ovary/fallopian tube, Pancreas/extrahepatic bile duct/gall bladder, Plasma cell lineage, Stomach cancers.

†††Episode sensitivity differs from test sensitivity, which is how likely the test is to find cancer in individuals who actually have cancer (i.e., their cancer status is known), which can only be calculated with case-controlled studies.

††††Accuracy of Cancer Signal Origin top two predictions (CSO1 or CSO2).

Important 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.

References
1. Giridhar K, et al. Presented at the American Society of Clinical Oncology Annual Meeting; May 29-June 2, 2026; Chicago, IL. Presentation LBA10509.

2. https://clinicaltrials.gov/study/NCT05155605

3. Schrag D, Beer TM, McDonnell CH, et al. Blood-based tests for multi-cancer early detection (PATHFINDER): a prospective cohort study. *Lancet*. 2023;402:1251-1260. doi: 10.1016/S0140-6736(23)01700-2

4. Swanton C, et al. Presented at the American Society of Clinical Oncology Annual Meeting; May 29 – June 2, 2026; Chicago, USA. Presentation LBA100

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