

Perspectives on the President's Precision Medicine Initiative



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President Obama's "precision medicine initiative" earmarked over \$200 million from his proposed 2016 budget to "bring us closer to curing diseases like cancer and diabetes - and to give all of us access to the personalized information we need to keep ourselves and our families healthier."^[1] The National Institutes of Health ("NIH") and the National Cancer Institute ("NCI") will be the major benefactors if the proposed budget for this initiative is approved. A recent article co-authored by Drs. Francis S. Collins and Harold Varmus, directors of the NIH and NCI, respectively, identifies precision medicine's critical needs and discusses how the President's initiative will help "accelerate progress toward a new era of precision medicine."^[2]

A Research Program with Reach and Depth

In their article published in the February 26, 2015 issue of The New England Journal of Medicine^[3] Drs. Collins and Varmus contend that personalized medicine needs a broad research program to encourage and test creative approaches to precision or personalized medicine, and to build needed evidence to guide clinical practice.

A Cancer Knowledge Network

In the near term, the initiative will focus on cancers while the longer term goal is to

generate knowledge applicable to the treatment and prevention of other diseases. Cancer is identified as the “clear choice”^[4] as a near term goal because cancers are common diseases and their incidence is increasing as the population ages. In addition, initial research into the genetic basis for disease focused on cancer, and discoveries to date have begun to influence risk assessment, diagnostic categories, and therapeutic strategies. While this progress is promising, there is a realization that to achieve a deeper understanding of cancer, more data is needed from the analysis of additional patient genomes and clinical trials. A “cancer knowledge network” will be built “to store the resulting molecular and medical data in digital form and to deliver them, in comprehensive ways, to scientists, health care workers, and patients.”^[5] This initial work in cancer will then be leveraged toward the adoption of precision medicine in other spheres, notably inherited genetic disorders and infectious disease.

A Million Patient Cohort

The authors note that current methodologies to identify actionable interventions may not be enough to understand disease sufficiently to implement precision medicine. The President’s initiative thus is designed to support and encourage the next generation of scientists to develop new approaches for “detecting, measuring, and analyzing a wide range of biomedical information – including molecular genomic, cellular, clinical, behavioral, physiological, and environmental parameters.”^[6] To achieve this objective, more information from a large patient population is needed. Thus, the second component of the initiative is to assemble a “cohort” of 1 million or more Americans volunteers, who will provide biologic specimens and personal information to enable observational studies to better understand disease and potential therapies. Unlike prior studies, it will allow patients to access their own health information and information about research using their data.

A New Regulatory Framework

In President Obama’s January 2015 address, he also noted that the nation’s process for approving new drugs and devices may require new procedures to allow patients and individuals to participate in research. Thus, the NIH is working with the Department of Health and Human Services to create procedures that allow patients to become active partners in modern science. The Food and Drug Administration also will work to advance the careful use of genomic technology in the drug approval process.

Near Term and Long Term Benefits

It is not expected that the President’s precision medicine initiative will yield immediate benefits. Much of the early research will lay the foundation for future discoveries and therapies. However, Drs. Collins and Varmus believe that even these initial studies may provide early insights into treatment of other common diseases. And with many ambitious research endeavors, there will be benefits that cannot be imagined or anticipated to the end of providing “everyone the best chance at good health.”^[7]

[1] Collins and Varmus (2015) A New Initiative on Precision Medicine, N Engl. J Med, Vol.372, No. 9:793-95, at page 793, quoting President Barack Obama, State of the Union Address, January 20, 2015. See also our prior posts of [January 25, 2015](#) and [February 2, 2015](#) discussing the President's Precision Medicine Initiative.

[2] Collins and Varmus (2015) A New Initiative on Precision Medicine, N Engl. J Med, Vol.372, No. 9:793-795, at page 793.

[3] Id.

[4] Id.

[5] Id. at 794.

[6] Id.

[7] Id. at 795.

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