

Framingham Heart Study launches new project to develop blood tests for heart disease

March 12 2009

The landmark Framingham Heart Study (FHS) is launching a major initiative to discover risk factors and markers that could lead to new blood tests to identify individuals at high risk of heart disease and stroke. A public-private partnership has been established to enable researchers to apply cutting-edge technology to stored blood samples from thousands of FHS participants. FHS is funded by the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health, and conducted in collaboration with Boston University (BU) School of Medicine and School of Public Health.

Called the Systems Approach to Biomarker Research in [Cardiovascular Disease](#) (SABRe CVD), the initiative will identify and validate new biomarkers - such as proteins or molecules in the [blood](#) -- for [heart disease](#). An important component of the biomarker research will be conducted under a five-year cooperative research and development agreement (CRADA) with BG Medicine, a Massachusetts-based biotechnology research company, which has developed patented technology to detect and validate subtle biological changes at the molecular level.

A CRADA is a unique type of agreement between a federal laboratory and one or more non-federal parties for conducting specified research or development that could lead to useful, marketable products that benefit public health. This collaboration is the first time that the [Framingham](#)

[Heart Study](#) is partnering with a commercial company in a CRADA research project.

"The Framingham Heart Study is one of NIH's shining stars - during its 60-year history, it has yielded some of the most important basic knowledge about [risk factors](#) for cardiovascular disease, such as high blood cholesterol and [high blood pressure](#)," said NHLBI Director Elizabeth G. Nabel, M.D. "This new agreement takes our research to a whole new level. Imagine having a simple blood test to tell us if a patient is at high risk for a heart attack or stroke -- we could do so much more to prevent or delay these often debilitating and deadly diseases."

Researchers from NHLBI, BU, and BG Medicine will study about 1,000 blood biomarkers. Frozen blood samples, imaging studies, and other medical test results gathered over the years from more than 7,000 FHS participants of diverse ages will be analyzed to identify which blood biomarkers are associated with heart disease, metabolic syndrome, and related risk factors. Researchers will use only materials from participants who have consented to sharing their specimens and data with commercial sector scientists, and all shared information will be de-identified to protect participants' privacy.

Heart disease is the leading cause of death in the United States and worldwide. Metabolic syndrome refers to a group of risk factors linked to overweight and obesity that increases the risk for heart disease, type 2 diabetes, and stroke. Metabolic syndrome is diagnosed in individuals who have at least three of the following: overweight or obesity with large waist circumference; high blood pressure; high levels of triglycerides (a type of fat in the blood); low levels of HDL ("good") cholesterol; and high blood sugar, which can be an early sign of diabetes.

"This partnership will help us bolster new discoveries about heart disease risk factors by applying the latest technology to data collected by

Framingham researchers, while continuing to respect and safeguard our participants' privacy," said Daniel Levy, M.D., director of FHS and of the NHLBI Center for Population Studies. Dr. Levy is also Professor of Medicine at Boston University School of Medicine.

The NHLBI and BU have reviewed the SABRe CVD studies with several FHS oversight boards, including its Observational Studies Monitoring Board and Ethics Advisory Board. SABRe CVD leaders will ensure that participants' data and blood samples are used according to participants' stated preferences and following the highest ethical standards.

"This collaborative research effort will add to our understanding of the complex interactions between certain risk factors and disease," said Karen Antman, M.D., BUSM dean and provost of the Boston University Medical Campus. "We are greatly indebted to the thousands of FHS participants who continue to contribute to major scientific advances through exciting research projects like this."

"It is an honor and a privilege to be able to collaborate with Framingham Heart Study researchers on this important project," said Pieter Muntendam, M.D., chief executive officer of BG Medicine. "The advanced research platforms available through BG Medicine will enable the kind of biomarker research that was not possible just a couple of years ago."

Other projects that compose the SABRe CVD initiative will explore protein biomarkers of cardiovascular disease and gene expression changes associated with the biomarkers. Data from these studies will be accessible to other scientists through dbGAP (Database for Genotype and Phenotype), in accordance with data-sharing policies.

[More information:](#) Framingham Heart Study,

www.nhlbi.nih.gov/about/framingham/index.html

Source: NIH/National Heart, Lung and Blood Institute

Citation: Framingham Heart Study launches new project to develop blood tests for heart disease (2009, March 12) retrieved 4 May 2024 from

<https://medicalxpress.com/news/2009-03-framingham-heart-blood-disease.html>

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