

# The Precision Medicine Initiative

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On February 25, 2016, the White House hosted a [Precision Medicine Initiative \(PMI\) Summit](#) to mark the one year anniversary of the initiative's launch, first announced in last year's State of the Union address. The mission of the PMI is "[\(t\)o enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care.](#)" The PMI primarily involves three federal agencies—the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Office of the National Coordinator for Health Information Technology (ONC)—although other federal agencies have collaborated on and contributed to the effort.

Since the initiative's inception, NIH has awarded multiple [grants](#) to begin building an extensive biobank, develop health care provider organizations (HPOs), and develop recruitment strategies for a million-person national research cohort program, now called the [All of Us Research Program](#); NIH expects to begin enrolling participants this year. To ensure the opportunity for participation of underserved individuals, NIH and the Health Resources and Services Administration (HRSA) awarded funding for a pilot program that is to determine infrastructure needs for health centers to serve as HPOs. In addition, FDA has developed [precisionFDA](#) to facilitate data sharing and validation of new genomic assays in precision medicine.

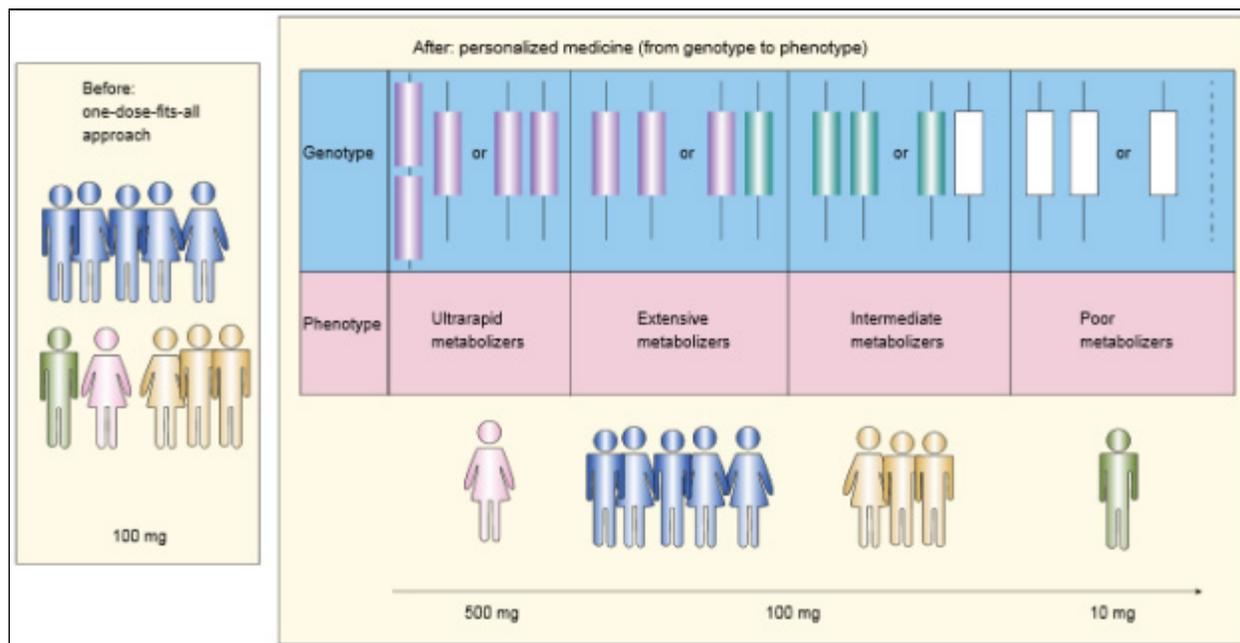
## What Is Precision Medicine?

Precision medicine is a relatively new term for what has traditionally been called personalized medicine, the idea of providing health care to individuals based on specific patient characteristics. Currently, medical care is usually provided in a "trial and error" manner, with treatment adjusted based on real-time patient response. Precision medicine would tailor medical treatment to the individual patient, thus aiming to improve health outcomes and save health care costs.

Precision medicine is defined by the [National Academy of Sciences \(NAS\)](#) as "the use of genomic, epigenomic, exposure and other data to define individual patterns of disease, potentially leading to better individual treatment." This term has been used interchangeably with [personalized medicine](#)—generally, the use of a diagnostic device and a therapeutic product to provide the best therapy, at the right dose, at the correct time for a particular patient—and

sometimes with [pharmacogenomics](#)—the study of how individual genetic variation affects a person's response to drugs.

Figure 1. An Illustration of Precision Medicine: Selecting Drug Dosage Based on Individual Genotype



**Source:** H Xie, FW Frueh, "Pharmacogenomics steps toward personalized medicine," *Personalized Medicine*, vol.2, no. 4, pp. 333, 2005.

Currently, more than [100 FDA-approved drugs](#) contain pharmacogenomic information in their labeling; for example, the blood thinner warfarin has labeling with information about the CYP2C9 genotype and related dosing considerations. A genetic test to determine [CYP2C9 genotype](#) provides information about the speed at which an individual metabolizes warfarin. This, in turn, allows those who metabolize the drug more slowly to be identified and given lower doses, and vice versa ([Figure 1](#)).

#### FY2017 Funding for the Precision Medicine Initiative

FY2017 funding levels for the PMI are unclear currently because full-year appropriations for FDA and NIH were not enacted prior to the start of FY2017. Instead, temporary funding for these agencies has been provided through December 9, 2016, by a continuing resolution (Division C, Continuing Appropriations and Military Construction, Veterans Affairs, and Related Agencies Appropriations Act, 2017, and Zika Response and Preparedness Act, [P.L. 114-223](#)), which generally continues discretionary funding at FY2016 levels, reduced by 0.496%. The FY2017 President's budget requested a [total of \\$309 million](#) for the PMI: \$4 million to FDA, \$5 million to ONC, and the remaining \$300 million to NIH. In FY2016, NIH received \$200 million: \$70 million for the National Cancer Institute (NCI) and \$130 million from the Common Fund for the research cohort. FDA received \$2.392 million, and ONC did not receive funding.

The FY2017 President's request proposed an increase over [FY2016 of \\$100 million in mandatory funding](#) for NIH. The increase is targeted for the scale-up of a national research cohort of 1 million or more volunteers, whose health, genetic, environmental, and other data would be collected and used in studies to identify novel therapeutics and prevention strategies. The requested \$5 million in ONC funding would be used to support the research cohort by developing interoperability standards and requirements regarding privacy to allow for the secure exchange of information across various data systems.

The NIH funds would also be used by the [National Cancer Institute](#) to support studies in cancer genomics, including

those looking at how cancers can become resistant to therapy; at combinations of cancer drugs; and at how genomic changes predict therapeutic effectiveness.

The requested \$4 million in funding for FDA would be focused on acquiring additional expertise and developing databases to support the regulatory structure necessary to advance precision medicine and protect public health. Specifically, FDA would use some of this new funding to develop tools that will facilitate a [regulatory approach for Next Generation Sequencing \(NGS\) technologies](#).

### Congressional Interest in Precision Medicine

Precision medicine has attracted bicameral and bipartisan attention in Congress. In 2014 the House Committee on Energy and Commerce launched the [21<sup>st</sup> Century Cures initiative](#) to examine the regulation of drugs and devices in the context of advances in science. This effort culminated in the 21<sup>st</sup> Century Cures Act ([H.R. 6](#)), which passed the House on July 10, 2015. The bill contains provisions that would address precision medicine and other complementary efforts such as privacy.

On March 17, 2016, the Advancing Precision Medicine Act of 2016 ([S. 2713](#)) was introduced, and on April 18, 2016, it was reported out of the Senate Committee on Health, Education, Labor, and Pensions. This bill would codify the PMI, enhance privacy protections for sensitive identifiable data, and allow data-sharing of specified genomic information. This bill is one of 18 medical innovation bills constituting the committee's [bipartisan initiative](#) to "examine the process for getting safe treatments, devices and cures to patients and the roles of the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) in that process," a response to the House's 21<sup>st</sup> Century Cures initiative.