



GRAIL Announces Collaboration with U.S. Department of Veterans Affairs and the Veterans Health Foundation to Evaluate Galleri® Multi-Cancer Early Detection Test

May 31, 2022

Collaboration Will Provide Galleri Test to 10,000 Veterans Across the U.S. Over the Next Three Years; VA Pittsburgh Healthcare System Announced as First of Approximately 10 Participating Sites

Collaboration is Part of REFLECTION, a Real-World Observational Study Evaluating Performance of Galleri in Clinical Settings

MENLO PARK, Calif., May 31, 2022 — GRAIL, LLC, a healthcare company whose mission is to detect cancer early when it can be cured, announced today a collaboration with the U.S. Department of Veterans Affairs (VA) Veterans Health Administration, America's largest integrated health care system, and the Veterans Health Foundation to provide Galleri®, GRAIL's groundbreaking multi-cancer early detection (MCED) blood test, to 10,000 veterans across approximately 10 participating VA sites over the next three years. The VA Pittsburgh Healthcare System is the first VA site that will be participating.

Through the collaboration, eligible U.S. military veterans will be able to receive the Galleri test and can enroll in GRAIL's [REFLECTION](#) registry, an observational, multi-center, real-world evidence study. REFLECTION will assess Galleri's performance, when combined with recommended cancer screenings, to find earlier cancer in the population, when there is a higher chance of successful and potentially curative treatment. REFLECTION will enroll 35,000 healthy volunteers and evaluate the performance of Galleri in diverse clinical settings as part of routine medical care.

"Cancer is a significant issue for U.S. veterans, many of whom are at high risk," said Dr. Charles Atwood, pulmonologist and lead researcher on the REFLECTION study at VA Pittsburgh. "GRAIL's multi-cancer early detection test will be provided to veterans, in addition to current recommended screenings, with the aim of improving early diagnoses and outcomes."

The Galleri test is a first-of-its-kind MCED blood test. In a [clinical study](#), the Galleri test demonstrated the ability to detect signals across more than 50 types of cancers, over 45 of which lack recommended screening tests today. Using advanced genomics and machine learning, the test also determines the origin of the cancer signal, which can then guide diagnostic workup. Early detection of cancer is known to improve cancer outcomes, yet today, the majority of cancers are detected in late stages because only five cancer types have recommended screenings – breast, cervical, colon, lung and prostate cancers.

"As the largest national integrated health system in the U.S., the VA delivers unparalleled care to our veterans, many of whom are at elevated risk of developing cancer. We are thrilled to collaborate with the VA, the Veterans Health Foundation and U.S. veterans for this important real-world evaluation of the Galleri test and its potential to transform early cancer detection," said Bob Ragusa, chief executive officer at GRAIL. "Together, we hope participation in the REFLECTION registry study and receiving a Galleri test will lead to more cancer diagnoses at an earlier stage, when treatment is more likely to be successful."

Nationwide, 1.2 million veterans who have used VA health care since the beginning of fiscal year 2021 have received a cancer diagnosis. That number includes 14 percent of veterans treated at VA Pittsburgh in the same time frame.

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About VA Pittsburgh Healthcare System

VA Pittsburgh Healthcare System (VAPHS) is one of the largest and most progressive VA health care systems in the nation. More than 4,000 employees serve nearly 80,000 veterans every year, providing a range of services from complex transplant medicine to routine primary care. VAPHS is a leader in virtual care delivery through telehealth technology; a center of research and learning with 130 research investigators and \$14.8 million in funding in fiscal year 2021; and a provider of state-of-the-art healthcare training to some 1,500 student trainees annually. VAPHS provides care at medical centers in Pittsburgh's Oakland neighborhood and nearby O'Hara Township, both in Pennsylvania, and five outpatient clinics in Belmont County, Ohio, and Beaver, Fayette, Washington and Westmoreland counties in Pennsylvania. An additional site of care is expected to open in Monroeville, Pennsylvania, in 2023. Veterans can call 412-360-6162 to check eligibility or enrollment. Stay up to date at pittsburgh.va.gov, [Facebook](#) and [Twitter](#).

About Veterans Health Foundation

Established in 1991, the Veterans Health Foundation (VHF), formerly the Veterans Research Foundation of Pittsburgh, facilitates and supports extramural research and educational activities by collaborating with VA Pittsburgh Healthcare System, private companies, government agencies, foundations, and academic institutions. Title 38 USC §7361-7366 authorizes VA medical centers to establish nonprofit research and education corporations to accept and administer private and non-VA federal funds in support of VA's research and education missions. The congressional intent in enabling these corporations is to provide VA facilities with a flexible funding mechanism for the conduct of research as well as staff and patient education.

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, please 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 cancer 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 health care 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 may not detect a cancer signal across 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 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.

For GRAIL:

Corporate Communications
Trish Rowland
Cammy Duong
pr@grail.com

Investor Relations
Alex Dobbin
ir@grail.com