



GRAIL and National Health Service (NHS) England Complete Enrollment of 140,000 Participants in Largest Study of Multi-Cancer Early Detection Test

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NHS-Galleri Trial is Evaluating Clinical Utility of GRAIL's Galleri[®], a Multi-Cancer Early Detection Test, Alongside Current Standard of Care in England

NHS-Galleri Trial Prioritized Equitable Recruitment Approaches Designed to Achieve Representation of People from Minority Ethnic Backgrounds

MENLO PARK, Calif., July 18, 2022 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, announced today that the NHS-Galleri trial successfully completed enrollment in just over 10 months. The trial, which is the largest-ever study of a multi-cancer early detection (MCED) test, has enrolled 140,000 healthy volunteers aged 50-77 from select regions throughout England who have not had a cancer diagnosis or undergone treatment for cancer in the last three years.

The NHS-Galleri trial is a randomized, controlled clinical trial being conducted in England alongside standard cancer screening with diagnostic follow-up in the NHS' clinical practice setting. Regions were selected to include areas of high cancer mortality, socioeconomic disparities, and ethnic diversity, using innovative methods to enroll a study population with participants traditionally less likely to take part in medical research. Participants visited one of 150 mobile clinics operating at locations around England and were recruited through activities including community group briefings, leaflet distribution in community settings, engagement through community champions, and targeted social media campaigns.

"Meeting the goal of enrolling 140,000 people is a significant achievement, allowing us to evaluate an unprecedented number of volunteers without symptoms of cancer and representing diverse socio-economic and ethnic populations," said Charles Swanton, MD, PhD, a cancer researcher and oncologist at University College London and the Francis Crick Institute, chief clinician at Cancer Research UK, and co-chief investigator of the study. "Whilst the first year of the trial may pick up cancers that have existed for some time, the second and third years provide the best opportunity to explore the expected benefits of picking up new cancers at an early stage when treatment is generally more successful. By screening participants annually over three years, we will be able to explore how MCED tests can be used alongside existing NHS screening programs."

The study's aim is to determine if the Galleri test, alongside standard cancer screening, can find asymptomatic cancers at earlier stages than they are found in clinical care today. The study will assess absolute numbers of stage 3 and 4 cancers diagnosed following three annual Galleri tests. The first screen will aim to identify the prevalent cancers in the population, while the second and third screens will aim to identify cancers that have newly emerged.

"NHS-Galleri has set a new standard in the speed of set-up and recruitment to clinical trials," said Professor Peter Sasieni, Director of The Cancer Research UK & King's College London Cancer Prevention Trials Unit and one of the trial's lead investigators. "Previous trials of this magnitude would typically have taken five times as long. Accelerating research means that we will find out sooner whether new technology has a role in the control of cancer and, if it does, introducing it within the NHS quickly so that more people can benefit."

This trial supports the NHS Long Term Plan ambition to catch three quarters of cancers at an early stage, when they are less advanced, and treatment has a higher chance of being successful and potentially curative. Based on initial results, the NHS may roll out the test to an additional 1 million people.

"Today marks an important milestone in our long-term efforts to catch and treat cancer earlier," said Amanda Pritchard, chief executive at NHS. "We know that certain cancers are harder to detect and a late diagnosis can be devastating for patients and their families, and this trial means thousands could benefit from a diagnosis even before symptoms appear."

In a previous [clinical study](#), the Galleri test demonstrated the ability to detect a shared signal from more than 50 types of cancer, many of which lack recommended screening tests today in the UK. Early clinical trials report that GRAIL's Galleri test has a false positive rate under 1% and can predict where a cancer signal originated with 89% accuracy.

"We are so grateful for the public's enthusiasm for this trial and to all those who have volunteered," said Sir Harpal Kumar, president at GRAIL Europe. "We are hopeful Galleri will work well alongside existing cancer screening in the UK, can provide clinicians with an accurate prediction of where the cancer is located in the body, and help the NHS reduce the number of cancers detected at a late stage."

The study is sponsored by GRAIL and is being run by The Cancer Research UK and King's College London Cancer Prevention Trials Unit (UK), in collaboration with eight cancer alliances in England. The study design of the trial was presented at the American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #TPS6606) in June 2022.

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About NHS-Galleri Trial

For the prospective, blinded, randomized controlled trial, study participants will provide a blood sample during three annual visits to a mobile health clinic—at baseline, year 1 and year 2. After the first visit, participants are randomized 1:1 into either the intervention or control arm. Participants in the intervention arm will have their blood tested by the Galleri test. Blood samples from subjects in the control arm will not be tested immediately, but will be stored for potential future testing. If a cancer signal is detected for those in the intervention arm, research staff will explain the result and schedule an appointment for follow-up tests at an NHS hospital local to the participant. All participants in the study will be followed for cancer and other related outcomes via NHS databases and will be reminded to continue to have guideline-recommended cancer screenings.

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 developing pioneering technology to detect and identify multiple deadly cancer types early. The company is using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art computer science and data science to enhance the scientific understanding of cancer biology, and to develop its multi-cancer early detection blood test. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom. GRAIL, LLC, is a subsidiary of Illumina, Inc. (NASDAQ:ILMN) currently held separate from Illumina Inc. under the terms of the Interim Measures Order of the European Commission dated 29 October 2021.

For more information, visit grail.com.

About Galleri®

The earlier that cancer is detected, the higher the chance of successful outcomes. The Galleri multi-cancer early detection test can detect signals across more than 50 types of cancer, as defined by the American Joint Committee on Cancer Staging Manual, through a routine blood draw. When a cancer signal is detected, the Galleri test predicts the cancer signal origin, or where the cancer is located in the body, with high accuracy to help guide the next steps to diagnosis. 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. It is intended for use in people with an elevated risk of cancer, such as those aged 50 or older.

For more information about Galleri, visit galleri.com.

Important Galleri 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 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 U.S. 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.

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