

Precision Medicine Initiative

Aims at customizing patient care by taking into account an individual's genetics, environment, and lifestyle to develop personalized treatment strategies.

Updated last **April 28, 2016**
for the 01/20/2015 announced Initiative.

WHAT IT DOES

[The Precision Medicine Initiative](#) (PMI) is a \$215 million project that seeks to improve medical care by increasing research, resources, and infrastructural support for tailored healthcare. The initiative is based on the premise that taking into account personalized information about genetics, environment, and lifestyle while making treatment decisions will improve the precision and success of patient care.

According to the White House, the official PMI [mission](#) is “to enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized treatments.”

The initiative has five [main objectives](#):

1. More and better treatments for cancer – The [National Cancer Institute](#), allocated \$70 million of the PMI funding, is focusing on four broad areas:
 - *Expanding Precision Medicine Clinical Trials* by assigning patients to therapy based on the genetic alterations that are thought to be driving their cancer. [NCI-Molecular Analysis for Therapy Choice \(NCI-MATCH\)](#) is exploring treating adult patients based on the molecular profiles of their tumors, regardless of the type of cancer they have. The NCI Pediatric MATCH trial is expected to open in late 2016.
 - *Overcoming Drug Resistance* by using tumor profiling and laboratory models to better understand how and why tumors begin to grow again after initially responding to therapy.
 - *Developing New Laboratory Models for Research* by increasing the number of human cancer cell lines and patient-derived tumor samples available for researchers to study.
 - *Establishing a National “Cancer Knowledge Network”* by creating a national database of genomic tumor information, clinical data, and outcomes. This resource will be available for use by scientists, health care professionals, and patients alike.
2. Creation of a voluntary national research cohort – The [National Institutes of Health](#) (NIH) will use \$130 million in PMI funding to launch a research cohort of one million participants who will contribute diverse sources of data—including medical records, profiles of the patient's genes, metabolites (chemical makeup), and microorganisms in and on the body, environmental and lifestyle data, patient-generated information, and personal device and sensor data. The project seeks to take advantage of existing research and clinical networks and to be broadly accessible to researchers from multiple disciplines. The [Office of the National Coordinator for Health Information Technology](#) (ONC) is also allocated \$5 million to support the development of standards and requirements to ensure the privacy and security of data exchanged across systems.
3. Commitment to protecting privacy – The White House is working with HHS and several other Federal agencies to identify and address legal and technical issues related to the privacy and security of patient data. [Privacy and Trust Principles](#) have been developed that encompass the following categories:
 - Inclusive, collaborative, and adaptable *governance*,
 - *Transparency* toward participants and the public,
 - *Respect* of participant preferences,
 - *Empowerment* of participants through access to information,
 - Ensuring appropriate *data sharing, access, and use*, and
 - Maintaining *data quality and integrity*.

4. Regulatory modernization - The [Food and Drug Administration](#) (FDA) will use \$10 million of PMI funding to promote development of high-quality, curated databases to support the regulatory structure needed to advance innovation in precision medicine and protect public health. As part of this effort, the agency has created [precisionFDA](#), a community research and development portal that enables testing, piloting, and validating bioinformatics approaches to processing next generation sequencing. This initiative will facilitate faster and more reliable generation of knowledge about genetic information important to patient care.
5. Public-private partnerships - The Obama Administration will use existing research cohorts, patient groups, and the private sector to develop the infrastructure needed to advance the Initiative. The Administration will call on academic medical centers, foundations, researchers, privacy experts, medical ethicists, and medical product innovators to lay the foundation for this effort, including developing new approaches to patient participation and empowerment

RELEVANT SCIENCE

Initially referred to as “[personalized medicine](#)”, the term “precision medicine” has gained increasing [acceptance](#) following a National Academy of Sciences [report](#) in 2011. The report called for combining genetic and other molecular data with medical records for large groups of people into a single “knowledge network” that would be used to better understand disease and tailor treatments.

Though biomedical researchers have applied considerable effort in the last few decades to investigate the relationship between specific genetic alterations and epidemiology and progression of disease, recent scientific and technological advances (including a dramatic decrease in genome sequencing costs) have set the stage for the PMI. Similar, albeit smaller initiatives are already underway in the U.S. ([Resilience Project](#) and [Framingham Heart Study](#)) and abroad (United Kingdom - [100,000 Genomes Project](#), Japan - [DNA Data Bank of Japan](#), and Iceland - [deCODE Genetics](#)).

ENDORSEMENTS & OPPOSITION

President Obama [stated](#) that the promise of the PMI is “...delivering the right treatments at the right time, every time, to the right person.” Understanding the genetic underpinnings of disease on an individual level would allow physicians to prescribe treatments with the best predicted outcomes. Although enhanced funding and support for genomic research is welcomed by many researchers, clinicians, and patients, some have begun to voice concerns.

Endorsements:

- The majority of biomedical researchers, medical professionals, and pertinent advocacy groups such as the [American Association for Cancer Research](#) and [Research America!](#) have supported the PMI.
- NIH Director Dr. [Francis Collins](#) has been one of the PMI’s most vocal supporters. He has produced testimonies to the [Senate](#) and [House](#) and participated in numerous interviews ([PBS](#), [New England Journal of Medicine](#) (NEJM)) and commentaries ([The Journal of the American Medical Association](#), [NEJM](#)) to advocate for the necessity and benefits of this initiative.

Opposition:

- Critics have voiced concerns over a number of issues, including the level of [funding](#), [feasibility](#), unrealistic public [expectations](#), and matters of [privacy](#).
- Other critics have [commented](#) that physicians are not qualified or properly trained to interpret complex genetic testing and/or communicate the results to their patients.
- Some have [speculated](#) that a focus on health disparities and social determinants of health would be more beneficial to public health

STATUS

The White House hosted a '[Precision Medicine Initiative Summit](#)' in February, 2016 to celebrate the Initiative's one-year anniversary. On the same day, President Obama also released [a summary of key actions to accelerate PMI](#).

RELATED POLICIES

- The [21st Century Cures Act](#), passed by the House, addresses a number of elements targeted by the PMI. The Senate chose to cover similar topics through a series of separate bills (including [S 2713 'Advancing Precision Medicine Act'](#) and [S 1101 'Medical Electronic Data Technology Enhancement for Consumers' Health Act'](#), which now await action on the Senate floor.
- The Department of Veterans Affairs has enrolled over 450,000 veterans in the [Million Veteran Program](#) (MVP), which seeks to study how genes affect health. To do this, MVP will build one of the world's largest medical databases by safely collecting blood samples and health information from one million veteran volunteers. Collected data will be stored anonymously for use in researching diseases like diabetes and cancer as well as military-related illnesses like post-traumatic stress disorder. The Department of Defense is partnering with the VA to facilitate the enrollment of active-duty men and women into MVP.
- The Department of Health and Human Services' [Office for Civil Rights](#) is [developing regulatory guidance](#) to ensure that individuals and HIPAA-covered entities understand the patient's right to access their health information, enabling them to donate it for research.

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RECOMMENDED CITATION

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