

Personalized Medicine

Research Project

"Last Printed Issue"

This will be the last printed issue of the PMRP newsletter. Future issues will be in electronic format only. We certainly do want to keep in touch with you and keep you informed about our latest research. To do so, we will put all future issues of the newsletter online (along with older archived issues). You can access these at: www.marshfieldresearch.org/chg

We also want your help and partnership as we move forward with the Precision Medicine Initiative. We envision that you will be full partners in the quest to revolutionize and change health care for the better. To do so, it would help us if we can get your e-mail address to reach you.

Please e-mail the following information to this e-mail address:

chg@mcrf.mfldclin.edu

- First name
- Last name
- E-mail address
- Date of birth (to distinguish you from others with the same name)



The Precision Medicine Initiative

There is an upcoming, exciting new opportunity for health research known as the Precision Medicine Initiative (PMI). This Initiative will have the same basic goal as the Personalized Medicine Research Project (PMRP), that is, to take account of a person's genes, lifestyle, environment and behavior to develop new ways to prevent or treat disease in the individual. This "personalized" or "precision" approach to health care helps us to understand why some patients respond well to a drug while others do not, and provides doctors with better tools to fight disease.

The PMI will build on the foundation of current research in personalized medicine to expand greatly the opportunities for scientists to investigate disease. "PMRP represents a pioneering effort in precision medicine, and it is encouraging to see the mission of PMRP translated to a larger scale in the form of the Precision Medicine

Initiative," remarks Cathy McCarty, Ph.D., the eMERGE Principal Investigator.

A major aim of the Initiative is to assemble a group of one million volunteers nationally to participate in research. Volunteers will be asked to contribute biological specimens (e.g., a blood sample) and their health data to enable researchers to develop new methods to improve health. The biological specimens will be studied to find out information about a person's genes, the different types of cells in the body, the chemicals that play a role in how cells function, and the collection of microorganisms (e.g., bacteria) in and on the body. Health data (e.g., laboratory test results) will be collected from electronic medical records and from the volunteers themselves (e.g., by answering questions about diet on a questionnaire). Privacy of each volunteer's medical records and other data will be assured.

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From the Director, Center for Human Genetics



**Murray
Brilliant, Ph.D.**

"Ups and Downs"

The past few months have been quite eventful for PMRP. For the past 8 years, much of our research efforts (and this newsletter) have been funded through our eMERGE grant

from the National Institutes of Health (NIH). Unfortunately, our application to continue as an eMERGE site was not funded. While we will have funds to finish our previous studies over the next year, we (along with three other previous

eMERGE sites) will not be part of the new eMERGE3 network.

It is often said that when one door closes, another one opens. In his State of the Union address and in a subsequent White House event, President Obama (with bi-partisan support from both houses of Congress) touted a new initiative, "Precision Medicine." I was fortunate to be invited to the White House for the announcement because of the legacy of PMRP. This was based on the efforts over the years of many people, such as Drs. Michael Caldwell, Cathy McCarty, Russ Wilke, Phil Giampietro, Steve Wesbrook and many others who had the foresight to recruit and build PMRP. Of course this would not be possible without you, the 20,000 volunteers that make up PMRP.

In virtually every public talk about his vision for Precision Medicine, Dr. Francis Collins, the Director of the NIH, makes mention of the Marshfield Clinic and the work that we have done with PMRP. We are very hopeful that we (along with you) will be part of the new Precision Medicine Initiative. This issue marks the transformation from Personalized Medicine to Precision Medicine.

Learn More

You can learn more about the Precision Medicine Initiative by visiting this website:

<http://www.nih.gov/precisionmedicine/>

From the eMERGE Principal Investigator



**Cathy
McCarty, Ph.D.**

Greetings from Duluth!

All good things must come to an end" was penned by Geoffrey Chaucer, an English poet and author of *The Canterbury Tales*, in 1374. We have told you in

past newsletters about the long process to generate research ideas and then apply for grant funding to do the research. You have also heard lots about the various activities of the eMERGE grant that was funded by the National Human Genome Research Institute at the National Institutes of Health (NIH) since 2007. Unfortunately, eMERGE2 is coming to an end. I cried the last day of the final eMERGE2 steering committee in June. We were not selected through the peer review process to be part of eMERGE3 which officially started on August 1. One of the reasons given was that we don't have a lot of racial/ethnic diversity in the population, which is true and there is nothing that we can do about that. NIH has been very happy with our work and

has asked us to stay involved to the extent that we have the resources to do that. We have some unused grant dollars that can be held over for a calendar year, through July 31, 2016 and look forward to continued involvement, but at a reduced level.

Our "site" in eMERGE was composed of researchers from three different sites – me at Essentia Health in Duluth, Marylyn Ritchie and her team at Pennsylvania State University and Murray Brilliant and the wonderful team at Marshfield. We enjoy working together, so our plan is to start the process of developing research ideas to collaborate on, and then apply for research funding to support the projects.

Here is a list of a few of our accomplishments over the eight years of eMERGE1 and eMERGE2:

- Implemented a computer-based consent process to enroll participants in the Personalized Medicine Research Project so that people could better understand what it meant to participate
- Implemented a form to allow eye care professionals to record clinical findings to make it easier to conduct research using the electronic records

- Supported three Ph.D. students with data for their dissertations
- Contributed data to the eMERGE network to support research to understand the genetic basis of more than 30 health outcomes
- Worked with our Community Advisory Group to understand concerns patients might have about sharing data with other researchers and themselves
- Created a large database that will continue to allow us to study genetic and environmental causes of disease

We've come a long way together, starting with your willingness to participate in this study. I started with a quote and will end with another. In the words of the poet T.S. Elliott, "...to make an end is to make a beginning". The upcoming end to our funded involvement in eMERGE is just the beginning of many new opportunities because of the resource that we developed. Thanks for allowing me to share it with you.

Cancer research in the Precision Medicine Initiative



Cancers are one of the leading causes of death in the United States and worldwide. Changes in our genes can lead to cancer. Different genetic changes cause different types of cancer, and each type of cancer has its own “genetic signature”, that is, a specific pattern of damaging genetic changes. This knowledge about the causes of cancer has already led to the development of cancer drugs that act against specific types of genetic damage, and some of these drugs are providing benefit to cancer patients. The Precision

Medicine Initiative will seek to expand these efforts to prevent and treat more types of cancers successfully.

The Initiative will fund research studies that select treatments for cancer patients based on the genetic signature of the cancer and not just on the type of cancer (e.g., lung cancer or colon cancer) that the patients have. The studies will group together patients whose cancer has a similar genetic signature. Then, all patients in a group

will be treated with the same drug or combination of drugs known to act against the damaging genetic changes that are part of the cancer’s genetic signature. This will help researchers to identify new anti-cancer drugs faster and to determine the subgroup of cancer patients who receive the most benefit from a specific drug or drug combination.

The Initiative will also sponsor research on the genetic signature of cancers

that respond to a drug at first and then stop responding. This is known as drug resistance, and it limits the ability of drugs to fight cancer. These studies will design new methods for testing how cancer cells respond to treatment and will develop solutions to drug resistance in cancer. Also, these studies will increase our understanding of unexplained drug resistance and will help define subgroups of patients for future studies of new anti-cancer drugs.

Building a “cancer knowledge network” will be a key part of the Initiative’s cancer research objective. This network will be in the form of a database for storing genetic and clinical data that are generated in the cancer research studies described. This database will be useful to scientists, health care providers, and patients. It is hoped that the information in this database can be used to predict how a patient will respond to a particular anti-cancer drug.

Through the efforts outlined here, the Precision Medicine Initiative is making a great investment in the genetic approach to cancer treatment. These efforts will no doubt provide a framework for applying precision medicine to other complex diseases.

Protecting patient privacy in the Precision Medicine Initiative

The Precision Medicine Initiative is fully committed to protecting patient data while creating new avenues to improve human health. Safeguards will be put in place to ensure that there are strong protections for patient privacy. Scientists will be allowed to have access to medical and

genetic data on the group of one million American volunteers to perform research for generating new insights into disease prevention and treatment. However, the data will be shared in a secure manner and only with the consent of participants in the cohort. Further, a number of experts

will be asked for their input on the legal and technical aspects of data security. These experts include patient groups, experts on ethics and privacy issues, and civil liberties advocates. Protecting your patient data is indeed a priority, both in PMRP and the Precision Medicine Initiative!

Partnerships for building the Precision Medicine Initiative

To make the Precision Medicine Initiative a long-lasting and successful effort that will have a positive impact on health, the voice of the larger community needs to be heard. The Initiative views patients as valuable partners in health care and health research, and wants patients and other community members to have an active say in how it moves forward.

From its very beginning, the Initiative will continually invite ideas from all who are interested in promoting health. It wants to hear from patients, patient advocacy groups, doctors, experts on privacy issues, medical centers, and organizations that design and develop medical products. This means that you as a PMRP participant can share your suggestions about how the

Initiative can make a difference to health care. Your input is important in making the Precision Medicine Initiative a success!

Please e-mail us at **chg@mcrf.mfldclin.edu** to give your input. Thanks!

The Precision Medicine Initiative

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The group of volunteers will be assembled, in part, from existing studies that have a system to collect genetic and other health data on their participants. PMRP fits the profile of studies that can be a source of volunteers because it has an already developed system for performing research in precision medicine. "PMRP is well placed to make an important contribution to the Precision Medicine Initiative," notes Murray Brilliant, Ph.D., Director of the Center for Human Genetics at Marshfield Clinic. The Initiative will examine the successes and limitations of these existing studies to determine the most efficient ways to assemble the group of volunteers.

Many different types of scientists will work together to investigate critical health problems using data collected from the group of one million volunteers. The PMI will provide financial support for a nationwide network of scientists to study what causes disease to occur and what goes wrong in our bodies as diseases progress over time, and to create and test new strategies to stop disease. For example, scientists will be able to search for changes in a person's genes that increase the chances of getting a common disease such as high blood pressure or that helps doctors understand whether a patient will respond well to a drug given at a certain dose.

The PMI will set the stage for a new model of doing science. This model will emphasize the active involvement of participants in research studies and the broad sharing of research data in a responsible manner. In fact, the one million volunteers will have access to their own health data, as well as research using their data, to help them make decisions about their own health. Volunteers will therefore form a dynamic community that helps to put precision medicine into practice.

The PMI is poised to move precision medicine into everyday medical practice. The Initiative has the potential to speed up medical discoveries, help doctors choose the best treatments for their patients, and improve scientific knowledge. The health data contributed by one million volunteers will be a critical part of the Initiative because the data will allow researchers to address scientific questions about disease. We hope that as a PMRP participant you see the great value in improving health care through this Initiative. We thank you for your participation in PMRP and appreciate your support of the Precision Medicine Initiative.

Contact Us

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