The President’s Precision Medicine Initiative

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Precision Medicine:

• An emerging approach for disease prevention and treatment that takes into account people’s individual variation in genes, environment and lifestyle.

• Not a new concept
  – Medicine has always been “personalized”
  – Consider prescription eyeglasses, blood typing...

• However, most therapies available today are designed for an “average patient.”

• PM is about moving away from this “one-size-fits-all” approach.
Precision Medicine Success Stories

William Elder Jr.
Emily Whitehead
Elana Simon
Melanie Nix
Hugh and Beatrice Rienhoff
Kareem Abdul-Jabbar
Noah and Alexis Beery
“And that’s why we’re here today. Because something called precision medicine ... gives us one of the greatest opportunities for new medical breakthroughs that we have ever seen.”

President Barack Obama
January 30, 2015
Precision Medicine Initiative (PMI)

Mission Statement

To enable a new era of medicine through research and technology that empowers patients, researchers, and providers to work together toward development of individualized treatments.
Precision Medicine Initiative: Why Now?

Genomics

Data Science

EHRs

Technologies

Patient Partnerships
# Precision Medicine Initiative:
## Timing is Everything

<table>
<thead>
<tr>
<th></th>
<th>Ten Years Ago</th>
<th>Now</th>
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</thead>
<tbody>
<tr>
<td>Cost of sequencing a human genome</td>
<td>$22,000,000</td>
<td>$1000 - $5000</td>
</tr>
<tr>
<td>Amount of Time to Sequence a Human Genome</td>
<td>2 years</td>
<td>&lt;1 day</td>
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<tr>
<td>Number of smart phones in the United States</td>
<td>1 million (&lt;2%)</td>
<td>160 million (58%)</td>
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<tr>
<td>EHR Adoption (% providers)</td>
<td>20-30%</td>
<td>&gt;90%</td>
</tr>
<tr>
<td>Computing Power</td>
<td>n</td>
<td>n x 16</td>
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Precision Medicine Initiative

**Vision:** Build a broad research program to encourage creative approaches to precision medicine, test them rigorously, and, ultimately, use them to build the evidence base needed to guide clinical practice.

- **Near Term:** apply the tenets of precision medicine to a major health threat – cancer
- **Longer Term:** generate the knowledge base necessary to move precision medicine into virtually all areas of health and disease
PMI: Core Components

• Cancer component (NCI)
  – Expand genetically-based clinical cancer trials
  – Explore fundamental aspects of cancer biology
  – Identify new cancer subtypes, therapeutic targets
  – Create a “cancer knowledge network” to generate and share new knowledge to fuel scientific discovery and guide treatment options.

• Creation of a national research cohort (NIH, others)
  – One million or more Americans who volunteer to participate in research.
  – Participants to have the opportunity to contribute diverse sources of data (e.g., medical records; genetic information; environmental and lifestyle data; data from mobile devices)
  – Broadly accessible to qualified researchers
  – Forge new model for scientific research that emphasizes engaged participants and open, responsible data sharing

• Regulatory modernization
  – Identify and support changes to advance precision medicine and protect public health
  – Development of a new approach for regulating NGS technologies (FDA)
Core Activities

Cross-government working groups
- Participant engagement
- Stakeholder outreach
- Data infrastructure
- Regulatory modernization
- Privacy

NIH Advisory Committee Working Group
- Recommendations on Cohort Design
PMI and Privacy

**Goal:** Establish a framework for protecting the privacy and security of participants’ information in PMI

- Develop a set of privacy principles to guide the development of the PMI cohort
- Identify gaps and other issues in current privacy and security protections, and propose policy changes to address those gaps.
Questions?

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