

# P R E S I D E N T ' S C A N C E R P A N E L

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## NATIONAL CANCER PROGRAM

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### Emerging Opportunities to Streamline Cancer Drug Development

December 9, 2016

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Today, we live in an exciting era in which advances in the understanding of the molecular basis of cancer and the role of the immune system are creating opportunities for more effective, potentially curative, treatments. Some breakthrough therapies already are improving outcomes for many patients. However, innovative treatment strategies pose new challenges for research and development, and the resulting drugs often come at substantial cost to patients, their families, and the healthcare system. The President's Cancer Panel is focusing on these issues in its 2016–2017 series of meetings, *Ensuring Patients' Access to High-Value Cancer Drugs*.

On December 9, 2016, the Panel convened its second workshop in the series in Arlington, Virginia, bringing together leaders and stakeholders in cancer research and drug development—patients and patient advocates, oncologists, statisticians, and intellectual property specialists, as well as representatives from the biopharmaceutical industry, academic research institutions, the U.S. Food and Drug Administration (FDA), and other government agencies. Key scientific, regulatory, and clinical trial factors that influence cancer drug development were considered, and participants discussed actions that could be taken to optimize drug development processes, accelerate learning from clinical trials, and ensure timely market entry of innovative and highly effective drugs.

The Panel heard concerns about lack of coordination and duplication of effort in cancer drug development. Several participants suggested that sharing and more effective use of data would facilitate more efficient drug development. Clinical trial results—including both positive and negative outcomes—should be made public, and electronic health record data should be used to evaluate the benefits of drugs in clinical practice and identify opportunities for improvement (this issue is addressed in the 2016 Panel report [Improving Cancer-Related Outcomes with Connected Health](#)). Knowledge of the underlying biology of cancer and mechanisms of drug action also could be increased if academic researchers had earlier access to investigational agents and were able to evaluate drug combinations in model systems.

Participants also noted opportunities to make cancer clinical trials more effective and efficient through innovative trial designs, including adaptive and fluid approaches that allow researchers to build on early results and allocate resources to investigation of the most promising interventions. The importance of continuing to identify and test potentially synergistic combination therapies that may help avoid or overcome drug resistance was emphasized. The Panel was gratified to hear about ongoing work by FDA, academic research centers, and the biopharmaceutical industry to accelerate progress through innovative trial design and collaboration.

In the midst of excitement about progress in drug discovery and concerns about problems in our systems, we must not lose sight of the ultimate goal of creating high-value drugs for patients—drugs that offer potential for cure, significantly longer survival, and/or increased quality of life when used in real-world settings. Use of patient-reported outcomes is helping researchers and healthcare providers assess patients' needs, preferences, and responses to treatment. Clinical trials should incorporate questions important to patients, and financial and logistical barriers to trial participation should be eliminated whenever possible.

Information about future workshops in this series will be posted to the [President's Cancer Panel website](#) as it becomes available. Workshop findings and recommendations will be presented in the Panel's 2017 Report to the President of the United States.