

Seasons Greetings! Happy Holidays!

It is with great joy and gratitude we bring you BioMe News, a newsletter for participants who signed up for the Mount Sinai Biobank Program. This year we gave our Biobank Program the name 'BioMe - medicine personalized for you.' In choosing the name BioMe, we thought about participants like you and what you have truly contributed to this project.

As a participant in the BioMe Biobank Program, you are among over 22,000 other members of the communities that Mount Sinai serves, who have joined because they want to help researchers improve health and healthcare in the future. The BioMe Biobank Program has grown to become the largest human subjects research program at Mount Sinai. Since the day you enrolled as a participant, either during one of your medical care visits with your Mount Sinai doctors if you are a patient, or during your work here if



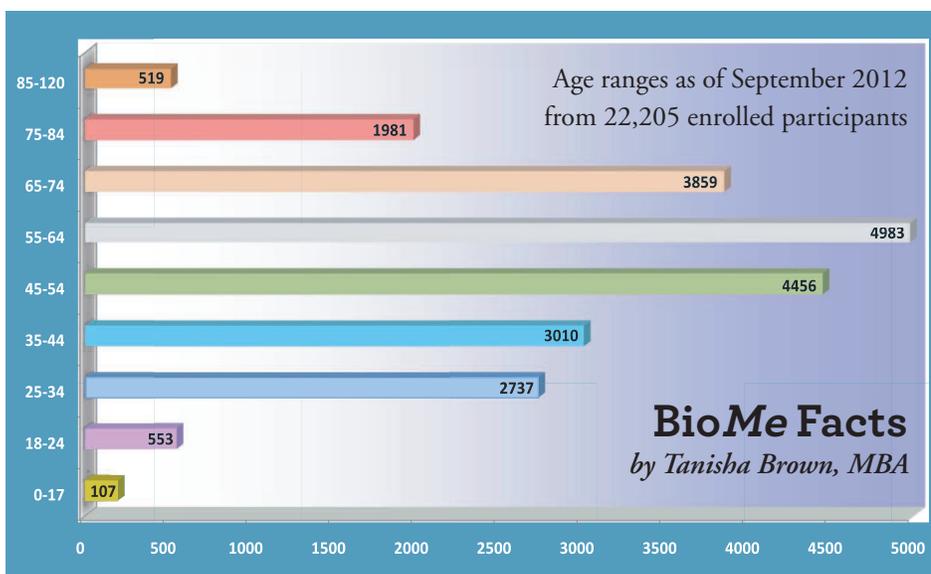
you are a Mount Sinai employee, a lot of new and exciting research activities have happened and we are pleased to tell you about them in this issue of the BioMe News newsletter.

BioMe News brings you updates twice a year on our progress in research and

future research opportunities for which you may qualify and that may help your health. We hope you find this newsletter of interest.

Sincerely,

Your BioMe Team



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Our Team

by *Tanisha Brown, MBA*

Our BioMe team is a group of friendly professionals with varied backgrounds and expertise. When participants are consented by BioMe recruiters, we ensure all participants receive personalized care from the very start. We aim to address all participants' questions and concerns and encourage feedback from our participants to help improve the way we approach new donors.

The BioMe recruiters work vigorously and are stationed at different locations throughout Mount Sinai and its affiliates, approaching potential participants and informing them about the BioMe Biobank Program. They are the core of the BioMe Biobank Program, meeting with potential participants, reviewing the Informed Consent Form and responding to pertinent questions and/or concerns from our donors like you. They ensure that the consent process is complete and all participants' information is entered accurately. The

BioMe recruiters ensure that all participants have a positive and pleasant experience during their time with us.

Our licensed BioMe laboratory technicians receive participants' donated blood samples from the recruiters and begin sample processing. Our technicians work meticulously ensuring that all blood samples are processed and stored safely for future research use. The entire BioMe team is one hundred percent committed to safeguarding participants' privacy at every step.

Research Studies using BioMe *by Yolanda Keppel*

The purpose of the BioMe Biobank is to enable research to improve healthcare for our communities. More than 50 Mount Sinai researchers have already made use of the samples and data for their studies. Here we tell you about new studies that were approved in 2012 and made use of BioMe Biobank in their research.

Role of Microbiome in Crohn's Disease

Inga Peter, PhD

Dr. Peter is trying to identify types of bacteria that reside in the intestine of healthy individuals and compare them to individuals with Crohn's disease. "Our preliminary data indicate that individuals with Crohn's disease, an autoimmune condition in which the immune system attacks its own healthy tissue in gastrointestinal track, causing chronic inflammation, have less variety of non-harmful microorganism in their gut than individuals who do not have the disease. If we can identify specific bacteria that is absent in Crohn's disease patient, we may design new treatments that would provide such bacteria, including probiotic foods," says Dr. Peter.



Hepatitis C and Interferon Induced Thyroiditis

Yaron Tomer, MD

Hepatitis C virus (HCV) is the most common chronic blood-borne infection in the U.S. This research project tests the hypothesis (explanation of previous observations) that HCV and interferon alpha (a medication used to treat HCV) can trigger thyroiditis (inflammation of the thyroid gland) in genetically vulnerable individuals.

Association Studies of Tandem Repeat Genes with Common Human Disease

Andrew Sharp, PhD

Dr. Sharp's research is focusing on 20 of the most highly variable Tandem Repeats (TR) genes. TR genes represent a highly variable part of the genome. The genome is the entire set of genetic instructions found in a cell.

Erwin Bottinger, MD

Principal Investigator & Director of The Charles Bronfman Institute for Personalized Medicine

Omri Gottesman, MD

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BioMe Facts



13,143 of the enrolled participants are females and 9,062 are males.

News about research projects using BioMe samples and/or data

In this issue of the BioMe News, we want to tell you more about new studies to bring genetic testing results into clinical care for BioMe participants like you.

A genetic test may help predict kidney disease risk in African Americans with high blood pressure

by Erwin Bottinger, MD

Compared to European Americans, African Americans are four to five times more likely to develop kidney failure. Family members of African Americans with kidney failure are also more likely to develop kidney failure, suggesting that genetic factors may contribute to and change kidney disease risk between races. Recent studies show that different forms of a gene called APOL1 helps to explain why some African Americans are likely to develop kidney disease.



Erwin Bottinger, MD

“We examined these APOL1 risk variants in 15,000 of our BioMe participants, including 5,000 with African ancestry. The results of APOL1 variant testing for our Mount Sinai patients showed that our African American patients with high blood pressure who inherited two copies of the APOL1 variants are four times more likely to have kidney disease compared to those with one or no APOL1 variant copy,” says Dr. Bottinger, the principal investigator of the BioMe Biobank and the Director of The Charles Bronfman Institute for Personalized Medicine. “The results from Mount Sinai patients are compelling enough to examine how APOL1 genetic testing may be used in early screening to determine people’s risk for kidney failure. If genetic risk is detected early an appropriate treatment could potentially safeguard against kidney failure. Here at Mount Sinai, we are already working on a new study to make testing for APOL1 gene variants available for our patients and their physicians and to examine whether this will help prevent kidney failure in African Americans with high blood pressure,” says Dr. Bottinger.

Personalized medicine is a new form of medicine where doctors use biological information and other data to develop customized medical care that provides the right treatment to the right patient at the right time. This type of research has the potential to create new means of:

- Detecting and treating diseases earlier
- Reducing adverse medication reactions
- Unlocking cures for serious diseases
- Reducing healthcare cost.

Pharmacogenetics (PGx): Using genetic tests to help prescribe medications that really work

by Omri Gottesman, MD

“As a result of programs such as BioMe, we have learned a lot about the role that genetics play in the way that people develop diseases and respond to treatments,” says Dr. Gottesman. “One of the most promising areas is the field of pharmacogenomics, which deals with how patients’ genetic makeup may influence their response to a medication – either that a medication works better or worse, or whether patients are more or less likely to suffer side effects.” Here at The Charles Bronfman Institute for Personalized Medicine, we have developed the CLIPMERGE system. CLIPMERGE stands for CLINical Implementation of Personalized Medicine through Electronic health Records and GENomics. CLIPMERGE is an advanced computer application that analyzes patient data, both genetic and clinical, and tries to predict whether there is a risk to a patient that should be communicated to their doctor through a process called Clinical Decision Support.



Omri Gottesman, MD

Clinical Decision Support:

- Consists of computerized alerts that appear on the physicians’ computer screen as they are entering information, such as prescribing a medication, through a hospital’s Electronic Medical Record.
- Might alert the physician to the fact that the patient has an allergy to that medication, or in the case of our current study, CLIPMERGE PGx, may advise them that there is something in a patient’s genetic makeup that means that the drug or dose they chose to prescribe may not be the best choice.

In the near future, it is hoped that doctors will be able to routinely use information about their patient’s genetic makeup to choose those drugs and drug doses that offer the greatest chance of helping.

Did you know?

BioMe started enrollment on 9/18/07



BioMe News

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New BioMe Studies for You

We would like to know you better. Therefore, a member of the BioMe team will be in touch in the next few months to ask you questions about how physically active you are, what food you eat, whether you smoke, etc. If you are interested in participating, do not hesitate to contact us at (212) 241-5556. A member of the BioMe team can meet you either in person or over the phone. You will be compensated for your time spent with us.

CLIPMERGE Pharmacogenetics (PGx) is a research study that will examine how the use of patient's genetic information may help doctors make better and safer prescribing decisions (**Principal Investigator: Omri Gottesman, MD**)

We will be sending letters to about 3,000 BioMe participants inviting them to take part in CLIPMERGE PGx.

The purpose of the project is to learn how to communicate genetic information to doctors and whether they find it useful. It is hoped that as a result of projects such as CLIPMERGE PGx, it will become routine for doctors to use their patient's genetic information to make healthcare decisions. The study is

funded by The Charles Bronfman Institute for Personalized Medicine. To learn more about CLIPMERGE PGx and to find out if you are eligible to participate, please call the clinical research coordinator Ana Mejia at (212) 241-7562.

The New York Chronic Kidney Disease (CKD) Biomarker Discovery Program is a research project designed to gain information and identify new markers that will better predict the risks for kidney disease in patients with diabetes or high blood pressure. (**Principal Investigator: Erwin Bottinger, MD**)

The purpose of this research project is to study urine samples for kidney function collected from participants enrolled in the BioMe Project. It is hoped that the information learned from this study will lead to new tests to predict kidney disease, in particular in individuals who have diabetes or high blood pressure. The study is funded by a grant from the National Institute for Diabetes Digestive and Kidney Disease (NIDDK, Grant # 5U01DK085688). To learn more about the New York CKD Biomarker Discovery Program and to find out if you are eligible to participate, please call the clinical research coordinator, Ana Mejia at (212) 241-7562.