NHS-Galleri Trial

Data as presented at the 2026 ASCO® Annual Meeting

The NHS-Galleri trial is the first and only randomized controlled trial to assess how well a multi-cancer early detection (MCED) blood test works when added to standard NHS care.[1,2] More than 142,000 people in England, aged 50 to 77 at enrollment and with no symptoms of cancer, took part.[2] Participants were randomly assigned to receive the Galleri test or not (intervention and control arms), allowing researchers to compare outcomes between the two groups.[2]

Participants provided three blood samples over two years, about 12 months apart.[2] The primary objective of the NHS-Galleri trial is to show a reduction in combined late-stage (III/IV) cancers in people who received the Galleri® test compared with those who did not.[2] Key prespecified secondary objectives include reduction in Stage IV cancer and performance of the Galleri test.[2]

Stage Effect[1]

Stage III/IV cancers

In a prespecified group of 12 cancers responsible for two-thirds of cancer deaths*, there was no statistically significant difference in Stage III/IV cancers between the intervention arm and the control arm for cancers diagnosed up to one year after the final screening appointment. This means the primary endpoint was not met (overall [after all three screening rounds] incidence rate ratio: 1.03 (95% CI: 0.92, 1.14); p = 0.6324). In this group of 12 cancers, a decrease in Stage III/IV cancers was observed after the first screening round with repeated annual screening in the intervention arm.

Stage IV

Stage IV cancer diagnoses decreased with each year of sequential screening, with a 9% reduction in the first ("prevalent") screening round, a 22% reduction in the second ("incident") round, and a 26% reduction in the third ("incident") round in the prespecified group of 12 cancers. Overall, in this prespecified secondary endpoint, a 14% reduction in Stage IV cancers was observed. These results were nominally statistically significant.

The prevalent round detects undiagnosed cancers already present in the population at the time of initial screening, while subsequent "incident" rounds detect cancers that develop or progress between screening rounds and become detectable. Thus, the incident rounds most closely approximate the likely steady-state impact of an annual screening program.

A Greater Than 20% Reduction in Stage IV Cancers Was Observed in the Second and Third Screening Rounds ("Incident" Rounds) in the Group of 12 Cancers.†

	Stage III/IV Cancers Diagnosed		Stage IV Cancers Diagnosed	
Screening Round	**Incidence Rate Ratio**	**Intervention vs Control (% Difference)[a]**	**Incidence Rate Ratio**	**Intervention vs Control (% Difference)[a]**
Overall	1.03 (0.92, 1.14)	↑ 3%	0.86 (0.744, 0.998)	↓ 14%
First Screening Round (Prevalent)	1.19 (0.98, 1.43)	↑ 19%	0.91 (0.71, 1.18)	↓ 9%
Second Screening Round (Incident)	0.95 (0.77, 1.17)	↓ 5%	0.78 (0.57, 1.06)	↓ 22%
Third Screening Round (Incident)	0.88 (0.73, 1.07)	↓ 12%	0.74 (0.57, 0.95)	↓ 26%

[a]Percent difference was calculated with incidence rate ratios as part of the prespecified analysis.

Similar reductions of 20% or more were observed in the second and third screening rounds for all stageable cancers overall.

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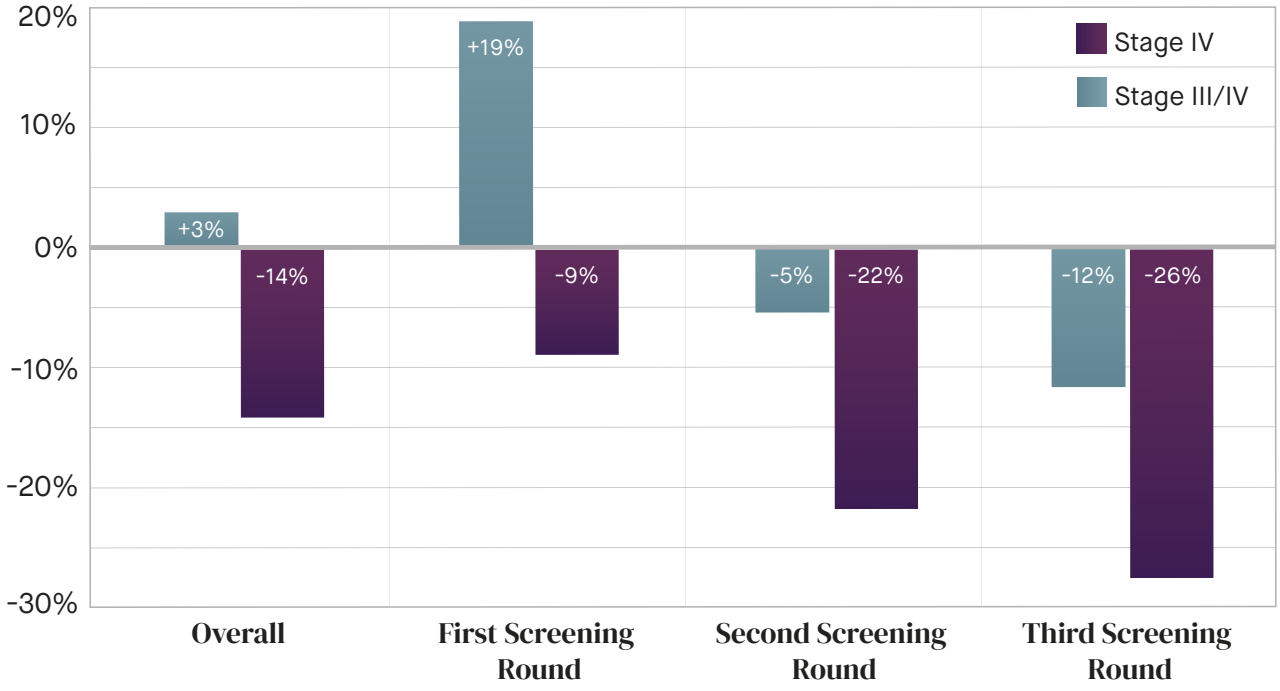
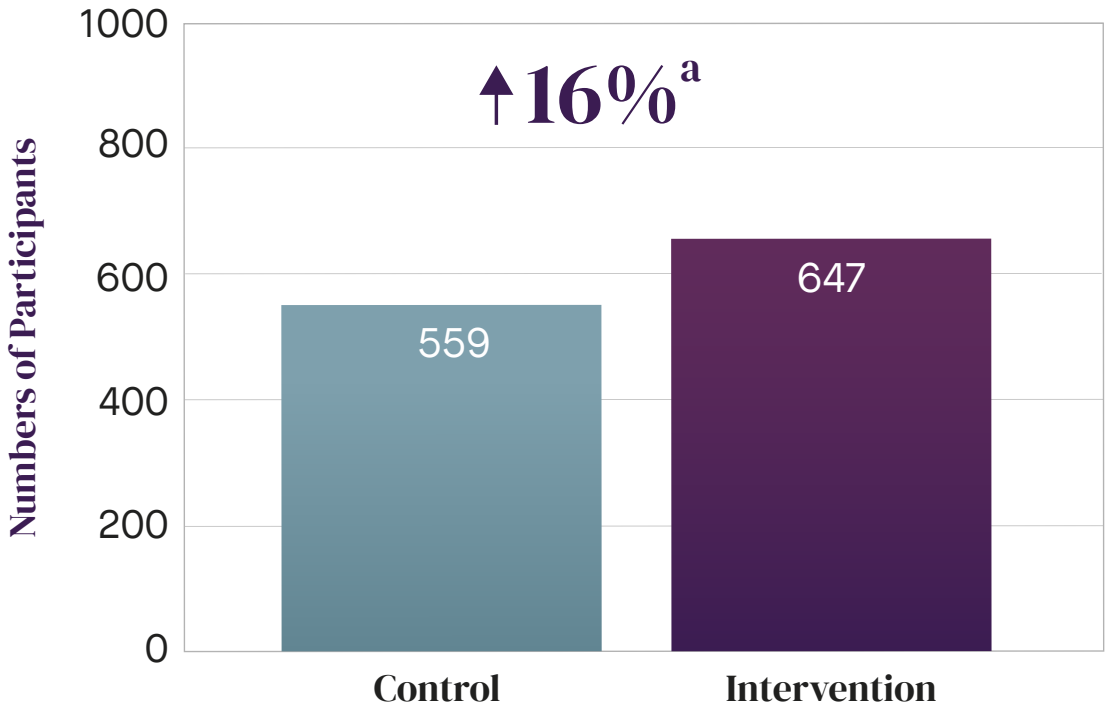
Percent Difference in Stage III/IV and Stage IV Cancers Diagnosed Between Intervention and Control Arms†



Stage I-II

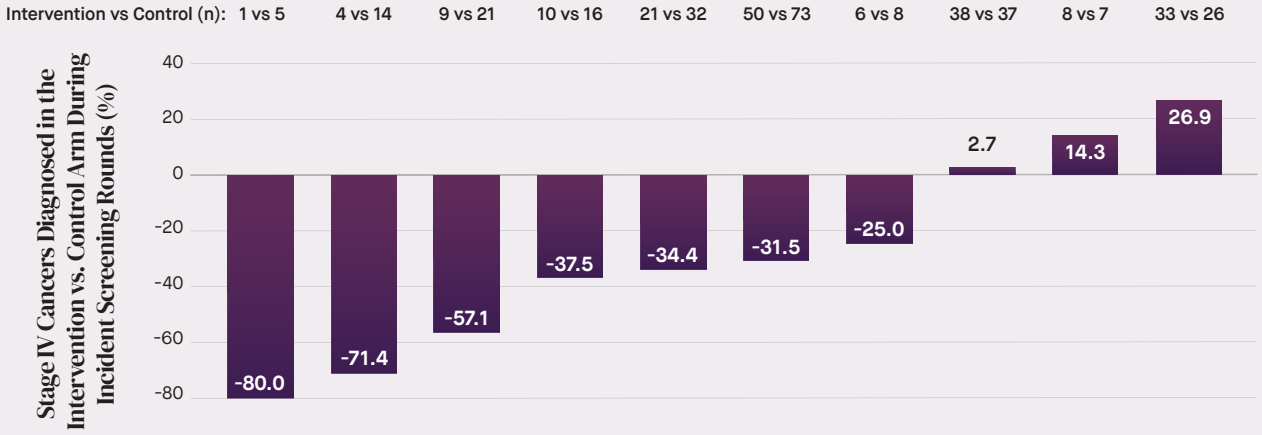
Stage I and II cancers diagnosed increased by 16% for the group of 12 prespecified cancer types after three rounds of screening, including very large increases in many types typically diagnosed very late, such as ovarian, esophageal, pancreatic, and liver cancers.



[a]Percent difference was calculated with incidence rate ratios as part of the prespecified analysis, not raw cancer counts (graphed in bar charts for illustrative purposes).

Exploratory Analysis[1]

Meaningful Reductions in Stage IV Diagnoses Were Observed in Cancer Types Where 5-Year Survival is Substantially Higher When Diagnosed at Stage III Versus IV[†]



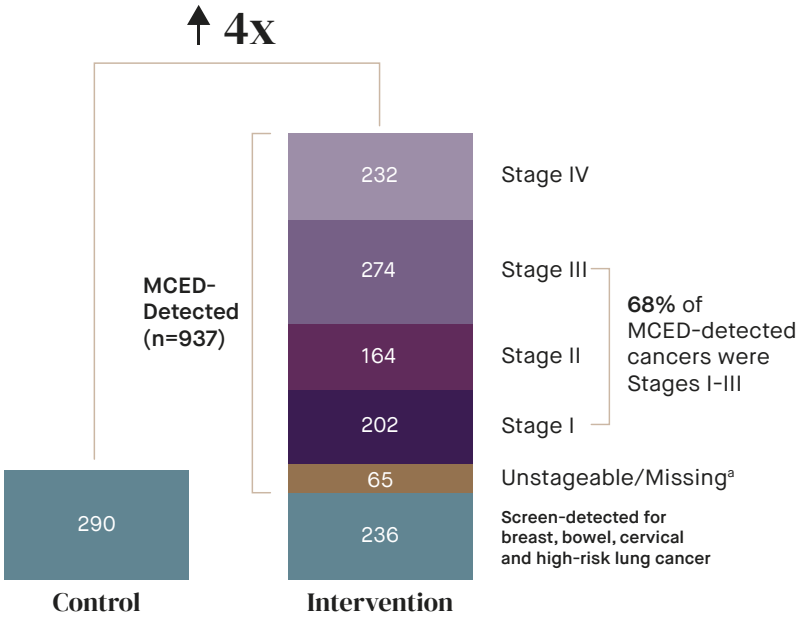
		Bladder	Liver/bile duct	Esophagus	Head & neck	Colorectum	Lung	Stomach	Lymphoma	Ovary	Pancreas
England 5-year net survival estimates**[3]	Stage IV	5.8%	2.6%	6.2%	38.4%	11.0%	4.5%	4.5%	65.7%	16.2%	2.1%
	Stage III	31.8%	13.5%	24.7%	54.5%	64.2%	16.7%	24.6%	72.6%	32.4%	8.7%
	Difference	+26%	+10.9%	+18.5%	+16.1%	+53.2%	+12.2%	+20.1%	+6.9%	+16.2%	+6.6%

Cancer Detection[1]

The Galleri test increased the number of screen-detected cancers **fourfold** when added to UK standard of care screening for breast, bowel, cervical, and high-risk lung cancer.

The addition of the Galleri test decreased the number of clinically detected cancers after symptomatic presentation by 21%, with emergency presentations*** decreasing by 25%.

Screen-Detected Cancers



[a]Includes 10 unstageable cancers (no staging system exists) and 55 cancers with missing staging information

Aggregate Test Performance Over 3 Screening Rounds for All Cancer Types[1]

The Galleri test's performance was consistent with what has been reported from GRAIL's North American studies.[1,4,5]

Positive predictive value (PPV) was 52.0%
At first screening round, PPV was 58.0%

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

Cancer detection rate was 0.48%

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

Episode sensitivity was 30.7% across all cancer types, and 54.7% for the group of 12 prespecified cancers

Episode sensitivity refers to the ability to detect cancers that were subsequently diagnosed within 12 months after each Galleri screening blood draw.

Specificity was 99.55%, reflecting a false positive rate of 0.45%

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 92.5%, giving doctors the actionable information to guide rapid diagnostic resolution following a positive MCED test result

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.

No serious, study-related adverse events were reported.

More Data to Come[1]

More data will be reported in the coming months and years, including the psychological impact of having a cancer signal detected following an MCED blood test; the cost effectiveness of screening with the Galleri test in the NHS; longer-term results; and the modelled and observed effect of Galleri screening on mortality.

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†**A statistically significant reduction was not observed** in combined stage III/IV diagnoses across three screening rounds for the 12 prespecified cancers.

*The 12 cancer types include anus, bladder, colorectal, esophagus, head and neck, liver/bile duct, lung, lymphoma, myeloma/plasma cell neoplasm, ovary, pancreas, stomach. The NHS-Galleri trial was designed to first assess the primary objective in these 12 cancers. Had that data reached statistical significance, the primary objective would have been assessed in all routinely staged cancer types other than prostate, and then in all stageable cancers combined.

**For patients diagnosed in England 2016-2020 (all ages) by stage at diagnosis

***Cancers diagnosed via accident and emergency (A&E), emergency GP referral, emergency transfer, emergency admission or attendance. This estimate is a supportive sensitivity analysis after targeted review of 39 participants with an MCED-positive result and emergency presentation route to diagnosis. Of these, 12 had documented evidence against emergency presentation and were no longer classified as emergency presentation in this analysis; all randomized participants were included.

****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. Swanton C. NHS-Galleri: Primary Results From a Randomised Controlled Trial to Assess the Clinical Utility of a Multi-Cancer Early Detection (MCED) Test in Population Screening [presentation]. American Society of Clinical Oncology (ASCO) Annual Meeting; 2026 May 29-June 2.
2. https://clinicaltrials.gov/study/NCT05611632
3. Cancer Survival in England, cancers diagnosed 2018 to 2022, followed up to 2023. 2026. https://digital.nhs.uk/data-and-information/publications/statistical/cancer-survival-in-england/
4. Nabavizadeh N, McDonnell C, Kurbegov D, et al. Safety and Performance of a Multi-Cancer Early Detection (MCED) Test in an Intended-Use Population: Initial Results from the Registrational PATHFINDER 2 Study. ESMO 2025. Presentation LBA64.
5. 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

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