Sustaining Progress Against Cancer in an Era of Cost Containment

June 2012

This Discussion Paper has been provided to attendees of the national conference Turning the Tide Against Cancer Through Sustained Medical Innovation, held June 12, 2012 in Washington, D.C.
Foreword

For more than 35 years, it has been my honor to work alongside some of the most innovative and pioneering thought leaders in industry, academia, and government. During this time, there have been special periods when transformative technologies and transformative ideas have spurred scientific discovery, propelled biopharmaceutical research and development, and empowered patients to seek a more active role in their health and wellness.

I believe we are at such a juncture today, where the sheer volume of and access to scientific and health data—coupled with a renewed focus on the patient and improving the quality of care—are contributing to a fundamental shift in the systems to support continued medical innovation.

As part of the preparation for the Turning the Tide Against Cancer Through Sustained Medical Innovation Conference, Feinstein Kean Healthcare was privileged to develop and produce this Discussion Paper, based on interviews we conducted with more than 30 experts, as a pro bono contribution to the cancer community. Its content reflects the insights, hopes, and vision for the future from these experts, who are currently working to address the challenges of cancer and improve the lives of people living with the disease.

During the interview process, we were struck by the fact that so many prestigious leaders took the time to be interviewed, and by how many expressed the view that the upcoming June 12 dialogue among the different stakeholders would be extremely valuable and long overdue. Virtually all of these experts fervently encouraged the conveners not to stop with the conference itself, but to persist in sustaining community-wide efforts to align the scientific opportunity, the clinical need, and the policy framework, lest we risk parting ways, to the detriment of all.

Feinstein Kean Healthcare extends its appreciation to all who participated as interviewees, including members of the Conference Advisory Committee, and especially to the Personalized Medicine Coalition and American Association for Cancer Research for their editorial review of this paper. Special thanks as well to Tracy Lessor, Ph.D., M.B.A., FKH vice president, who served as writer.

Respectfully,

Marcia A. Kean, M.B.A.
Co-convener, Turning the Tide Against Cancer
Editor, Discussion Paper
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Executive Summary

Progress against cancer is at a critical turning point. As noted in the *AACR Cancer Progress Report 2011*, advances in science and technology show the potential for significant gains in the near future, while revealing unimagined biological complexities. At the same time, these opportunities are occurring in an environment of intense pressure for fiscal restraint. The ways in which we define research, regulatory, and policy pathways to address the opportunities and challenges before us will play a decisive role in determining whether we sustain progress against cancer.

To help define these pathways, the Personalized Medicine Coalition, the American Association for Cancer Research, and Feinstein Kean Healthcare are convening a national conference on June 12, 2012 in Washington, D.C.—*Turning the Tide Against Cancer Through Sustained Medical Innovation*. The central purpose of the conference is to consider the status and future of innovation in cancer research and care. The Conference brings together leaders from various sectors to focus on three broad areas:

- **A changing cancer care ecosystem**: Emerging evidence-generation tools and the development of new models and systems that are founded on recent scientific advances, the changing role of the patient in research, and how the cancer community is adapting.
- **Valuing innovation and progress**: Defining and demonstrating value in cancer care, stakeholder perception of value, and current approaches to measuring value.
- **Potential paths forward**: Defining actionable policy solutions to ensure continued innovation in oncology.

Methodology

Feinstein Kean Healthcare conducted in-depth, one-on-one interviews with 35 experts (see Interviewee list, page 25), representing multiple constituencies in the oncology ecosystem: academics, policymakers, providers, payers, product innovators, and patient advocates, and then summarized their views in this Discussion Paper. Although not every perspective on every topic discussed in the interviews could be captured, the most common themes are represented here, reflecting areas of both strong agreement and considerable controversy.

Findings

Several common themes emerged from our interviews, reflecting broad recognition that:

- Science is at an inflection point in oncology. Biology and ‘-omics’ technologies are providing the ability to characterize tumors in great detail at the molecular level, thereby redefining how we classify, diagnose, and treat cancer.
- Emerging innovations will dramatically improve patient care, and could ultimately help address the challenge of rising healthcare costs by changing cancer from a frequently fatal to a chronic disease, and gaining efficiencies from diagnosing disease more precisely in each individual and treating each patient with the appropriate therapy.
- Strong incentives for innovation are needed to realize the opportunity for ‘turning the tide’ against cancer.
- Continued efforts are needed to make cancer care truly patient-centric. While significant progress has been made in that regard, many interviewees called for stronger policy

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incentives and decision-support tools to foster greater patient engagement and doctor-patient decision-making.

- Policy solutions are needed that align with scientific trends and patient-centered care, and that are responsive to the dynamic nature of innovation in our time.
- Tools for knowledge generation and models for value assessment must evolve, to enable more rapid conversion of data to information to knowledge, and to enable delivery of that knowledge to the bedside in a continuum known as the Rapid Learning Healthcare System.
- Change cannot occur without significant, continuous community-wide commitment.

The concept of value will play a central role in aligning policy with progress, according to the interviewees. Among the key findings was acknowledgement that:

- Our society has not clarified a definition of value that all stakeholders can agree on, but that such a definition would undoubtedly have to reflect the centrality and empowerment of the patient.
- Value is perceived differently by different stakeholder groups, and is even perceived differently among individuals within a particular stakeholder community, such as patients.
- Current tools for measuring and assessing value are probably not geared to address the increasingly rapid, complex, and dynamic level of innovation. Many called for a shift from "static" and retrospective assessment models to "dynamic" and prospective models.
- Other challenges around the concept of value have yet to be fully addressed, including improved measures of care quality, more comprehensive metrics for value, better tools for generation of data and its transformation into knowledge, and recognition of the ways in which value evolves and is realized in real-world clinical practice.

A wide spectrum of potential paths forward emerged in the interviews, including ideas for:

- A deliberate and comprehensive shift to patient-centered care, including more effective tools and policy incentives for patient engagement and patient-provider decision support.
- An effort to define and implement strong regulatory and reimbursement strategies for personalized medicine.
- Strategic-level support for biomarker research.
- Reforms to align comparative effectiveness research (CER) and health technology assessment (HTA) with patient-centeredness and the dynamic nature of medical progress.
- Stronger frameworks and incentives for partnerships and collaborations that will need to play an increasingly central role in progress against cancer.
- Support for high-quality care via effective care delivery models and more comprehensive quality measures.
- Strategic support for the development and implementation of a Rapid Learning Healthcare System in cancer.

Next Steps
It is the hope and intention of the Conference conveners and the Conference Advisory Committee* that the findings of this Discussion Paper, and the dialogue that unfolds at the Conference, will catalyze a strong new phase of community-wide commitment to solutions that sustain progress against cancer.

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A Changing Cancer Care Ecosystem

The field of oncology is experiencing extensive and ongoing change as the result of unprecedented scientific and technological advancements made since the completion of the Human Genome Project. As we unravel the immense biological complexity of the more than 200 diseases we collectively call cancer, we are continuously re-examining how these diseases should be classified, diagnosed, and treated.

Our ever-increasing understanding of the molecular basis of disease, combined with our relentless effort to apply these insights into clinical care, is forming the foundation of personalized cancer care. The early successes of molecularly targeted therapies for some forms of cancer provide a hopeful glimpse into a future in which prevention and treatment strategies will be individualized and based on the molecular makeup of the patient and/or the patient’s tumor.

Many believe these advances have brought us to a critical juncture in the fight against cancer, a point at which new scientific understanding of cancer is opening up exciting new possibilities in prevention, detection, and treatment. Yet these advances are occurring at a time when policymakers are holding the line on spending at the National Institutes of Health (NIH) and other government institutions, and are increasingly facing great pressure to contain rising healthcare costs. Sustaining continued progress means supporting funding for cancer research and biomedical science and aligning policy with science in support of high-quality, innovative care.

“We have made remarkable progress. With the advent of targeted therapies, we have the ability to directly impact the growth of cancer. So on the one hand, the efficacy is unprecedented because these therapies are more selective and targeted, and on the other hand the side effect profile is often more favorable.”

Kenneth C. Anderson, M.D., Director, Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics, Dana-Farber Cancer Institute; Kraft Family Professor of Medicine, Harvard Medical School

Those interviewed for this Discussion Paper consistently identified several major trends in oncology science and innovation that they believe hold particular promise for changing the future of cancer care. Achieving this vision will require new approaches and extensive innovation across all sectors in discovery and clinical research, and a research infrastructure and health policy framework that can support a rapidly changing cancer care ecosystem.

Vision of Cancer Care

While most interviewees agree that cancer research and care face tremendous scientific and policy challenges, they are generally optimistic about the ability to make significant progress against cancer in the coming decade, thanks to unprecedented recent scientific and technological advances.
Most interviewees agree that there is great potential to render cancer a chronic and manageable disease within 10 years, as we rapidly translate our knowledge of the molecular underpinnings of cancer into new strategies for prevention, risk assessment, diagnosis and treatment. The hallmarks of a more patient-centered, evidence-based, and inter-connected cancer ecosystem will include:

- Greater use of molecular biomarkers in the clinic to provide a more accurate disease diagnosis and guide clinical decision-making;
- Molecularly targeted therapies used in combination to form personalized treatment cocktails based on the molecular characteristics of each patient’s genetic makeup and cancer biology;
- Patients’ needs and values placed at the center of cancer care, informing drug development and clinical decision-making efforts throughout the care continuum, from prevention through end-of-life care; and
- Doctor-patient decision-making informed by greater connectivity across the healthcare ecosystem to more rapidly apply evidence-based learnings to patient care.

In this vision, patients will become more actively involved in both preventing and managing their disease. This greater involvement will be driven by the ability of patients to access their own Electronic Health Records (EHRs), as well as by online communities and social networking sites that serve as virtual support groups by helping patients find the right chemopreventions and preventive behaviors, approved treatments, or clinical trials of experimental treatments for their particular cancer subtype.

Achieving this vision in a potential era of cost containment requires developing and advancing policies that simultaneously address the challenge of sustaining progress towards high-value cancer care and the challenge of rising healthcare costs.

“Remember HIV?... thanks to a wave of new discoveries that came both from academic centers and the pharmaceutical industry, the HIV crisis was transformed into a stable condition which is managed very differently by society where good drugs are available. They are controlling the disease, and society has been saving an enormous amount of money as a result of these innovative drugs by providing better care out of hospitals.”

Hervé Hoppenot, President, Novartis Oncology
Promising Scientific Opportunities for “Turning the Tide” Against Cancer

Interviewees identified several major trends in science and research that represent significant opportunities for turning the tide against cancer, the greatest of which are being discovered as we dig very deeply into the molecular basis of disease while at the same time fully examining the biological context within which the tumor lives. Understanding both of these complementary aspects of cancer biology is providing a comprehensive picture of how cancer behaves—from the impact of individual gene mutations to external environmental stresses—and how we might exploit this information to effectively prevent, detect, and treat these diseases.

**Understanding the Biology to Outsmart Cancer**

Virtually all interviewees noted that efforts to characterize tumors in great detail at the molecular level are redefining how we classify, diagnose, and treat cancer. For example, we now know that breast cancer is not one disease but is made up of at least 10 different molecular subtypes, each of which responds to treatment in markedly different ways because they are not the same disease at the molecular level. This type of information is accelerating the discovery of biomarkers, or biological markers of disease, that are driving the development of targeted therapies and biomarker-based tests to predict cancer risk, diagnose disease, and guide therapy. Today, about 10 percent of all marketed drugs—most of which are for cancer—recommend or require genetic testing for optimal treatment. It is likely that this percentage will climb significantly in coming years, as more than 60 percent of all drugs in preclinical development rely on biomarker data.

> “One of my biggest dreams for cancer is that we keep on moving toward less toxic treatment. In some ways that’s the promise of targeted therapies and personalized medicine. And so I hope we can deliver on that.”

Gwen Darien, Director, The Pathways Project

Cures for cancer continue to elude researchers because these diseases are not only extremely complex, but also amazingly clever. Tumor heterogeneity—mixed populations of cancer cells, each carrying different mutations within a single tumor—is one of the most challenging scientific problems facing researchers and product innovators. A recent study in the *New England Journal of Medicine* found that almost two-thirds of mutations identified in a single kidney tumor biopsy were not uniformly detected throughout the tumor.3 To add to this complexity, different regions of a patient’s tumor not only have different mutations in the same genes, but also have gene expression signatures that reflect good and poor prognosis in different regions of the same tumor. This heterogeneity is a cause for concern with respect to the accuracy of diagnostic test results obtained from a single tumor biopsy. A major opportunity for treatment lies with identifying and targeting the original “driver” mutations, which appear to remain ubiquitous throughout the tumor; however, this approach becomes exceedingly difficult in advanced stages of disease.

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Many interviewees believe that, in light of the challenges of treating extremely heterogeneous tumors, patients will increasingly be treated at the time of cancer diagnosis with a combination of targeted therapies, rather than serial treatment with individual drugs. In support of this approach, continuous molecular re-assessment is expected to become an integral part of the treatment strategy to remain aligned with the rapidly evolving tumor biology. The shift to early treatment combinations can be expected to amplify the rapid evolution in the use of new therapies and in the understanding of their optimal role and value after initial market authorization.

**Approaching Cancer as a Complex Adaptive System**

The critical molecular pathways implicated in cancer development never work in isolation; instead, these pathways operate in highly structured and integrated biological networks to form a complex adaptive system. This complexity necessitates the power of sophisticated mathematics and computer modeling to search for meaningful interactions between networks and analyze the changing dynamics between healthy and disease states. These analyses require a systems-based approach, which relies on the convergence of biology, bioinformatics, and computational modeling to collect, aggregate, and analyze large-scale molecular data sets, or ‘big data’, and develop algorithms that turn the data into usable knowledge. The emerging algorithms, which range from analyzing gene expression patterns to visualizing tumors using virtual models, will greatly advance our understanding of cancer as a complex adaptive system, and this knowledge will be applied towards a more holistic approach to patient care.

> “I think it’s going to be possible to have drug signatures where you’ll be giving cocktails of drugs rather than single-gene, single-drug target therapies.”

**Lawrence J. Lesko, Ph.D., F.C.P., Professor and Director, Center for Pharmacometrics and Systems Pharmacology, University of Florida College of Pharmacy (Lake Nona)**

**Multiplexing Technologies**

Data obtained from whole genome sequencing and multiplexing technologies, which enable the measurement of tens to thousands of genes, proteins, or metabolites simultaneously from one sample, serve as the ‘inputs’ for most large-scale efforts to characterize cancer, discover novel biomarkers, and develop computational models of disease. The advancement of these technologies is extremely important for maximizing the amount of biological information that can be obtained from valuable tumor biospecimens.

**Prevention and Early Detection**

Most interviewees agree that there is not enough focus on two very important patient-centric issues that can significantly alleviate the cancer burden: prevention and early detection. Innovative approaches to cancer prevention, risk assessment, and early detection, including cancer vaccines, genetic signatures of disease risk, circulating tumor cells, and microRNAs, are among the most promising scientific opportunities to effectively reduce disease burden.

**Evidence Generation**

Some interviewees noted that current models of evidence generation were developed decades ago, and as a result do not reflect current molecular understanding of cancer. However, the increasing digitization of healthcare data is creating new opportunities for research outside of the traditional structures. Most interviewees agree that new models of evidence generation are needed that allow clinical trials to be conducted in a more integrated fashion and evidence to be obtained and
incorporated from routine clinical practice through interoperable EHRs. Additionally, the ability to track patients longitudinally in the real-world setting throughout their lifetime via EHRs—with the appropriate patient privacy safeguards and consent agreements—provides an opportunity to identify which drugs, diagnostics, and interventions work best for specific patient sub-populations following regulatory approval of a new product, and then to apply this knowledge in a dynamic, continuously updated way in the clinic to improve patient care.

“There is no question that when we talk about turning the tide against cancer, the most exciting opportunities, the new opportunities in fact, are understanding the biology and applying that biology to new treatments. We are certainly at a turning point.”

J. Leonard Lichtenfeld, M.D., MACP, Deputy Chief Medical Officer, American Cancer Society

Growing Trend of Collaborations and Team Science
There is a noticeable increase in collaborations and partnerships across the biomedical community. This trend is driven by the funding of large-scale scientific endeavors or ‘team science’ initiatives, such as The Cancer Genome Atlas; an increasing need for a multidisciplinary approach to research and development as datasets become exponentially larger and significantly more complex; rising drug development costs and falling product development productivity; and dwindling research budgets. Most interviewees agree that pre-competitive collaborations, in which companies and organizations share research data that have traditionally been considered proprietary commercial assets (e.g., genomic datasets or clinical trial comparator arm data), provide a great opportunity to drive future innovation and improve productivity while reducing the cost of research and development. Indeed, the extreme complexity of cancer is believed to demand multidisciplinary, ‘team science’ approaches that can only be achieved within a highly collaborative biomedical ecosystem.

Emerging Innovative Models and Systems
Many emerging innovative models and systems show great promise for turning the tide against cancer. Although not exhaustive, the models described below are among those most commonly mentioned by interviewees.

I-SPY2: Adaptive Clinical Trials
With its focus on real-time evidence generation and implementation, the creative I-SPY2 adaptive clinical trial was identified in interviews as a noteworthy addition to conventional randomized, controlled clinical trials. This trial design serves as a model not only for future oncology trials, but for a Rapid Learning Healthcare System overall, in several ways:

- Utilizes outcome data from each patient as she progresses through the study to inform treatment assignments for the next patient;
- Incorporates pre-competitive collaboration for biomarker identification;
- Streamlines the trial model, resulting in reduced length, fewer patients, and fewer requisite resources;
- Tests investigational agents from multiple companies in combination with standard of care treatments;
- Tests investigational agents in newly diagnosed patients—a potentially curable patient population;
• Utilizes a unique public-private partnership and collaboration model among the Foundation for the National Institutes of Health (FNIH), the Food and Drug Administration (FDA), the National Cancer Institute (NCI), more than 20 leading academic cancer centers, the Safeway Foundation, QuantumLeap Healthcare Collaborative, and patient advocates, and receives funding from a number of pharmaceutical companies; and

• Makes study data publicly available.

“In trials like I-SPY, we not only accelerate our ability to test ideas and concepts but we also fundamentally change the nature of our process.”

Laura Esserman, M.D., M.B.A., Professor of Surgery and Radiology, University of California, San Francisco; Director, Carol Franc Buck Breast Care Center; Co-Leader, Breast Oncology Program, UCSF Helen Diller Family Comprehensive Cancer Center

**Moffitt Total Cancer Care™**

By collecting clinical data throughout a patient's lifetime, molecularly profiling all tumors, and making data accessible for patients, clinicians, and researchers, the Moffitt Cancer Center’s Total Cancer Care™ project is one example of a comprehensive strategy for improving patient care through a rapid learning model. This approach, which has enrolled more than 80,000 patients in its observational study:

• Leverages partnerships with patients, community clinicians, industry, and academia to focus on new technologies to improve screening methods, define new standards of care, and develop new therapeutic technologies;

• Collects and stores a large number of patient biospecimens, genomic profiles, and clinical information for future in-depth analysis by researchers to improve the standard of care and drive discovery;

• Provides standardized data quality and easy access to information through a hub-and-spoke model;

• Follows patients throughout their lifetime, and provides individualized, evidence-based decisions for screening, diagnosis, and treatment of cancer based on integration and analysis of data from scientific discovery and health outcomes; and

• Incorporates preventive measures, including the study of genetic predispositions, impact of lifestyles, and integrative medicine.

**Multiple Myeloma Research Foundation**

By leading multiple dynamic, innovative research activities, the Multiple Myeloma Research Foundation has created a unique patient-centric and patient-driven model that:

• Drives collaboration among patients, academic and community medical centers, industry, and payers;

• Encompasses a tissue bank, clinical network, and a genomics initiative;

• Incorporates pre-competitive collaboration: consortium members have priority access to data for six months before it is shared on a public portal, which is being designed to be similar to an Amazon system; and

• Is building an online community for myeloma patients and directing them to trials and new treatments that might be appropriate for them.
This model is being widely credited for significantly increasing the number of therapeutic options available to multiple myeloma patients, as well as increasing the expected survival time for patients.

“I believe that the diseases that will do the best are those that can form a community.”

Kathy Giusti, M.B.A., Founder and CEO, Multiple Myeloma Research Foundation and Multiple Myeloma Research Consortium

Army of Women/ Dr. Susan Love Research Foundation
The Army of Women initiative was cited as an important model for mobilizing consumers and researchers to focus on prevention efforts and is one example of the broader emergence of patient engagement models. This initiative:

- Empowers the consumer to control the research agenda and the data;
- Deploys a consumer-owned, consumer-driven participatory model; and
- Recruits healthy women to partner with researchers on prevention studies.

NCI’s Biospecimen Research Network /cancer HUman Biobank (caHUB)
The National Cancer Institute's Biospecimen Research Network and caHUB (which develops evidence-based best practices for the collection, process, storage, and analysis of biospecimens) is a key entity for the development of biospecimen standards. This program:

- Supports scientific research to bolster the evidence base for biospecimen collection, handling, and processing practices;
- Leads the development of policies and processes for collection and management of biospecimen resources; and
- Partners nationally and internationally to harmonize biospecimen and biobanking standards.
Valuing Innovation and Progress

The scientific trends and opportunities described above are occurring in conjunction with a growing debate about federal spending and rising healthcare costs. To achieve a future of cancer care in which innovation drives value, it is essential for policy to align with both innovation and value.

A few interviewees maintained that, in aggregate, current policy supports innovation and value in cancer care; however, a larger number of interviewees believe unsustainable rising costs threaten the system’s ability to accelerate progress in cancer research and care. Regardless of one’s viewpoint, it appears clear that cost-containment in cancer care, and in healthcare in general, is likely to be a pressing issue in the years ahead. As a result, issues related to how we value progress in cancer care will be central to defining pathways for sustaining innovation in this environment.

Defining Value

There are many challenges within the research and care continuum that must be overcome in order to turn the tide against cancer, but many of these challenges cannot be fully resolved and prioritized until we can first define value. Interviewees underscored the extent to which value is ‘in the eye of the beholder’, and to which perceptions of value (both clinical and economic) vary among stakeholders, including patients, industry, insurers, politicians, physicians, advocacy, and interest groups. Many interviewees also noted that perceptions of value often vary significantly within stakeholder groups (e.g., individual patients may view the value of different treatment options very differently depending on their preferences and circumstances). As a result, while there was wide support for the goal of high-value cancer care, there also was broad recognition that reaching consensus on a single definition of value will prove challenging. However, many interviewees felt strongly that, while all views of value must be considered, the patient’s concept of value must be given a

“We’re talking about whether three months of added survival with certain drugs makes a difference. But that’s a median, which means some people are living for six months or maybe longer as a result of benefiting from those drugs.”

J. Leonard Lichtenfeld, M.D., MACP, Deputy Chief Medical Officer, American Cancer Society
primary role at the center of the cancer care ecosystem. When all is said and done, policy-level or societal-level decision-making must be centered on the patient’s needs and values.

“How do you have a humanistic economic conversation? I don’t know how to do it, but I think that’s something really worth spending some time talking about.”

Gwen Darien, Director, The Pathways Project

Virtually all interviewees are in agreement that defining value is not just a matter of defining the right metrics, but developing approaches to assessing value that can accommodate differences in perspectives of value and changes in the value of interventions over time—that is, systems of continuous learning that can evaluate patient care in an ongoing, prospective way to gain deeper insight into what works best for patients over time. Some interviewees termed this “dynamic” or “prospective” assessment versus “static” or “retrospective” assessment of care.

“Value is personal: it really depends on...your very personal situation.”

Felix W. Frueh, Ph.D., President, Medco Research Institute, LLC, Express Scripts, Inc.

Measuring Value and Aligning with the State of Science

The interviews conducted for this Discussion Paper focused on issues of assessing and rewarding value of real-world cancer care as a central element of sustaining innovation in a cost-contained environment. Within this framework, most interviewees recognized that new tests and treatments for cancer enter use with varying levels of evidence and prior regulatory evaluation. Some interventions, such as drugs and various medical technologies, must be approved by FDA before entering the market, while others such as new surgical techniques and novel diagnostic tests offered by clinical laboratories may not be subject to FDA review at all.

“You cannot evaluate a new drug treatment on day one post approval. Newly approved drugs often appear to provide minor survival benefits of a few months. However, the clinical trial that led to a drug’s approval is often narrow—monotherapy to advanced stage patients. It is critical therefore to monitor the real life use of that drug to recognize the actual efficacy now that it is likely to be given in combination with other drugs and to patients who are not at an advanced stage.”

Mara Aspinall, President and CEO, Ventana Medical Systems, Inc.

There is general agreement among interviewees that it is important to understand the comparative clinical and economic value of the various dimensions of cancer care. At the same time, many pointed out that the current scientific, research, and care delivery ecosystem makes the effort to gain this understanding extraordinarily complex, and point to challenges related to value perspectives and measurements.
The interviews revealed something of a paradox: there is an exponential increase in the amount of information available to guide patient care decisions, yet there is also broad consensus that current approaches to assessing the value of innovative technologies and care delivery, (e.g., comparative effectiveness research (CER), cost-effectiveness analysis (CEA), and health technology assessments (HTA)), are far from optimal in this new era of rapidly advancing personalized oncology. Some interviewees view this as a tension between a “dynamic” cancer ecosystem marked by rapid advances in technology, scientific research, and clinical evidence on the one hand, and “static” tools for value assessment on the other. Many call for significant reforms, or entirely new models, for generating and assessing evidence of value in oncology.

“If health technology assessment were to be done right by somebody it would be a good idea, but there are a lot of bad health technology assessments floating around.”

Bruce Quinn, M.D., Ph.D., Senior Health Policy Specialist, Foley Hoag LLP

“HTA and cost-effectiveness are very helpful for helping doctors and patients make the right decisions in their particular circumstances and we need more of that patient-level support.”

Mark McClellan, M.D., Ph.D., Director, Engelberg Center for Healthcare Reform; Senior Fellow, Economic Studies; Leonard D. Schaeffer Director’s Chair in Health Policy Studies, Brookings Institution

“Health technology assessment and cost-effective analysis could play a role if in fact they were more scientifically based.”

Anna Barker, Ph.D., Director, Transformative Healthcare Networks; Co-Director, Complex Adaptive Systems Initiative; Professor, School of Life Sciences, Arizona State University

The rapid acceleration of science and technology that is taking place within oncology will require an acceleration of the evidence generation capabilities around value. Equally important, new evidence assessment capabilities are needed in order to provide accurate, patient-centered, and current assessments of clinical and economic value. Current CER, CEA, and HTA models will become increasingly challenged by personalized medicine because point-in-time assessments of treatments will become obsolete as patients are continually monitored and reassessed to identify optimal treatment regimens designed for their precise molecular subtype to include targeted therapies, personalized treatment cocktails, and biomarker-driven clinical decision-making.

“We show routinely that as we get a better understanding of the disease and better understanding of the treatments available, we use them better over time. So I think we need to get away from the idea that cost effectiveness is a calculation that’s static and that what we know at the time of approval is meaningful over the entire life of a product. We can acknowledge that a therapy may look like it’s on the margin at time of approval but that over time the cost effectiveness calculation is likely to change. For those treatments that don’t work and don’t improve—they won’t be around very long.”

Thomas F. Goss, Pharm.D., Senior Vice President, Boston Healthcare Associates
The biggest limitations identified in current value assessment approaches are that they are unable to recognize and support the incremental nature of the evolution of value; are not dynamic, continuous processes and thus cannot keep pace with advancements in science and medicine; and give inadequate consideration to patient quality of life, patient preference, and indirect measures of value like productivity. These challenges and limitations led some interviewees to suggest that the United States consider a new system that provides alternative approaches to measuring and applying value-based information. As these measurements will likely add more cost into the system, they said, it is important to invest in the right measurements and assessment models. This perspective is consistent with recent literature highlighting the challenges with health technology assessments in oncology and a recommendation for an increased focus on patient-provider decision-making versus centralized decision-making as the locus of evidence-based value judgments.4

“CER isn’t just about head to head comparison of first-line metastatic therapy, it’s actually trying to figure out a world where we’re moving quickly towards sequential therapies in the metastatic setting, how you decide which thing in the toolbox when.”

Amy Abernethy, M.D., Associate Professor of Medicine, Division of Medical Oncology, Department of Medicine, Duke University School of Medicine; Director, Duke Cancer Care Research Program

The call for a new system is not inconsistent with calls for more evidence to inform oncology decision-making, yet it does suggest that simply putting more money and emphasis on existing value assessment models will not lead to success. There was broad recognition that new approaches are needed in which CER, CEA, and HTA models better align with progress in cancer care by:

- **Recognizing divergent perspectives on value and centering on patient value as defined by patient needs and preferences.** Numerous interviewees acknowledged the challenges of making value more patient-centered: there are a variety of dimensions that constitute value, including overall survival, quality of life, and impact on the caregiver; patient preferences can change depending on where a patient is in the disease process; and patients may place greater emphasis on certain outcomes than other stakeholders (e.g., quality of life improvements).

- **Personalizing value measurements.** Interviewees highlighted the limitations of current models of CER and CEA that measure population averages and thus do not take into account the specific needs and preferences of individual patients.

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4 Neumann, PJ, Bliss, SK, Chambers, JD. *Health Aff* 2012 Apr; 31(4):700-708.
consideration biological differences among patients and their tumors, which is the foundation of personalized medicine. This limitation suggests that more sophisticated approaches are needed that can handle the extreme heterogeneity of cancer and consider value at the individual level instead of at the population level.

- **Incorporating broader measures of value.** Many interviewees suggest that broader measures of value such as patient preference and quality of life should be incorporated into value assessments. Some interviewees note that some metrics, such as quality-adjusted life years, can incorporate these broader measures. Others, however, note that such measures often do not reflect variations in patient values and may be better-suited for societal versus individual value judgments. This may indicate a disconnect between methods for assessing broad societal value at the policy level, and tools designed to support value-based decisions at the level of individual patient and physician treatment decisions.

- **Measuring evolving value of innovative treatments.** It is generally true in medicine that patient outcomes improve over time as we gain experience with new treatments and interventions. For example, patients who receive a transplant live significantly longer today than they did when these procedures were first introduced because we have developed a greater understanding about who should receive them, and the technologies of that approach have improved. Another example is the benefit of Velcade® (bortezomib) in increasing the overall survival of patients with newly diagnosed multiple myeloma by 13 months—knowledge that only became apparent five years after the drug’s FDA approval. In addition, some interviewees pointed out that progress frequently occurs through an incremental process in which individual advances ultimately yield significant gains for patients. One example of this is colorectal cancer, where patients now benefit from earlier intervention with multiple treatment options. For this reason, interviewees opined that value assessment must be a dynamic, continuous, prospective process because the true value of a treatment to patients and society—its clinical *effectiveness*—cannot be known at the time of FDA approval.

### Rewarding Innovation

Although most interviewees do not believe that it is feasible to completely align the competing perspectives on value, some believe that identifying overlapping interests among the stakeholders (for example, reduced toxicity might be a metric that all could agree constitutes value) could provide a pathway to rewarding high value innovation. Additionally, a heavy focus should be placed on incentivizing innovative technologies that focus on prevention, risk assessment, early detection of disease, co-development of targeted treatments and companion diagnostics, as well as treatments that address quality of life issues.

> “Let’s not look at the MEAN survival for a new drug...let’s look at who got 12 months additional survival, and who got almost none. Then, let’s ask if we can define another companion diagnostic to treat the right people.”

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*Ira Klein, M.D., M.B.A., FACP, Chief of Staff, Office of the Chief Medical Officer, Aetna*
innovation by removing the requisite ‘stepping stones’ that enable knowledge to accumulate on the road to progress. Many interviewees noted the challenges inherent in creating coverage, coding, reimbursement, and payment policies that appropriately support and value innovation, pointing to mechanisms that allow for early introduction and subsequent evidence generation for new tests and treatments.

“Research is an evolutionary process—it takes time to translate. There has been enormous impact in recent years, but you don’t get answers overnight. Whether you’re looking through the lens of pain and suffering or whether you’re looking through the lens of job creation, the biotech industry or U.S. competitiveness, we have to sustain innovation.”

Ellen Sigal, Ph.D., Founder and Chairperson, Friends of Cancer Research

Multiple interviewees—who hold widely divergent viewpoints on the subject—noted that several attempts to resolve the tension between static value assessment and dynamic progress have involved “access with evidence development” or “risk sharing” approaches such as those tested by the Centers for Medicare and Medicaid Services in the United States (so-called “coverage with evidence development”) and by the U.K.’s National Institute for Health and Clinical Excellence (NICE). Under these models, the payer grants some type of provisional or early coverage, but conditions it on additional research demonstrating added clinical value. A few interviewees believe this approach or a version thereof should be considered in the United States, because it incentivizes personalized medicine strategies—identifying patient populations in advance who will respond to treatment—and changes the industry model from producing products to producing services. Others, however, said that significant challenges have been encountered in some of the early attempts at applying this type of policy and cautioned that it may not be possible to implement more broadly.

“The NICE process in the United Kingdom is really imperfect in terms of fostering innovation and, in particular, encouraging efforts to identify the subpopulation of patients that will actually obtain significant benefit from an intervention. If NICE determines that, ‘well, this does not provide enough value for the overall population,’ then the entire population, including the subset that might truly benefit, is denied the therapy. When a trial shows a benefit in an unselected population that should really encourage efforts to learn who from the overall group of patients is likely to respond and then make the treatment available to that group once determined.”

Al Benson, III, M.D., FACP, Associate Director for Clinical Investigations, Robert H. Lurie Comprehensive Cancer Center of Northwestern University
Potential Paths Forward

Interviewees underscored some of the most important innovative scientific discoveries that are creating new possibilities for turning the tide against cancer, in addition to heretofore unimaginable challenges, such as cancer’s extreme heterogeneity and adaptability, particularly in later stages of disease. These discoveries have brought us to a true turning point—one in which opportunities can be realized and barriers overcome—during a time of unprecedented pressure on federal spending for research, as well as concerns that cost containment measures are becoming more likely.

This section organizes the major ideas presented by interviewees as potential solutions, which collectively could begin to define a path forward to sustain innovation and turn the tide against cancer. In addition to identifying many important opportunities, barriers, and potential paths forward, participants consistently stress the need for a sustained, community-wide commitment to solutions. The approaches described below are intended to spur discussion of a framework that could form the basis of that commitment.

Support the Shift to Patient-Centered Care in Oncology

A consistent theme among interviews was the need to define value from a patient-centric perspective, which requires bringing the patient into the value equation in more meaningful ways. Interviewees put forth the following suggestions:

- Engage patients in defining value and value-based research.
- Define and utilize value measures that matter to patients (e.g., quality of life and patient preference).
- Engage patients and caregivers in treatment decision-making.
- Support physicians, patients, and caregivers in shared decision-making (evidence-based value decisions at the individual level) through the use of clinical decision support tools.

“There has to be a way that we can respect an individual’s privacy and still have meaningful information sharing that allows us to learn, to innovate, to progress.”

Thomas F. Goss, Pharm.D., Senior Vice President, Boston Healthcare Associates
Develop Regulatory and Reimbursement Policies to Advance Personalized Medicine
A consistent theme among interviews was that innovation can drive value, and personalized medicine is a key element of innovation for oncology. Specific suggestions to sustain innovation and advance personalized medicine include:

- Develop clear yet flexible regulatory pathways that can evolve to keep pace with advancements in science and medicine. Many interviewees believe new pathways and standards must be defined to support the rapid, efficient development of new targeted oncology therapies and diagnostic tests.
- Improve coverage and reimbursement policies to support adoption of medically appropriate personalized medicine products. Ensure evidence standards are appropriate for novel interventions such as new molecular diagnostics.
- Structure new payment models, including accountable care organizations and cancer care pathways, in ways that enable physicians to tailor care based on genetic or other diagnostic information, clinical circumstances, or patient preferences. This will allow for appropriate adoption of advances in care that may have higher initial costs but yield higher value over time.

“Developing regulatory and reimbursement policies that are flexible enough to respond to innovation, but also clear enough to ensure quality and safety, is a key challenge.”

Mark McClellan, M.D., Ph.D., Director, Engelberg Center for Healthcare Reform; Senior Fellow, Economic Studies; Leonard D. Schaeffer Director’s Chair in Health Policy Studies, Brookings Institution

Advance Research on Molecular-Based Biomarkers
Most interviewees agree that a lack of standards-based, high-quality, clinically annotated biospecimens and a lack of standards-based technologies and methodologies used to interrogate these biospecimens are significant barriers to biomarker discovery and development. These issues help explain why the majority of biomarker candidates discovered cannot be clinically validated and why many biomarker studies cannot be replicated.

Clear standards, widely accepted methods, and more flexible policies governing the use of biospecimens are needed to encourage the development of more biomarker-based tests needed to move personalized cancer care forward. Improper methods of biospecimen collection, storage and/or handling can change the biology of the specimen, meaning that the biospecimen does not reflect the molecular characterization of the patient’s tumor, and data obtained from such biospecimens can be misleading or unusable. Researchers are also challenged by the lack of clinical
annotation and by legal, ethical, and policy restrictions that govern biospecimen use. Furthermore, researchers use various technologies to discover biomarkers and each of these technologies lack standard methods and reagents, which results in pervasive problems with reproducibility and hinders the development of biomarker-based tests.

A common theme among interviewees was the need for quality and reference standards for biomarker discovery and validation research. Without these standards, valuable tissue samples will be wasted and biomarker discovery and clinical validation will be compromised. Specific suggestions include:

- Incentivize the development and adoption of standards for biospecimen collection (including clinical annotation), handling, storage, and analysis.
- Support a national (or international) biorepository that is managed either by government or by a neutral collaboration among organizations to serve as ‘honest broker’.
- Incentivize the development and use of standards for ‘‐omics’ technologies used in biomarker discovery.

Support the Development of Molecular Diagnostics
Given the current regulatory and reimbursement environment for diagnostics, many interviewees believe that the business model for the development of molecular diagnostics is challenged. A disconnect exists between the regulatory pathways for drugs and diagnostics. The lack of regulatory clarity for diagnostics creates great uncertainty and risk, which in turn undermines and discourages innovation.

The time, resources, and skill sets required to develop innovative molecular diagnostics are not compatible with a payment policy that largely considers time and materials in the reimbursement calculation. As a result, randomized, controlled clinical trials are prohibitively expensive for molecular diagnostic innovators and such trials may not be justifiable based on the expected return on investment. Overall, interviewees stressed that the desired state of personalized cancer medicine will not be possible without a flourishing pipeline of molecular diagnostic tests. Specific suggestions to support their development include:

- Develop regulatory and reimbursements policies that incentivize the development of innovative diagnostic technologies needed to diagnose disease and predict cancer risk.
- Foster a regulatory and reimbursement environment that values and rewards the co-development of

The Need for a Biomarker Discovery and Development Pipeline

“Biomarker research is flawed...we need standards for biospecimen collection and handling and for biomarker discovery.”

George Poste, D.V.M., Ph.D.
Chief Scientist, Complex Adaptive Systems Initiative; Regents’ Professor and Del E. Webb Chair in Health Innovation, Arizona State University

Biomarkers are central to accelerating the implementation of personalized medicine, but the absence of a biomarker discovery and development pipeline with stringent quality standards in place impedes their identification and clinical development. The development of such a pipeline as part of a collaborative, multidisciplinary effort—from biospecimen collection through clinical validation—would serve to reduce unneeded spending and catalyze innovation.

“We need a standards-based, end-to-end biomarker discovery and development pipeline: we need high-quality data, algorithms to analyze the data, and a predictable system to actually take it to patients. We will get this done.”

Anna Barker, Ph.D., Director,
Transformative Healthcare Networks,
Co-Director, Complex Adaptive Systems Initiative; Professor, School of Life Sciences, Arizona State University
innovative targeted treatments and companion diagnostics and incentivizes their co-development through tax incentives or other funding mechanisms.

- Support provisional approval and coverage for molecular diagnostics.

**Align CER and HTA with the Patient and the Science**

There is broad support among interviewees for utilizing CER and HTA in helping to assess the value of innovative technologies; however, there is also broad agreement that these tools must adapt to the emerging science. Specifically, CER and HTA must align with patient needs and values, as well as the emerging science and changing clinical practice of oncology, and they both must shift from a retrospective, static paradigm to a prospective, dynamic paradigm. Absent this shift, these tools will lag further and further behind the rapid pace of change within oncology science and clinical practice. Several interviewees suggested that this shift may require the creation of a Rapid Learning Healthcare System in oncology described below. In addition, suggestions include:

- Develop new tools and approaches to CER and HTA that reflect a commitment to patient engagement and adopt policies that match this commitment.
- Engage physicians, clinical experts, and scientists with relevant subject matter and technical expertise to guide CER and HTA. The oncology community has strong mechanisms for defining and disseminating knowledge via societies and clinical experts, but these mechanisms (e.g., professional society guidelines) are frequently disconnected from policy-level decision-making. Steps should be identified to more directly link these capabilities in the clinical community to payers and policy-level decisions. For example, the Patient-Centered Outcomes Research Institute (PCORI) should establish advisory panels of clinical experts and scientists from the fields of oncology and personalized medicine to inform their agendas.
- Recognize and accommodate biological differences among individual patients and patient sub-groups in CER and HTA. Some interviewees noted that, done well, CER and HTA can help optimize decision-making by patients and physicians because these tools may ultimately provide more information about differences in patient sub-groups. Many interviewees also cautioned, however, that CER and HTA frequently are performed and applied in ways that obscure the differences and render results based on broad population averages. Consensus should be developed on approaches to CER and HTA that are more patient-centered by better reflecting individual and sub-group differences.
- Establish the methods and infrastructure (e.g., linked observational data sets) to guide patient-centered research on real-world effectiveness.
- Develop tools that effectively disseminate meaningful information to patients and providers.
- Incorporate into HTA a wider range of value measures, particularly those that matter to patients but often are overlooked, such as quality of life or patient experience.
- Develop flexible policies for CER and HTA that allow for continued learning about new tests, treatments, and interventions.

**Support Partnerships and Collaborations**

Harnessing the immense biological complexity of cancer cannot be achieved through the efforts of one scientist, one institution, or one scientific discipline. A silo mentality in which key players in cancer research and care think only in terms of their own sector or institution is incompatible with scientific progress. A highly collaborative multidisciplinary ecosystem is needed in which all stakeholders—industry, academia, government, clinicians, patients, and advocates—work towards a common vision to translate scientific discoveries into better patient care. However, new models
of collaboration require a cultural shift as well as incentives for data sharing. Specific suggestions include:

- Support and incentivize, through tax incentives, funding, and/or policy changes, organizations that are actively participating in pre-competitive (and wherever feasible, standards-based) data sharing.
- Incentivize and develop regulatory policies that allow multiple companies to test investigational targeted agents as therapeutic combinations.

**Support Basic and Translational Research**

A common theme among interviewees is the importance of maintaining steady, consistent, and strong support of the basic and clinical research enterprise, both in the public and private sectors, in continued efforts to build a robust infrastructure, maintain U.S. leadership in biomedical research, and provide a sustainable career path for young scientists. Most interviewees agree that the instability of research funding is a significant deterrent to attracting the young generation to a scientific career. They raise the concern that this issue may well result in a key labor shortage at the very moment when scientific opportunities are at their greatest, as well as that a diminishing pool of scientists puts the United States at a competitive disadvantage in the global economy. Recognizing that the current fiscal environment puts federal research funding at risk, several interviewees advocated for a strategic re-examination of how this funding is invested. Some ideas put forth by interviewees were:

- Examine the balance of basic, translational, and clinical research to optimize discovery for patient benefit, with some interviewees believing that greater focus is needed on translational research.
- Establish the infrastructure and incentives to foster collaborative research efforts.
- Incentivize grantee adherence to best practices for biospecimen collection and storage and data sharing, with some interviewees advocating for making such adherence a requisite for funding.
- Identify alternative funding mechanisms to solve the most pressing technical and clinical challenges, such as contract work using the Department of Defense model.
- Incentivize cutting-edge, disruptive research, with some interviewees advocating for larger, dedicated resources for younger investigators who may be apt to take greater risks.

“There is not enough money in the healthcare system or in the pharmaceutical industry to endlessly conduct clinical trials on several thousand patients for every drug and wait at least five to 10 years for results.”

*Laura van't Veer, Ph.D.*, Leader, Breast Oncology Program; Director, Applied Genomics, UCSF Helen Diller Family Comprehensive Cancer Center

**Support Prevention, Risk Assessment, and Early Detection**

Cancer prevention is a considerable challenge because it requires individuals to make behavioral changes (e.g., stop smoking, exercise more, and eat a better diet). Innovative personalized risk assessment and preventive approaches have historically received significantly less attention and funding than treatment approaches; hence, greater incentives for prevention and risk assessment should be put in place.
**Expand Government Support for Implementation of Personalized Medicine**

Personalized medicine differs from traditional medicine not only in the science, but in the policies, culture, expertise, infrastructure, and vision needed for successful implementation. For this reason, interviewees suggest the development of a government-wide approach in support of implementation. Specific suggestions include:

- Review federal healthcare policies to develop a coordinated government-wide approach to innovation that aligns research, regulatory, and reimbursement policies and eliminates overlapping and conflicting agency responsibilities.
- Create an HHS Center for Personalized Medicine that could serve as a catalyst for a whole new system in support of these efforts, including facilitating collaboration between government agencies and developing pilot processes to test new policies.

> “I think people are rightly scared about making policies that are too stringent. So from a policymaker standpoint we have to be able to deal with the fact that science is a moving target. And our medical knowledge is a moving target. We need to make policies that understand that X or Y only makes sense under certain conditions. And when those conditions change, then the policy may need to change.”

**Kathleen Foley, Ph.D., Director, Strategic Consulting, Economic Valuation and Market Access, Thomson Reuters Healthcare**

**Improve Workforce Education**

Changes to the way that the healthcare workforce is educated and trained are needed to support the integration of personalized medicine strategies and biomarker-based treatment decision-making into cancer care. Specifically, the healthcare workforce education system must evolve to include genetics and genomics training so that all oncologists can deliver cutting-edge cancer treatments.

**Foster High-Quality Cancer Care Delivery**

Many interviewees put forth suggestions for policies that foster high-quality cancer care delivery in support of improved patient outcomes. Specific suggestions include:

- Develop public policies that guarantee patient access to ancillary healthcare services necessary in an age of personalized cancer care.
- Identify and reward new models of care delivery that foster high-quality, high-value care.
- Develop policies in support of practice-based evidence development, and put in place incentives to implement systems that link healthcare delivery metrics (e.g., patient outcomes, safety, service) to payment models.
- Develop systems to monitor patient healthcare utilization, limit duplicative healthcare services, and reduce hospital and emergency room visits.
“Let’s turn the system on its head. Let’s do practice-based evidence development.”

Denis Cortese, M.D., Foundation Professor and Director of the Healthcare Delivery and Policy Program, Arizona State University; President, Healthcare Transformation Institute; Emeritus President and CEO, Mayo Clinic

Support a Rapid Learning Healthcare System

One of the most common themes among interviewees was that a better system is needed to aggregate, analyze, and apply evidence-based knowledge to patient care on a national or international level. A Rapid Learning Healthcare System “will link research and care into a seamless process by using advances in information technology (IT) to continually and automatically collect and compile from clinical practice, disease registries, clinical trials, and other sources of information, the evidence needed to deliver the best, most up-to-date care that is personalized for each patient.”

“We need interoperable Electronic Health Records. We have to have a common language, or the infrastructure that allows people to collect data in different ways and still communicate. And we have to be able to query it—it has to be designed in a way that we can ask questions, and if we do that we’re going to learn a lot.”

John Mendelsohn, M.D., Past President; Director, Khalifa Institute for Personalized Cancer Therapy; The University of Texas MD Anderson Cancer Center

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“You have to create a system where you have the patients’ permission to follow them throughout their lifetime so that you can define the population that a particular technology or treatment is beneficial. This is where society will weigh in.”

William S. Dalton, Ph.D., M.D., President, CEO, and Center Director, H. Lee Moffitt Cancer Center and Research Institute

The foundation of a Rapid Learning Healthcare System is data liquidity, defined as the rapid, seamless, secure exchange of evidence-based information among authorized individuals. Building the infrastructure for data liquidity across the biomedical ecosystem will make it possible to aggregate and analyze data from multiple sources and turn these data into knowledge that advances clinical care. The National Cancer Institute’s caBIG® initiative developed a first-generation national framework for data exchange. The current challenge is to leverage these advances to develop a consistent framework for data exchange throughout the healthcare system. The solution to this challenging problem will require the involvement of a coalition of stakeholders.

“Today’s biomedical evidence—generation enterprise is still a pre-Industrial Revolution, inefficient, ‘cottage-level’ activity. It is technically feasible to achieve the 21st century evidence generation common in every other sector. But to get there, we will need to mobilize at an industrial scale the raw materials of information gathering and exchange.”

Ken Buetow, Ph.D., Director of Computational Sciences and Informatics, Complex Adaptive Systems Initiative, Arizona State University

“We can no longer accept that it takes 10 to 15 years to make a change in practice; we need a Rapid Learning Healthcare System. We need to be able to collect the data and analyze it in real time and come back to inform the care of that patient sitting in front of us at that moment. We can’t do slow learning anymore.”

Sharon B. Murphy, M.D., Scholar-in-Residence, Institute of Medicine

By facilitating system-wide learning and leveraging the clinical experience of all cancer patients, many interviewees believe, a Rapid Learning Healthcare System will help reduce the cost and accelerate the process of drug development. Policy incentives could stimulate the public-private partnerships and coalitions that are needed to create the national blueprint and the foundations for implementation. Additionally, policy incentives could facilitate the ‘data liquidity’ in preparation for a Rapid Learning Healthcare System. Specific suggestions are to:

- Incentivize vendors of Electronic Health Record systems to develop and maintain the technologies that enable interoperability between different EHRs (without jeopardizing patient privacy).
- Incentivize every single provider and hospital across the nation to install EHRs, with the requisite for interoperability among those systems.
- Accelerate the incorporation of research parameters into Meaningful Use guidelines for Electronic Health Records.
- Incentivize the collection of outcomes data in standards-based form as a condition of reimbursement for providers.
- Develop a policy framework that supports the accessibility of clinical data for researchers and incentivizes data sharing.
- Make standards-based data collection and data exchange capabilities a condition of funding research.
- Enforce current provisions that mandate the sharing of data from Federally-funded research in a timely way.

“Millions of current and future cancer patients are relying on us all to change the face of cancer on their behalf. We should ask no less of ourselves at this critical juncture. We are now maximizing the impact of fundamental discoveries made over the past 40 years by seizing on the unprecedented opportunities to translate these discoveries into improved patient care. Working together, we will turn the tide on cancer.”

Margaret Foti, Ph.D., M.D. (h.c.), CEO, American Association for Cancer Research
Discussion Paper Interviewees

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Kenneth C. Anderson, M.D.
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Kraft Family Professor of Medicine
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Mara Aspinall
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Anna Barker, Ph.D.*
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**Mark Trusheim**  
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