A National Cancer Policy Forum Workshop
in Collaboration with the
Forum on Drug Discovery, Development, and Translation

The Drug Development Paradigm in Oncology
A Workshop | December 12-13, 2016

Join the Conversation: #OncologyDrugDev
Overview of the Workshop

Richard L. Schilsky
Workshop Planning Committee Members

CHAIR: RICHARD L. SCHILSKY

AMY ABERNETHY       AMY MCKEE
JEFF ALLEN          REBECCA PENTZ
KENNETH ANDERSON    STEVEN PIANTADOSI
MARGARET ANDERSON   MACE ROTHENBERG
MONICA BERTAGNOLLI  DANIEL J. SARGENT
GIDEON BLUMENTHAL   DEBORAH SCHRAG
HEDVIG HRICAK       MARC THEORET
RONALD KLINE        SUZANNE L. TOPALIAN

NATIONAL CANCER POLICY FORUM STAFF
SHARYL NASS
ERIN BALOGH
CYNDI TRANG
SYLARA MARIE CRUZ

DRUG FORUM STAFF
ANNE CLAIBORNE
REBECCA ENGLISH
AMANDA WAGNER GEE
MORGAN BONAME
OLIVIA YOST
In Memoriam
Planning Committee Member Dan Sargent

Thanks to our Sponsors

Centers for Disease Control and Prevention
National Cancer Institute/National Institutes of Health
American Association for Cancer Research
American Cancer Society
American College of Radiology
American Society of Clinical Oncology
American Society of Hematology
American Society for Radiation Oncology
Association of American Cancer Institutes
AstraZeneca
Bristol-Myers Squibb
Cancer Support Community
CEO Roundtable on Cancer
Helsinn Group
LIVESTRONG Foundation
National Comprehensive Cancer Network
Novartis Oncology
Oncology Nursing Society
Pfizer

AbbVie
American Diabetes Association
American Society for Microbiology
Amgen Inc.
Association of American Medical Colleges
AstraZeneca
Baxalta
Burroughs Wellcome Fund
Critical Path Institute
Eli Lilly & Company
FasterCures
Food and Drug Administration
Friends of Cancer Research
GlaxoSmithKline
Johnson & Johnson
Merck & Co.
National Institutes of Health
New England Journal of Medicine
Pfizer Inc.
Sanofi
Takeda
Overarching Goals

To examine the current paradigm for cancer drug development:

• **Highlight challenges** with the traditional phased drug development process
• **Explore opportunities** to promote seamless cancer drug development and to learn throughout the life cycle of a drug

To suggest strategies to:

• **Improve the collection of information** across the cancer therapy lifecycle
• **Streamline and adapt drug development** plans based on compelling evidence
• **Consider ethical and regulatory implications** for seamless cancer drug development
Workshop Agenda December 12

Session 1
• Vision for a Seamless Cancer Drug Development Paradigm

Session 2
• Case Studies and Lessons Learned From Recent Experiences

Session 3
• Flexible Drug Development and Decision Making

Session 4
• Continuous Evidence Generation Across the Cancer Therapy Lifecycle
Workshop Agenda December 13

Moonshot
- The National Cancer Moonshot Initiative and Seamless Drug Development

Session 5
- Managing Benefit and Risk in Seamless Cancer Drug Development

Session 6
- Stakeholder Perspectives: Goals of the New Paradigm and Priorities for the Path Forward

Wrap Up
- Closing Remarks