

## Background: Precision Medicine Initiative & Cancer Moonshot

**Precision Medicine:** An emerging approach for disease prevention and treatment that takes into account people's individual variations in genes, environment, and lifestyle. Research efforts have been ongoing for years.

**Precision Medicine Initiative:** The Precision Medicine Initiative (PMI) aims to generate the scientific evidence needed to advance the concept of precision medicine into clinical practice.

### Background:

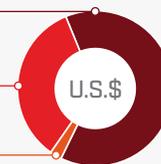
- ▶ 2015 State of the Union: President Obama announces the launch of the Precision Medicine Initiative – a “bold new research effort to revolutionize medicine” – led by the NIH.

### Goals of the PMI:

- ▶ A key arm of the PMI is the development of a research cohort that will engage a million or more Americans who volunteer to contribute their health data over many years to improve health outcomes, fuel the development of new treatments for disease, and catalyze a new era of data-based and more precise preventive care and medical treatment.
- ▶ This will pioneer a new research model that emphasizes engaged participants, responsible data sharing and enhanced but flexible privacy protections.
- ▶ Key expectations of the PMI include: advancing pharmacogenomics and the identification of new biomarkers and targets for disease treatment and prevention, with near-term emphasis on cancer.

### Funding:

- ▶ Congress appropriated \$205 million for PMI activities for FY2016
  - ▶ \$200 million to the NIH.
    - + \$130 million for the PMI-Cohort Project (PMI-CP).
    - + \$70 million to the National Cancer Institute (NCI) to lead efforts in cancer genomics, known as precision oncology.
  - ▶ \$5 million to ONC for the coordination and development of data standards relating to the PMI.



### PMI Today:

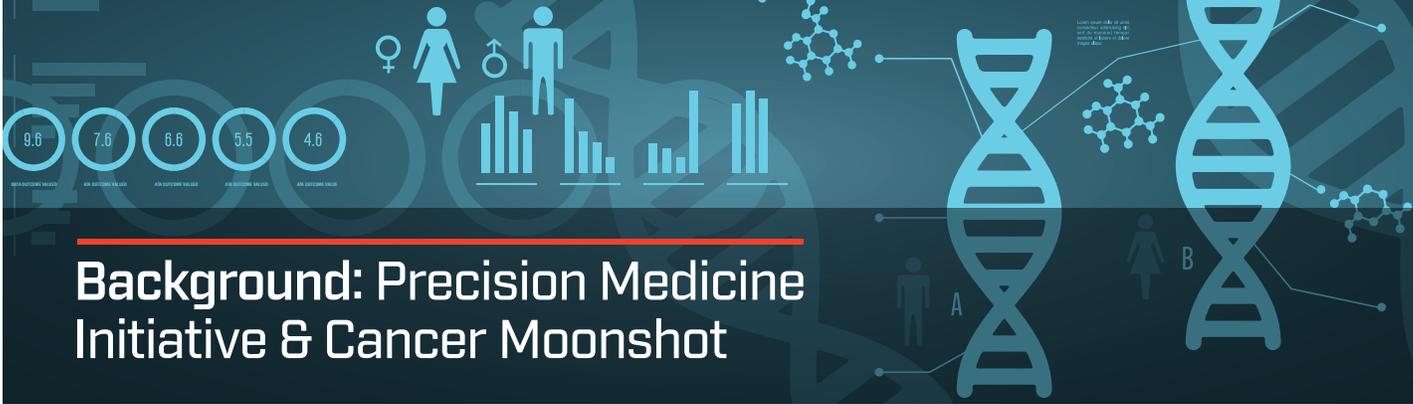
- ▶ September 2015: NIH Director Dr. Collins accepted the PMI Working Group's framework for building and managing the PMI research cohort.
- ▶ Q1 2016: NIH to review Program Funding Applications to support various aspects of the PMI Cohort Project (i.e. Coordinating Center, Technologies Center, Enrollment Centers, etc.). Funding awards have begun and are expected throughout the year.

To be maximally effective, these initiatives require the public and private sectors to work in tandem to realize the next generation of medicine. To this end, HITN released a White Paper in July 2015 that made the following recommendations to policymakers:

- ▶ Improve interoperability and data sharing for all health data;
- ▶ Meaningfully engage patients and the private sector;
- ▶ Use success metrics that incent clinical and basic science advances; and
- ▶ Reevaluate current privacy and consent laws to account for modern scientific and technological advances.



The White Paper is available at [www.healthitnow.org](http://www.healthitnow.org)



# Background: Precision Medicine Initiative & Cancer Moonshot

**Cancer Moonshot:** The White House formed a Cancer Moonshot Task Force, chaired by the Vice President, to establish a “whole-of-government” approach, marshaling resources from across the Federal government to address the singular goal of supporting cancer research and enabling progress in treatment and care.

**Background:**

- ▶ **2015 State of the Union:** President Obama announced that Vice President Biden will lead the charge on a new national commitment to end cancer, entitling the mission as the new “Moonshot”.

**Moonshot Task Force:**

- ▶ Made up of Executive Branch departments, agencies and offices pertinent to basic, translational and clinical research, therapy development, regulation of medical products and medical care related to cancer.
- ▶ Funded by the NIH
- ▶ The Task Force is advisory in nature only and is charged with developing recommendations by the end of 2016 on:
  - ▶ accelerating our understanding of cancer;
  - ▶ improving patient access and care;
  - ▶ supporting greater access to new research, data and computational capabilities;
  - ▶ encouraging the development of cancer treatments;
  - ▶ identifying and addressing unnecessary regulatory barriers;
  - ▶ ensuring optimal Federal investment; and
  - ▶ identifying opportunities to develop public-private partnerships and increasing the coordination of the Federal Government with the private sector.

**Funding:**

- ▶ \$195 million for “new cancer activities” at the NIH for FY2016.
- ▶ Requested \$755 million in mandatory funding for new cancer-related research activities at both the NIH and FDA for FY2017.

**Moonshot Today:**

- ▶ February 1, 2016: First meeting of the Cancer Moonshot Task Force

**Examples of research opportunities the Cancer Moonshot funds may apply to:**

- i Prevention & Cancer Vaccine Development
- ii Early Cancer Detection
- iii Cancer Immunotherapy & Combination Therapy
- iv Genomic Analysis of Tumors & Surrounding Cells

