

GRAIL Announces Circulating Cell-free Genome Atlas (CCGA) Study as Foundation for Development of Blood Test to Detect Cancer Early

- GRAIL to Apply High-Intensity Sequencing on an Unprecedented Scale to Build an Atlas of Cancer Biology -

- Initial Collaborators Include Guardian Research Network, Mayo Clinic and Hartford HealthCare Cancer Institute -

MENLO PARK, Calif., December 1, 2016 – GRAIL, Inc., a life sciences company whose mission is to detect cancer early when it can be cured, announced today that it has commenced its first multi-center clinical study, the Circulating Cell-free Genome Atlas (CCGA) study to facilitate the development of GRAIL's blood test for early-stage cancer detection. The CCGA study will characterize the landscape of cell-free DNA profiles in individuals with cancer and in healthy non-cancer participants using GRAIL's "high-intensity" (ultra-broad and ultra-deep) sequencing approach, leveraging Illumina sequencing technology. GRAIL was launched in January 2016, with initial investors including Illumina, ARCH Ventures, Jeff Bezos, Bill Gates, Sutter Hill Ventures and GV.

"For too many patients and their families, a late diagnosis of incurable cancer is devastating, and the complexity of cancer has made it challenging to find biomarkers for early stage detection when the cancer could be cured," stated Jose Baselga, M.D., Ph.D., Physician-in-Chief, Memorial Sloan Kettering Cancer Center, Chairman of GRAIL's Scientific Advisory Board (SAB) and member of the CCGA SAB. "The CCGA study will provide a critically important library of knowledge about cell-free nucleic acid profiles in cancer patients and new insights into the biology of cancer at its earliest stages. Of equal importance, the CCGA will characterize the heterogeneity of the population of individuals without cancer, and thus enable the development of models which distinguish people with and without cancer with unprecedented accuracy."

"Combining our ability to detect and characterize tumor DNA with our unparalleled computing power, we will convert vast amounts of genomic data into disease insight," said Jeff Huber, GRAIL's Chief Executive Officer. "Our approach will produce more than a terabyte of data per individual thereby creating datasets of a scale and complexity that are unprecedented in genomic medicine. Furthermore, we are committed to conducting large-scale studies to enable the most accurate detection of early stage disease. Initiating the CCGA study is an important first step for GRAIL and its collaborators, as we pursue our goal of reducing global cancer mortality."

The CCGA study has begun at several leading community and academic medical centers and eventually will include up to four-dozen clinical trial sites across the U.S. These medical centers will collect blood and tissue samples from patients recently diagnosed with cancer, and blood samples from healthy individuals. In its first phase, the CCGA study will enroll and analyze samples from 10,000 study participants. GRAIL and its advisors believe that studies enrolling tens of thousands of people will be needed to identify the patterns required to detect many types of cancer. To confirm

clinical validity and utility of these tests, studies enrolling hundreds of thousands of people will be needed.

The initial collaborators in the CCGA study include: medical centers of the Guardian Research Network, Mayo Clinic (Minnesota, Arizona and Florida) and Hartford HealthCare Cancer Institute, a member of the Memorial Sloan Kettering Cancer Alliance. More information about the CCGA study can be found at [NCT02889978](https://clinicaltrials.gov/ct2/show/study/NCT02889978).

“We are very pleased to be working with GRAIL and other collaborators on this landmark study and we have already begun enrolling study participants across our broad network of cancer centers and hospitals in the U.S.,” said Timothy Yeatman, M.D., President and Chief Scientific Officer of Guardian Research Network. “Detecting cancer at an earlier stage when it can be cured is an ambitious goal with the potential for immeasurable benefit to society. We are proud to support this initiative.”

GRAIL has assembled leading cancer research and clinical oncology experts from the academic and medical community to serve as CCGA Scientific Advisory Board members:

- Jose Baselga, M.D., Ph.D., Memorial Sloan Kettering Cancer Center
- Funda Meric-Bernstam, M.D., MD Anderson Cancer Center
- Benjamin Ebert, M.D., Harvard, Brigham and Women's Hospital, Broad Institute
- Keith Flaherty, M.D., Massachusetts General Hospital Cancer Center
- Gail Jarvik, M.D., Ph.D., University of Washington, Seattle
- Richard Klausner, M.D., GRAIL Director and co-founder
- Minetta Liu, M.D., Mayo Clinic
- Timothy Yeatman, M.D., Guardian Research Network, Gibbs Cancer Center and Research Institute

“Cancer is an incredibly complex and heterogeneous disease, making accurate, early stage detection extremely difficult,” said Brian Druker, M.D., Director, Knight Cancer Institute at Oregon Health & Science University; JELD-WEN Chair of Leukemia Research; Investigator, Howard Hughes Medical Institute, and a member of GRAIL’s Scientific Advisory Board. “The oncology field needs the expertise and resources to build the technology infrastructure to collect, analyze, categorize and use vast amounts of data. The CCGA study represents a critically important step in establishing this foundational knowledge.”

About the Circulating Cell-free Genome Atlas (CCGA) Study

The purpose of the CCGA study is to characterize the landscape of cell-free DNA profiles in individuals with and without cancer. The observational CCGA study will enroll at least 7,000 cancer patients and 3,000 healthy individuals, interrogating the biology of both tumor biopsy tissue samples and the circulating, tumor-derived nucleic acids in blood. Circulating tumor nucleic acids (ctNAs) in the blood are an emerging biomarker for earlier cancer detection. GRAIL and its collaborators will collect clinical outcomes on the enrolled participants for at least 5 years. The result will be a detailed atlas of cancer genetics that GRAIL will use to support its product development goals. The database, upon analysis, may be expanded to additional enrollment in specific cancers or healthy individuals. More information about the CCGA study can be found at [NCT02889978](https://clinicaltrials.gov/ct2/show/study/NCT02889978).

About GRAIL’s High-intensity Sequencing Approach

GRAIL's approach is to sequence circulating nucleic acids at unprecedented breadth and depth to optimize the detection of early-stage cancer. Combined with one of the largest clinical trial programs ever pursued in genomic medicine, GRAIL will be creating datasets of unprecedented scale to enable the deepest and most comprehensive understanding of cancer biology. GRAIL's technology infrastructure teams are at the forefront of modern practice in developing and deploying scalable, cloud-based databases and analysis engines. Further, GRAIL is utilizing, at scale, the latest tools of data science, including powerful approaches from machine learning such as hierarchical neural networks. GRAIL will apply such methods to all steps of the Company's data-generating pipeline including the ultimate challenge of classifying patients according to the presence, type, and severity of cancer. From the laboratory to the clinic, GRAIL's goal is to produce the highest quality data and transform them into clinically actionable insights to save lives.

About GRAIL

GRAIL is a life sciences company whose mission is to detect cancer early when it can be cured. GRAIL combines the power of high-intensity sequencing (ultra-broad and ultra-deep sequencing), leading-edge computer science, and large population-scale clinical studies to enhance the scientific understanding of cancer biology and develop a blood test for early-stage cancer detection. The company has secured over \$100 million in Series A financing from Illumina, Inc. and ARCH Venture Partners, with participating investors including Bezos Expeditions, Bill Gates, Sutter Hill Ventures, and GV (formerly Google Ventures). For more information, please visit www.grailbio.com

About Guardian Research Network

Guardian Research Network (GRN) is a nationwide consortium of high-performing community health systems that created a 21st century breakthrough platform for accelerating cures for cancer. GRN harnesses the power of big data to aggregate hundreds of thousands of patient clinical and molecular profiles into a dynamic knowledge architecture focused on the rapid identification of populations to deliver targeted and novel clinical therapies. GRN's goals are to expand patient access to leading therapies without leaving home; enhance precision medicine in local communities; democratize clinical trial access, with special benefit to underserved populations; and radically reduce the drug approval process. GRN founding members include: Gibbs Cancer Center & Research Institute, Spartanburg Regional Healthcare System, Spartanburg, SC; Baptist Health, Louisville, KY; Mercy, Saint Louis, MO; and the Bon Secours Health System, Marriottsville, MD. Join our efforts and learn more by visiting www.guardianresearch.org.

About Hartford HealthCare Cancer Institute

The Hartford HealthCare Cancer Institute is the charter member of the Memorial Sloan Kettering Cancer Alliance (MSK), a pioneering initiative to bring the latest advances in cancer research and therapies to patients in a community-based setting. The Hartford HealthCare Cancer Institute is made up of five comprehensive cancer centers at acute care hospitals across Connecticut, providing multidisciplinary, innovative and coordinated care within a model that emphasizes leading-edge clinical research and a team-based clinical philosophy. For more information on the Hartford HealthCare Cancer Institute, go to www.hartfordhealthcare.org. To learn more about the Hartford HealthCare Cancer Institute's participation in the Memorial Sloan Kettering Cancer Alliance, go to www.togetherahead.org.



NEWS RELEASE

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