



GRAIL Announces First Participant Enrolled in REACH Study Evaluating Clinical Impact of Galleri® Multi-Cancer Early Detection (MCED) Test in the Medicare Population

July 18, 2024

Community Health Network Has Begun Enrollment of the Prospective, Multi-Center Study to Assess the Real-World Clinical Impact of Galleri® in Addition to Currently Recommended Cancer Screenings

Study Enrollment Includes Focus on Diverse and Underrepresented Populations

Costs of Galleri and Related Items and Services for Study Participants Will be Covered by Medicare

MENLO PARK, Calif., July 18, 2024 /PRNewswire/ -- GRAIL, Inc. (Nasdaq: GRAL), a healthcare company whose mission is to detect cancer early when it can be cured, today announced that the first participant has been enrolled in the REACH/Galleri-Medicare study at Community Health Network, a leading integrated healthcare system in central Indiana with more than 200 sites of care. With age being the most significant risk factor for cancer, Medicare beneficiaries face a critical unmet need for early cancer detection.

GRAIL has enrolled the first participant in the REACH study to evaluate Galleri® in the Medicare population.

"We are excited about the REACH study and the work that GRAIL is doing to detect cancer early when it is more likely to be successfully treated," said Patrick McGill, M.D., Executive Vice President, Chief Transformation Officer and Principal Investigator of the REACH study at Community Health Network. "As a health network committed to exceptional care for patients, it was important for Community Health Network to participate in the REACH study. We really want to expand upon and understand the real-world evidence of the Galleri® test. Since the focus is on underrepresented minorities, we felt strongly that this was an opportunity to offer the test as part of the REACH study to many of the people who are traditionally or historically underrepresented in clinical studies. We feel strongly about the science of the test and the potential it holds to improve health outcomes for our Medicare patients."

The Real-world Evidence to Advance Multi-Cancer Early Detection Health Equity (REACH/Galleri-Medicare) study is a first-of-its-kind real-world evidence study designed to further evaluate the clinical impact of the Galleri multi-cancer early detection (MCED) test in Medicare beneficiaries. The study aims to enroll participants with a specific focus on inclusion of historically underrepresented communities, including seniors and people across diverse racial and ethnic minority groups, as well as socioeconomically disadvantaged and rural populations.

The three-year study seeks to compare up to 50,000 Medicare beneficiaries who have received usual care plus an annual Galleri test with a comparator arm of beneficiaries who receive usual care without a Galleri test, across up to 50 study sites. To measure clinical impact, the study will assess reduction in diagnosed stage IV cancers and safety associated with Galleri use, and health care resource utilization associated with cancer diagnostic workup in the Medicare population. The study is being conducted under an Investigational Device Exemption (IDE) application approved by the U.S. Food and Drug Administration (FDA), and the Centers for Medicare and Medicaid Services' approval of the study for Medicare coverage. Accordingly, for study participants, Medicare will cover the costs of the Galleri test and related and routine items and services received as part of the study.

"The first participant enrolled in the REACH study marks a significant milestone for GRAIL and its pursuit of broad access to Galleri for asymptomatic, early cancer detection. With approximately 80% of deaths caused by cancers lacking recommended screening tests, the Galleri test is a proactive tool to screen for a 'fingerprint' of many of the deadliest cancers, many of which go undetected until symptoms appear," said Josh Ofman, MD, MSHS, President at GRAIL. "The REACH study demonstrates our continued commitment to generate important clinical information that is representative of the intended patient population, including groups that are often underrepresented in clinical research. The findings from this study will add to our robust body of clinical evidence evaluating the potential for MCEDs to change the future of cancer detection, including in diverse populations."

Almost 70% of people that died from cancer last year in the United States were [age 65 and older](#). [More than half of all cancer diagnoses](#) in the United States are among Medicare beneficiaries who are at the highest risk for cancer due to age.

An overview of the REACH study ([NCT05673018](#)) can be viewed in [this video](#).

About Community Health Network

Headquartered in Indianapolis, Community Health Network has been deeply committed to the communities it serves since opening its first hospital, Community Hospital East, in 1956. Community Health Network puts patients first while offering a full continuum of healthcare services, world-class innovations and a new focus on population health management. Exceptional care, simply delivered, is what sets Community Health Network apart and what makes it a leading not-for-profit healthcare destination in central Indiana. For more information about Community Health Network, please visit [eCommunity.com](#).

About GRAIL, Inc.

GRAIL, Inc. 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 using the power of next-generation sequencing, population-scale clinical studies, and state-of-the-art machine learning, software, and automation to detect and identify multiple deadly cancer types in earlier stages. GRAIL's targeted methylation-based platform can support the continuum of care for screening and precision oncology, including multi-cancer early detection in symptomatic patients, risk stratification, minimal residual disease detection, biomarker subtyping, treatment and recurrence monitoring. GRAIL is headquartered in Menlo Park, CA with locations in Washington, D.C., North Carolina, and the United Kingdom.

For more information, visit [grail.com](#).

Important Information About the REACH Study

The Real-world Evidence to Advance Multi-Cancer Early Detection Health Equity (REACH/Galleri-Medicare) study is sponsored by GRAIL and will enroll approximately 50,000 Medicare beneficiaries who have received usual care plus a Galleri test with a matched comparator arm of beneficiaries who receive usual care alone across up to 50 health system study sites. The REACH Study is being conducted under the U.S. Food and Drug Administration's (FDA) approval of an investigational device exemption (IDE) application. More information about the REACH Study is available on clinicaltrials.gov.

The Galleri multi-cancer early detection (MCED) test is a new proactive tool to screen for cancer. Galleri is a blood test that screens for a "fingerprint" of many of the deadliest cancers, most of which have no recommended screening and often go undetected until symptoms appear.

In the REACH Study, the Galleri test is an investigational test with associated risks and benefits that are described in the study materials. Risks of the test include, but are not limited to, false-positive results (a cancer signal detected when cancer is not present), false-negative results (no cancer signal detected when cancer is present), and incorrect prediction of the origin of a cancer signal. The Galleri test should not replace any guideline-recommended screenings or other standard of care diagnostic or treatment options.

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 U.S. 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.

Forward Looking Statements

This press release contains forward-looking statements. In some cases, you can identify these statements by forward-looking words such as "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would," or "will," the negative of these terms, and other comparable terminology. These forward-looking statements, which are subject to risks, uncertainties, and assumptions about us, may include expectations and projections of future tests or products, technology, clinical studies, regulatory compliance, potential market opportunity, anticipated growth strategies, and anticipated trends in our business.

These statements are only predictions based on our current expectations and projections about future events and trends. There are important factors that could cause our actual results, level of activity, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements, including those factors discussed under the section entitled "Risk Factors" in the Registration Statement on Form 10 filed by GRAIL (the "Form 10"), as may be further amended. Moreover, we operate in a dynamic and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results, level of activity, performance, or achievements to differ materially and adversely from those contained in any forward-looking statements we may make.

Forward-looking statements relate to the future and, accordingly, are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of our control. Although we believe the expectations and projections expressed or implied by the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance, or achievements. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Except to the extent required by law, we undertake no obligation to update any of these forward-looking statements after the date of this press release to conform our prior statements to actual results or revised expectations or to reflect new information or the occurrence of unanticipated events.

This press release shall not constitute an offer of any securities for sale, nor shall there be any offer, sale or distribution of securities in any jurisdiction in which such offer, sale or distribution would be unlawful prior to appropriate registration or qualification under the securities laws of such jurisdiction.

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SOURCE GRAIL, Inc.

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