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Fact Sheet: Administration Announces New Actions to Advance the President's Precision Medicine Initiative

"And my hope is that this becomes the foundation, the architecture whereby 10 years from now we can look back and say that we have revolutionized medicine in areas like cancer, or Alzheimer's, or some of the diseases that cause so much pain and suffering for so many families all across the country."

President Barack Obama, January 2015

In January 2015, President Obama announced the Precision Medicine Initiative (PMI), a bold new research effort to revolutionize how we improve health and treat disease. The Precision Medicine Initiative will pioneer a new model of patient-powered research that promises to accelerate biomedical discoveries and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients.

Precision medicine is the ability to tailor both prevention strategies and treatment decisions to an individual's unique characteristics. Examples of this include, cancer specialists identifying the most effective drug or treatment based on the specific genetic change in a patient's cancer. Care teams remotely monitoring blood glucose levels and analyzing trends to help patients manage or even prevent diabetes. And when prescription drugs are needed to treat an illness, individualized information being used to make sure the right drug is given at the right dose.

Today, the Administration is announcing new investments, partnerships, and policies that aim to bring us significantly closer to our goal—using technology and the power of people. These steps include:

- \$55 million in new awards from the National Institutes of Health (NIH) to health care provider organizations, technology developers, and community health centers to launch the major steps to recruit a million or more voluntary research participants as partners into the PMI Cohort Program.

- A Food and Drug Administration proposal to streamline its oversight of genomic tests to respond to emerging technology while continuing to ensure safety and effectiveness; and
- The development of tools and technology to make data accessible and usable for researchers and participants.

These new milestones follow **actions taken earlier** this year by the Federal Government, the private sector, and non-profit organizations to advance precision medicine. These steps included actions by the Department of Health and Human Services, Department of Veterans Affairs, Department of Defense, and more than 40 private sector organizations. Research participants will be essential partners in PMI, donating their time, energy, and health information. Recognizing the important role that individuals play in PMI, the Administration is making it a priority to protect the privacy and security of the information that will be donated by PMI research participants. Toward this effort, the White House released **privacy and data security principles** to guide activities under PMI.

Steps to Recruit More than a Million Research Volunteers in PMI

The PMI Cohort Program is a landmark longitudinal research effort that will engage at least a million people in the United States to improve our ability to prevent and treat disease based on individual differences in genetics, environment, and lifestyle. Participants will be able to join the cohort either through partner healthcare organizations that have existing relationships in their communities or by enrolling directly through a computer, smartphone, or call center.

Today, the **NIH is announcing** an investment of \$55 million to build the foundational partnerships and infrastructure of the PMI Cohort Program, to launch the largest ever study of its kind. This investment will support several Healthcare Provider Organizations (HPOs), a Data and Research Support Center, and a Participant Technologies Center.

The HPOs will include regional and national medical centers, community health centers, and VA health centers to ensure that participants in the research reflect the geographic, ethnic, racial, and socioeconomic diversity of the country. These organizations will help build the research protocols and plans, inform their patients about the study, enroll interested individuals, and collect essential health data and biological specimens.

- **Regional medical centers:** NIH has selected four regional medical healthcare as the initial partners, bringing research expertise and the ability to reach large numbers of potential volunteers,

contributing to the overall diversity of the participants and regions reached by this phase of the program. These centers are:

- Columbia University Health Sciences, New York City, partnering with Weill Medical College of Cornell University and Harlem Hospital
- Northwestern University, Chicago, partnering with University of Chicago, Ann & Robert H. Lurie Children's Hospital of Chicago, Alliance of Chicago Community Health Services, LLC, and University of Illinois at Chicago.
- University of Arizona, Tucson, partnering with Banner Health
- University of Pittsburgh

- **Community Health Centers:** NIH is initially partnering with six Federally Qualified Health Centers (FQHCs), critical healthcare providers for the country's most vulnerable patients, in order to ensure that underserved communities are represented in biomedical research. The initial sites are:
 - Cherokee Health Systems, Knoxville, Tennessee
 - Community Health Center, Inc., Middletown, Connecticut
 - Eau Claire Cooperative Health Center, Columbia, South Carolina
 - HRHCare, Peekskill, New York
 - Jackson-Hinds Comprehensive Health Center, Jackson, Mississippi
 - San Ysidro Health Center, San Ysidro, California

- Partnership with the VA: Five years ago, the Department of Veterans Affairs launched the **Million Veteran Program** to allow researchers to study health issues critical to veterans. To date, more than 490,000 individuals across the country have stepped forward to serve their country once again by donating their data to science. Building off this success, today the VA is also partnering with the NIH to help enroll participants directly into the PMI Cohort Program and to share strategies, protocols, and best practices.

Steps to Support Data, Tools, and Technology for Researchers and Participants in the PMI Cohort

Just as important as ensuring the recruitment of a diverse and robust group of individuals to participate in PMI is the need to develop the tools and technology needed to make the data secure and useful to researchers and participants, and to maintain participant **privacy**.

- Developing a Data and Research Support Center: To ensure that the data collected through the PMI Cohort Program is accessible to researchers and research participants as part of a secure system, NIH is funding an award to Vanderbilt University, partnering with Verily (formerly Google Health)

and the Broad Institute (with additional collaborations with Columbia University, Northwestern, University of Michigan, and University of Texas at Houston), to create the data infrastructure of the PMI Cohort Program. This infrastructure will allow participants to contribute their clinical and lifestyle information in a secure environment, and receive individual and aggregated study results in return. It will also provide qualified researchers secure access to the data, and ensure that privacy and security are built into the program from day one.

- **Creating Tools and Technologies to Support Enrollment through a Participant Technologies Center:** NIH is also funding The Scripps Research Institute and Vibrent Health, in partnership with Sage Bionetworks, PatientsLikeMe, Walgreens, and other partners, to support the development of tools and technologies to enroll people directly into the study. These tools will enable individuals across the country and from all walks of life to participate in the study and contribute both survey information and a range of digital health data over time. These organizations will also explore the most dynamic and useful ways of sharing health and research information with participants.

Steps to Modernize the Regulatory Approach to Genomic Tests

In addition to building the infrastructure to support research through PMI, the Administration is also working to accelerate innovation around genomic tests. As part of PMI, **FDA is developing a flexible yet accountable approach** to oversight of genomic technologies. It also has launched a novel platform—precision FDA—that provides the community with a place to compare the accuracy of their DNA sequencing tests. Today as part of these efforts, FDA is publishing draft guidance that, when finalized, will provide a flexible and streamlined approach to ensuring the safety and effectiveness of these tests.

- **Bringing Accurate Genomic Tests to Market:** As precision medicine becomes a reality, patients and their providers need to rely on accurate diagnostics to help them make the best care decisions. To assure patient safety while recognizing rapid advances in science and technology, FDA is proposing a streamlined regulatory approach that developers can opt into that aims to speed the development and scalability of genomic tests. Today, the FDA is releasing **draft guidance** on standards for Next Generation Sequencing (NGS)-based in vitro diagnostics used for diagnosing germline diseases as well as **draft guidance** for the use of genetic databases to support clinical validity for NGS-based in vitro diagnostics. These new policies will make it easier for developers to market safe and effective genomic tests by relying on community-based standards and well-established sources of scientific evidence that meet appropriate standards. FDA will seek comment on this proposed approach for 90 days.