

ACCELERATING PROGRESS AGAINST CANCER

ASCO's Blueprint for
Transforming Clinical
and Translational
Cancer Research

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American Society of Clinical Oncology



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Imagining the Future: A Patient's Experience

You visit your doctor for your annual physical. She asks you to undergo a routine blood test. You wait a few minutes for the test to process and are called back to hear the results. She tells you that the test detected cancerous cells in your bloodstream, which are an indication of an early-stage cancer that is developing somewhere in your body.

The doctor reassures you that since the cancer was detected at a very early stage, there is a good chance that it can be managed or cured. She refers you to an oncologist and recommends additional tests to determine the molecular “fingerprint” of the cancerous cells. This takes just a few hours, and will provide vital information about the gene and protein abnormalities that may be driving the cancer.

When you meet your oncologist, he tells you that you have an early-stage cancer arising in the kidneys. But the tumor's location isn't really what he considers most important. In this molecular era of cancer treatment, what matters most is your genomic profile and the unique combination of molecular features of your cancer. In your case, the cancer is caused by a specific set of abnormal genes, which are disabling three key “hubs” in the vast network of molecular pathways that regulate the growth of your cancerous cells. As a result, the cells have become stuck in an “always grow” mode.

Your oncologist explains the standard treatment options available to target these hubs. He also notes that your electronic health record (EHR) indicates that based on your medical history and genomic predisposition – and on information from other patients like you who have undergone these treatments – you will probably have an adverse reaction to one of the standard therapies. The EHR also identifies a clinical trial of a new therapy, for which you qualify based on your molecular profile.

Your oncologist explains the risks and benefits of participating in the clinical trial, and you go home to think it over



and talk with your family. You review your EHR lab report and other personalized information on your computer and contact your local comprehensive cancer center's second opinion service to review your options. With the second opinion confirming your doctor's assessment, and feeling confident in your own knowledge, you return to your oncologist's office, enroll in the trial, and immediately receive electronic confirmation with information on next steps.

The treatment being studied in the trial includes two new drugs, which are attached to a microscopic "nanoparticle shuttle" that will deliver them directly to individual cancer cells, sparing healthy cells and minimizing side effects.

You also receive a saliva reader that plugs into your smart phone, together with a few mobile applications that allow you to record your symptoms during the trial and send information automatically to your EHR. Every eight hours, your phone will buzz to remind you to take your medicine and answer a short series of questions about how you're feeling. It alerts you that you should expect to be slightly fatigued and includes suggestions for managing this side effect.

The next day, a nurse calls you to make sure everything is working properly and to answer any questions. He tells you he will be monitoring your progress throughout the trial, and will contact you if the answers you provide indicate anything out of the ordinary. He also reminds you that all of your doctors – including your primary care physician and cardiologist – will be able to track your status through your EHR, so they can continue to make fully informed decisions about your other health care needs.

You feel reassured because your doctor and nurse know a great deal about the drivers of your cancer, and are helping you make informed decisions to manage your cancer while continuing to work and live an active life.

INTRODUCTION

A New Vision for Clinical and Translational Cancer Research

“We can no longer think of cancer as one disease. Even something like lung cancer could be hundreds of distinct cancers, each defined by specific molecular characteristics requiring different treatment approaches. This makes research more challenging, but the payoff for patients will be enormous.”

MICHAEL P. LINK, MD, PRESIDENT OF ASCO

It has been 40 years since President Nixon signed the National Cancer Act into law.¹ With this landmark legislation, the United States entered an era of rapid advancement in our understanding of cancer and our ability to prevent, detect and treat it. As a result, more people are surviving cancer than ever before, and quality of life for those with the disease has dramatically improved.²

While advances have been extraordinary in many ways, there is an urgent need to accelerate the pace of progress. Many cancers are not detected until their latest stages, and others have resisted most attempts at treatment. As a result, cancer still kills more than 500,000 people in the United States each year³ and the disease is projected to become the nation’s leading killer over the next decade as the population ages.⁴ Worldwide, the cancer problem is growing quickly.⁵

With recent breakthroughs in technology and in cancer “panomics” – the combination of genes, proteins, molecular pathways and unique patient characteristics that together drive the disease – there is new hope and unprecedented opportunity to make more rapid advances. Yet our nation’s translational and clinical research system is unprepared to deliver on this promise.

This report from the American Society of Clinical Oncology lays out a vision for an approach to clinical and translational cancer research that takes full advantage of today’s scientific and technological opportunities. If bold action is taken to achieve this vision, we can realize major new advances in cancer prevention, detection and treatment and improve the care of patients.

The report makes the following case for action:

- **Investments in cancer research have already saved and improved countless lives.**

While cancer has proved far more difficult to defeat than imagined when the National Cancer Act was enacted, today, two out of three people live at least five years after a cancer diagnosis, up from roughly one out of two in the 1970s. The nation’s cancer death rate has dropped 18 percent since the early 1990s, reversing decades of increases.³ And people with the disease are increasingly able to live active, fulfilling lives, due to better management of symptoms and treatments with fewer side effects.

- **Cancer science is in a period of revolutionary change.**

As a result of our rapidly growing understanding of the biology of cancer, treatments are increasingly targeted to the molecular “triggers” that cause normal cells to become cancerous. Researchers are using new technologies – from the fields of computational chemistry, imaging technology, nanotechnology, health information

technology and genetic engineering – to engineer therapies that target the multiple pathways that combine to drive a patient’s cancer, with hundreds of potential new targets yet to explore.

- **Clinical cancer research and patient care could be vastly more targeted, more efficient and more effective.**

With recent advances, it is not unrealistic to imagine that over the next decade, clinicians will increasingly be able to choose therapies that target the characteristics of each cancer and each patient. In addition, cancer diagnosis will be earlier, and diagnostic tests will provide molecular information that informs treatment decisions and management of side effects. A growing number of effective treatments will be targeted to defined patient populations. And new drugs will be developed simultaneously with the diagnostic tools that are needed to guide their use.

Treatments will be targeted not only at cancerous cells but also at pre-cancerous cells and the cell’s surrounding environment. Clinical trials will be launched and completed far more quickly. Every patient will have the opportunity to contribute to translational and clinical research thanks to advances in health information technology (HIT) that enable real-time collection and sharing of clinical information through electronic health records (EHRs).

- **But this vision is possible only if we transform the way translational and clinical cancer research is conducted.**

The nation’s cancer drug development and clinical research infrastructures have not kept pace with recent advances. The clinical trials system has been weakened by a labyrinth of regulatory requirements and years of under-funding. Traditional trial designs and drug development models are insufficient to fully capitalize on the potential of molecularly-targeted therapies. And companies are discouraged from sharing ideas or testing promising new treatments in combination due to a lack of incentives and the absence of a clear process for collaboration.^{6,7}

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Explore 40 Years of Progress in Cancer Research: ASCO’s CancerProgress.Net

In May 2011, ASCO launched CancerProgress.Net, a dynamic website that provides an interactive journey through four decades of advances in the prevention, diagnosis and treatment of cancer.

Created to mark the 40th anniversary of the National Cancer Act, CancerProgress.Net was developed under the guidance of 17 of the nation’s leading oncologists. Key features of the site include:

- An interactive timeline of cancer research advances – covering 14 different cancer types and every type of care, from prevention to molecularly targeted therapies
- “Data visualization” tools to help bring select cancer statistics to life
- Expert interviews and historical commentary from renowned leaders in oncology



- Downloadable slides and links to other resources

The site is updated regularly to feature major new advances in cancer research and patient care.



ABOUT THIS REPORT

This report from ASCO – which represents more than 30,000 physicians and other professionals who treat people with cancer and conduct clinical research – provides a high-level blueprint for transforming the translational and clinical cancer research system in the United States. It addresses three main areas in which changes are urgently needed:

1. **Establishing a new approach to therapeutic development**, driven by our more thorough understanding of cancer biology
2. **Designing smarter, faster clinical trials** that are appropriate for the era of molecularly-targeted therapies
3. **Harnessing information technology** to seamlessly integrate clinical and translational research and patient care, ensuring that every patient's experience can inform research and improve care

In each area, we describe the vision that ASCO believes can become a reality within the next decade and provide an initial blueprint for action.

We also outline the steps ASCO plans to take to achieve this vision, and we invite stakeholders in the cancer research community (e.g., policymakers, patient advocacy organizations, professional societies, public and private research sponsors and regulatory bodies) to join us. Over the next three years, ASCO will work with partners throughout the cancer research community to develop more detailed plans of action for each of the three areas covered in this report.

ASCO'S BLUEPRINT FOR ACTION

I. A NEW APPROACH TO THERAPEUTIC DEVELOPMENT

THE SITUATION TODAY

For decades, the development of new treatments for people with cancer involved choosing drugs for tumors based largely on their location within the body. Today, thanks to genomic advances and a deeper understanding of cancer biology, this approach is being replaced with development of approaches that target specific molecular characteristics of the cancer cell – the molecular “on-off” switches that are critical to driving cancer cells' uncontrolled growth.

This targeted approach has already improved treatment for many cancers, especially those that are driven by a single powerful mutation. One of the best-known examples is breast cancer that over-expresses the HER2 protein. Once one of the most difficult cancers to treat, this form of breast cancer is now highly treatable, thanks to the development of drugs that specifically block the cancer-fueling effects of HER2.⁸

For the vast majority of cancers, however, it has become increasingly clear that targeting a single molecular defect is not enough. Most cancers are driven by multiple mutations that provide pathways for cancer development, many or all of which may need to be targeted for the cancer's growth to be prevented or controlled. In addition, cancers that are ostensibly of one type – for example, lung cancer – can be driven by many different molecular defects and require very different treatments. In short, there is no single breast cancer or lung cancer or colon cancer, but rather several or even dozens of molecularly distinct cancers of each type that can arise.

While our understanding of this molecular basis for cancer is growing rapidly, our current approach to

developing and testing new therapies is ill-equipped to capitalize on that new knowledge:

- While new technologies are allowing us to decode the genomes of a growing number of cancers, researchers have a limited understanding of which molecular pathways within a person's cancer are most important to target.
- Researchers also have a limited understanding of how the cancer cell's environment – for example, the molecular characteristics of the surrounding tissue – influences the cancer's development and spread.
- We do not have proven, easily detectable and measurable biomarkers (see box, p. 8) to identify patients based on the molecular characteristics of their cancer, or to monitor the effectiveness of prevention and therapeutic strategies in real time.
- With molecularly targeted treatment and prevention strategies, more information about each patient's cancer is needed to identify the patients who are most likely to benefit from a given treatment. To realize the greatest potential benefits, development of treatments should be accompanied by development of diagnostic tests to identify appropriate patients and monitor the outcomes of those treatments in real time. Today, however, treatments and diagnostics are not typically developed and tested at the same time. An additional complication results because therapies and diagnostic tests are regulated by different government bodies.
- Currently there is no consensus among researchers or research funders about the most urgent and promising priorities for therapeutic and diagnostic

Biomarkers and Their Functions

Biomarkers are substances or biological features arising in tissue, blood or other bodily fluids that can be easily identified and used to diagnose or monitor a disease and its response to treatment. In practice, biomarkers are detected through various diagnostic tests – for example, blood or saliva tests, or imaging tools such as CT scans or magnetic resonance imaging (MRI).

Perhaps the best-known example of a biomarker is cholesterol level in blood, which serves as a marker for heart disease. Because of the strong link to heart disease, monitoring cholesterol in blood is an effective way to determine the effects of anti-cholesterol medications on reducing the risk of heart attacks.

In cancer, biomarkers will increasingly serve several important functions. More and more, they will determine if a person is at increased risk for certain cancers; enable physicians to diagnose some cancers at an early stage; and guide treatment decisions.

In cancer research, biomarkers are increasingly essential to identify new treatment targets; quickly identify patients who are eligible for specific trials; and monitor responses to therapy.

Current examples of cancer biomarkers include:

- CA125 for monitoring response to ovarian cancer treatment⁹
- Tumor glucose metabolism, as measured by PET imaging, to provide a more accurate prognosis¹⁰
- HER2 gene expression to determine the likelihood of benefitting from targeted breast cancer drugs such as trastuzumab (Herceptin) and lapatinib (Tykerb)⁸

development. As a result, there is widespread duplication of effort in some areas, including “me-too” trials of therapies. In addition, trial sponsors often focus on areas that are unlikely to result in major advances over existing options, while critical gaps in cancer prevention and treatment are left unaddressed.

- With multiple molecular triggers for each cancer, it is likely that a combination, or “cocktail” approach to treatment and prevention strategies will be required. Yet legal, financial and regulatory hurdles currently make it challenging for companies to work together to test promising combinations.
- Combining different strategies for prevention and treatment of cancer will require teams of researchers. Academic incentives, however, reward individual research efforts over team approaches.

ASCO'S VISION FOR THE NEXT DECADE

Within the next decade, ASCO envisions increasing reliance on molecularly-driven, collaborative approaches to cancer diagnostic and therapeutic development. Development of new treatment and prevention strategies will be governed primarily by the molecular characteristics of the cancer, rather than its location in the body. New, more collaborative research models and trial designs will enable testing of multiple drugs at once, and provide more meaningful insight into what does and doesn't work, and why. Physicians and researchers will have a robust set of biomarkers to guide prevention, diagnosis and treatment decisions for many more types of cancer. And new technologies will open the door to entirely new approaches to cancer prevention, detection and treatment.

The key elements of ASCO's vision are as follows:

Defining Cancer Based on Characteristics, Not Solely by Location in the Body

Cancer will no longer be identified primarily by the location in the body where it begins, but also by its

panomic characteristics – the complex combination of patient-specific molecular characteristics that drive the development and behavior of each cancer. Specifically, over the next decade:

- Researchers will decode the genomes of a large inventory of cancer types. This will include characterization of cancers at the earliest stages, as well as the cells that surround the cancer as it arises and spreads – the “cancer environment” – so that researchers can better understand the entire spectrum of biological changes that occur in the development of cancers.
- Researchers and clinicians will have the tools to quickly conduct a panomic analysis for every patient with cancer. This analysis will include an examination of the patient’s genomic makeup and a complete molecular characterization of their cancer cells.
- In combination, this information will provide a more sophisticated view of the cancer’s development –

and how to prevent, halt or reverse it. Researchers and clinicians will identify the series of critical molecular “hubs” that must be targeted simultaneously to shut down the entire “power grid” that drives the cancer cell’s development and growth.

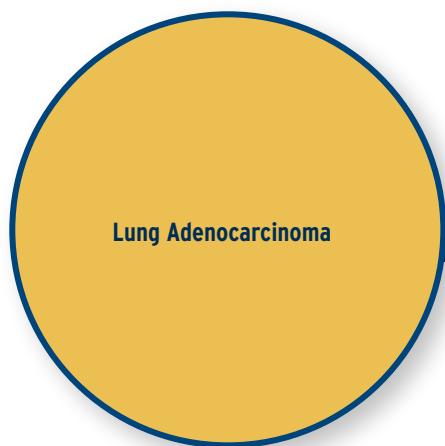
Molecularly-Driven Diagnostic and Therapeutic Development

Our expanded knowledge of cancer- and patient-specific molecular characteristics will help transform the approach to diagnostic and therapeutic development over the next decade:

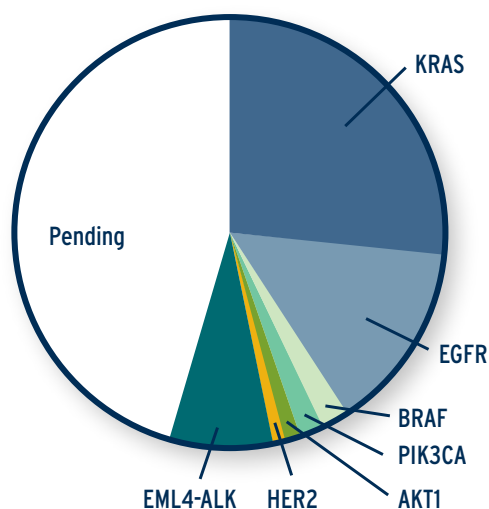
- Cancer treatment and prevention therapies will increasingly target the key molecular hubs that drive cancer growth – not just individual mutations. This will enable treatments to become much more personalized, taking into account when and how to intervene to hit the right targets in a given tumor, and how treatments are likely to affect each patient.
- Experts from a wider range of professional

Cancer in the Molecular Era: Identifying the Drivers of Lung Cancer

BEFORE: One Disease



TODAY: Many different forms of lung cancer driven by different molecular defects – with more yet to be identified



FUTURE ONCOLOGIST PERSPECTIVE Therapeutic Development

ASCO envisions that in a decade, the following experience will be routine:

We used to have to figure out the best treatment for a patient just by looking at the tumor under a microscope and assessing the patient's symptoms. That was like trying to fix a car by looking at the engine and listening to it idle. Now, we have the tools to take apart the engine and address the specific problem. With a fast blood test, I can find out what is driving my patient's cancer so that we can find the right treatment.

We can do this now because of decades of hard work studying the molecular engines of many different cancers, and it's been a real blessing to my patients.

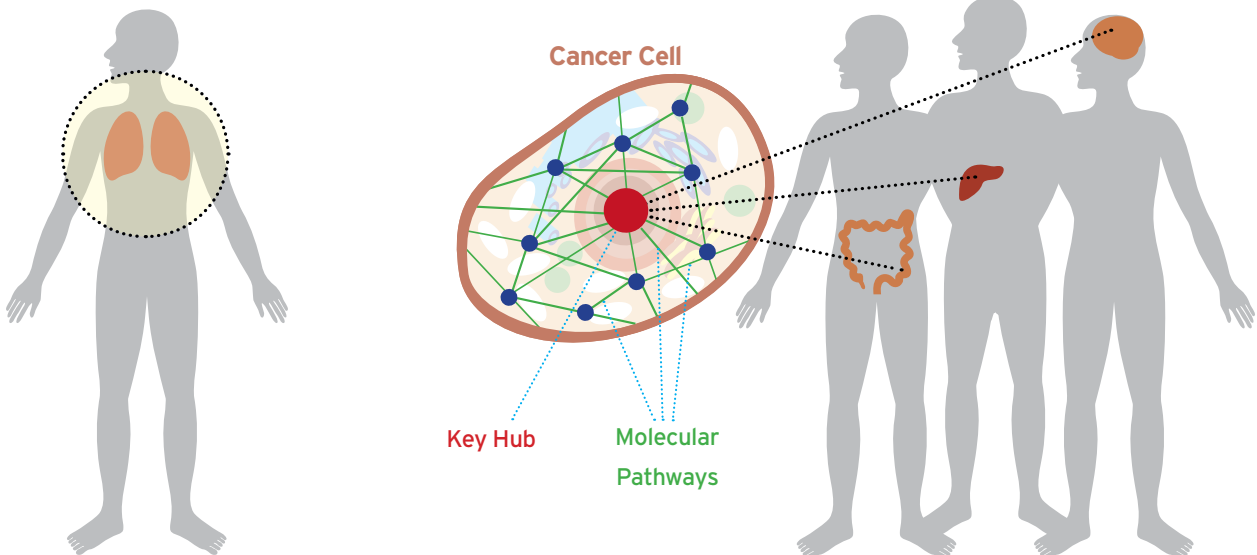


We don't have to go through multiple rounds of therapy and use a hit-or-miss approach with drugs that have awful side effects. We have greater assurance at the outset that we're choosing a drug that will work and that we are using a dose that is likely to be effective and minimize side effects.

A New Model for Therapeutic Development

OLD MODEL: Treatment is determined by a tumor's location in the body, without regard to the molecular characteristics of the patient or the tumor.

NEW MODEL: Treatment is determined by key molecular "hubs" that must be targeted within the cells, and is only administered to patients whose tumors are found to have those hubs – potentially without regard to the tumor's location in the body.



disciplines will collaborate on the development of innovative cancer treatment and prevention strategies, and new strategies will incorporate a greater variety of approaches. Already, for example, materials scientists and chemical engineers are helping to design new mechanisms to target cancer cells and avoid normal cells.

- Clinical trials will routinely collect information directly from participants to help determine how and why investigational therapies affect patients differently. This patient-reported data, including real-time reports of symptoms and other patient experiences, when combined with more complete information about the genetic make-up of their cancers, will help guide future research.
- Regulatory agencies, trial sponsors and researchers will begin discussions early in the therapeutic development process, enabling faster review and approval of new treatments and diagnostics. Together, regulators and researchers will develop new processes and decision-making tools to more effectively monitor, collect and incorporate data on effectiveness and potential side effects of different types and combinations of new treatment and prevention strategies.

More Robust Biomarkers

Over the next decade, ASCO envisions that researchers will identify and validate many new biomarkers (see box, p. 8) that can be used to help prevent cancers, detect cancers earlier, match patients with effective treatment and prevention strategies at the right doses, monitor clinical benefit and predict long-term outcomes. The availability of these new biomarkers will also accelerate research by helping to identify useful drug targets and patient populations most likely to benefit, and to more effectively monitor the impact of investigational treatments in trials:

- New devices will be able to rapidly analyze many potential biomarkers at the same time, allowing researchers to more quickly and easily identify those that can guide research and patient care.

FUTURE INDUSTRY PERSPECTIVE

Therapeutic Development

ASCO envisions that in a decade, the following experience will be routine:

With so much more known about cancer biology, thanks to a lot of collaborative work with other companies, NCI, and foundations, drug companies are now able to make better tools for doctors to use. It's great to be working together with other companies and these stakeholders in the early stages of drug development, to build knowledge we can all use in our research.

In the old days, it was like having only one tool to do all your home repairs – if it worked for removing the drywall it probably wouldn't work for the plumbing. Now, we are able to look at the entire molecular system that drives a specific cancer and design the tools needed to specifically fix each part of the system.

And we're not just developing drugs – we've also been working with engineers and materials scientists to come up with all kinds of new devices to detect and attack cancers. This cuts down on side effects and allows doctors to individualize the treatment based on the individual person and their cancer.

It's much more rewarding to develop these more comprehensive treatments than it was to work on drugs that would just attack one piece of the problem and increase life span by only weeks or months.

- Biomarkers and diagnostic assays will be developed and validated simultaneously with new cancer treatments – not as separate steps in the development process as they often are today. This will shorten the time before patients can benefit from new treatments, by accelerating the availability of diagnostic and monitoring tools that are required to guide the use of new therapies in the clinic.
- Advances in imaging technologies will expand the range of imaging options that can be used as biomarkers. This will provide faster and less invasive ways to detect and monitor cancers.
- New biomarkers will help to better define and quickly identify the patient populations for specific clinical trials, by allowing widespread, rapid screening for specific genetic mutations and other molecular features of the cancer.
- New biomarkers will enable expanded use of current therapies to new tumor types that share key molecular features. In a limited number of cases, this is already occurring. For example, trastuzumab, a treatment developed to target HER2 in breast cancer, has shown promise for gastric cancer that overexpresses the same protein.¹¹

New Methods of Cancer Prevention, Diagnosis and Treatment

Over the next decade, new technological advances will open the door to entirely new methods of preventing, diagnosing and treating cancer:

- Advances in materials science will allow researchers to aim therapy directly at the physical tumor site, increasing effectiveness and decreasing side effects. For example, refinements in the use of microscopic “nanoscale” technologies may better and more safely deliver drugs to their precise target.
- Tools will be developed to identify “circulating tumor cells” that have detached from a tumor and are traveling in the bloodstream. These cells may be used to detect cancer, measure the effectiveness of treat-

ments and monitor for cancer recurrence, without more invasive techniques.

- A greater understanding of biology, together with new technologies, will allow researchers and clinicians to identify and eradicate cancer stem cells – a class of cells that gives rise to other forms of cancer cells, and are thought to be the most critical to attack in order to stop cancer’s spread and recurrence.
- Thanks to improved understanding of both the genomics of cancer and tumor cells’ interaction with the rest of the body, researchers will be able to develop new immune therapies to harness the body’s own ability to seek out and destroy cancer cells.

RECOMMENDATIONS

ASCO recommends that the following actions be implemented over the next three years to accelerate therapeutic development and make this vision a reality:

Establish clear priorities for therapeutic and prevention strategies and biomarker development:

Identify and prioritize the targets that are most urgently needed to advance cancer patient care, and the biomarkers that will be essential to guide the use and measure the effectiveness of resulting therapies.

- ASCO will partner with other medical and scientific professional societies and the National Cancer Institute (NCI) – building on NCI’s existing “Provocative Questions” project¹² – to convene a series of workshops with basic, translational and clinical researchers, industry, the Food and Drug Administration (FDA), patient organizations and other stakeholders to:
 1. Identify and prioritize the most promising molecular pathways to be targeted.
 2. Identify new opportunities and approaches for biomarker development.
 3. Identify effective strategies to improve research on new methods and combinations of cancer prevention and treatment approaches.



Incentivize collaboration in therapeutic development:

To support more efficient development and evaluation of combined therapies and biomarkers that will be central to the future of cancer care, medical societies and cancer research advocates should evaluate the need for financial and regulatory incentives to ensure that industry and researchers can pursue the most urgent priorities.

Mechanisms for “pre-competitive” collaboration among companies, researchers, and government and philanthropic research sponsors should also be explored, particularly for the development of new biomarkers. The process of biomarker discovery and validation is complex, and requires networks of investigators capable of open, intensive interactions, as well as substantial funding support.

- ASCO will collaborate with partners at NCI and the Institute of Medicine (IOM) to convene a working group with industry, academia and other federal agencies to:
 1. Explore ways to promote a more collaborative ap-

proach to developing new prevention and therapeutic strategies. This discussion would seek to develop a strategy that lowers the consequences of failure to enable academic researchers and companies to become more innovative.

2. Develop consensus on whether modifications are needed to intellectual property law to facilitate and incentivize collaboration.
 3. Develop recommendations and a strategy to create a clear pathway for regulatory review and oversight of diagnostic tests that relate to use of biomarkers and therapies.
- ASCO applauds National Institutes of Health (NIH) and NCI efforts to encourage collaborative research between academic and community research centers.^{13,14} ASCO encourages NIH and NCI to continue to implement these types of changes. As part of the grants review process, NIH and NCI should also provide credit to research projects that involve a multi-disciplinary, collaborative approach.

II. FASTER, SMARTER CLINICAL TRIALS

THE SITUATION TODAY

Clinical cancer research – involving rigorous trials that test the safety and efficacy of new therapies in people – is the engine that drives progress against cancer. Clinical trials are the only way to translate cutting-edge laboratory discoveries into treatments that extend and improve the lives of patients. Four decades ago, the National Cancer Act led to major new U.S. investments in clinical cancer research. Since that time, clinical trials have yielded steady advances in our ability to treat, detect and prevent cancer, and have helped to significantly extend patient survival and reduce mortality.

While progress has been substantial, it has generally been the result of incremental advances over time. Today, the remarkable pace of scientific and technical change is opening the door to more rapid advances. Yet our nation’s clinical research system is poorly equipped to realize today’s scientific potential, and is in desperate need of modernization and repair:

- Research sponsors currently devote substantial resources to trials and therapies that promise only marginal improvements over current standards of care. In part, this is due to a lack of clear priorities or a shared understanding of what constitutes meaningful advances in patient outcomes.
- It can take up to five years to develop and initiate a cancer clinical trial, and the time to complete trials has increased steadily as a result of overlapping regulatory requirements and complex data reporting.⁶
- Low patient and physician participation rates lead to delays in completion or even cancellation of trials. It is estimated that less than 5 percent of adult cancer

patients participate in clinical trials, due to factors including extensive “exclusionary criteria” (factors used to limit participation in a trial, in order to protect patients and ensure a statistically valid trial result), low physician and patient awareness, uncertainty about insurance coverage and other barriers.

- Opportunities to conduct faster trials are limited by the small number of measures of efficacy that are acceptable to regulators – measures such as overall survival (the proportion of patients alive after a given time period), progression-free survival (the period during which a patient does not experience any new tumor growth or cancer spread during or after treatment) and disease-free survival (the length of time a patient is in complete remission following treatment). Researchers and regulators have been slow to reach consensus on the meaningfulness of other endpoints that could provide faster conclusions about the value of new therapies, in part due to insufficient ways to measure and document patient improvement.
- We now understand that seemingly identical cancers can be amazingly diverse at the molecular level, so that only narrow subpopulations of patients may respond to a particular treatment. However, most clinical trials continue to use broad patient populations that include many people who are unlikely to respond to a targeted treatment because their cancer does not have the relevant molecular defects. This lowers the apparent effectiveness of investigational treatments and exposes patients to unnecessary side effects.
- Trials do not routinely examine important indicators

of patient benefit, such as quality of life, that could help guide regulatory approval and future treatment decisions.

- Stagnant federal funding of the NCI’s Clinical Trials Cooperative Group Program in recent years (see below chart) has stalled vitally important research that industry has little incentive to conduct, including studies that combine therapies from different companies, test FDA-approved treatments against different cancers, compare the effectiveness of different treatments, address rare diseases with little market potential or examine new prevention strategies.⁶
- The United States is gradually losing its leadership position in clinical cancer research, as important trials move overseas in search of more trial participants, less burdensome regulatory requirements and lower-cost health systems.

ASCO’S VISION FOR THE NEXT DECADE

Over the next decade, ASCO envisions a clinical cancer research system that is guided by clear priorities and is flexible enough to pursue new scientific opportunities as they emerge. With innovative trial designs and consensus on research priorities, researchers will conduct faster, more efficient trials that apply available resources to the most urgent needs of people with cancer.

Major elements of this vision include the following:

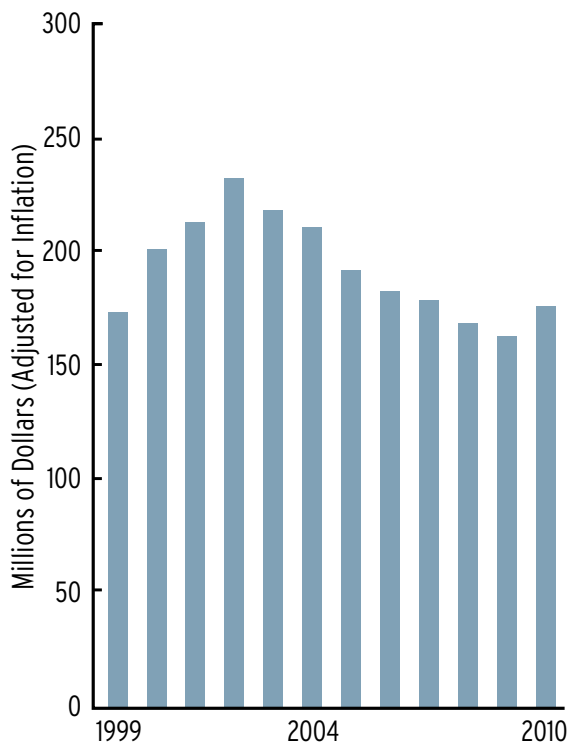
- Researchers, industry, patient organizations and government agencies will reach broad consensus on research priorities that hold the greatest potential to improve patient care and address public health need. Trials pursuing those areas will be prioritized for funding by research sponsors.
- As cancer biology is better understood, the criteria for participating in a trial will be based almost

The Central Role of NCI’s Clinical Trials Cooperative Group Program

Most federally-funded studies of new cancer treatments are conducted under the NCI-funded Clinical Trials Cooperative Group Program. Through a network of more than 3,100 institutions and 14,000 researchers, the Cooperative Groups enroll more than 25,000 patients annually in cancer clinical trials and have made enormous contributions to the nation’s progress against cancer.¹⁵

Cooperative Group trials have brought breakthroughs in adjuvant chemotherapy for breast and colon cancers, breast-conserving lumpectomy to avoid mastectomy (surgical removal of the breast) and new standards of care for blood cancers, brain tumors and many others.

Yet funding for the Cooperative Group Program has declined in real terms in the past decade, threatening this vital component of the nation’s clinical cancer research system (see chart).



Source: ASCO
Data from the National Cancer Institute; inflation adjustments based on the National Institutes of Health Biomedical Research and Development Price Index

FUTURE RESEARCHER PERSPECTIVE

Clinical Trials

ASCO envisions that in a decade, the following experience will be routine:

Clinical trials are far more successful because we have a much better idea of what to look for and who to look for it in.

Our multi-talented teams can quickly take ideas from the lab to the bedside because we have biomarkers that allow us to measure a patient's response to therapy in a matter of weeks, not years.

We can also take the data from the clinic back to the lab and refine our trials or come up with entirely new ideas. This smooth back-and-forth allows us to zero in on what is driving the cancer. That means we can select patients who will be most likely respond, instead of testing a drug on everyone and trying to figure out why it works really well for only a few people.

And since we don't need as many people for any one trial, we can do more trials and develop more treatments faster. It's also easier to find people to participate, now that we have tools for patients to be more involved. Everyone who is interested can receive alerts when a suitable trial opens.



exclusively on the molecular characteristics of each patient's cancer. Trials will provide answers faster and more conclusively, because they will include only the participants most likely to respond to the treatment being studied.

- While researchers will need to screen larger numbers of patients to identify participants for each



Smaller Trials, Bigger Chance for Success

OLD MODEL: Large numbers of patients, not selected by molecular characteristics; lower chance of demonstrating effectiveness, since many participants do not have the molecular defects being targeted



NEW MODEL: Small patient populations, all with the relevant mutations or genetic defects; greater chance of desired results, since all participants have the potential to respond



trial, this task will be made easier through increased international collaboration between scientific and regulatory bodies. Such collaboration will enable researchers to more readily recruit patients from many different countries.

- Clinical trials will increasingly use adaptive designs that allow researchers to adjust a given study's population during the course of the trial, based on biomarkers that are found to be important as the trial proceeds. By ensuring that study populations consist of those patients who are likely to benefit, it will be possible to shorten the time that is required to complete trials and speed the development of new treatment and prevention strategies. Increased interaction between clinical, translational, basic science and health services researchers will enable ideas to flow more quickly from the lab to the clinic and back. Given the growing complexity of cancer science, a wider range of disciplines will be involved in the development of clinical and translational research concepts and protocols (e.g., materials scientists, engineers and epidemiologists).
- In addition to survival and anti-cancer response, therapeutic developers will routinely gather data on quality of life when testing new therapies in clinical trials. This will enable greater recognition of the value of a treatment based not only on patients' survival, but on the *quality* of their survival. The FDA and therapeutic developers will increasingly work together to enable consideration of these factors in approval decisions and to include this information on drug labels. This will provide clinicians and patients with more information about the benefits of approved treatments.
- ClinicalTrials.gov, the nation's registry of federally and privately supported clinical trials, will include more critical information in a useful format, such as information on initiated projects in early development and trial results. This more robust database will enable investigators to build on results of completed research, prevent duplication and help identify the most important research opportunities.

RECOMMENDATIONS

ASCO recommends the following actions be implemented over the next three years to modernize the way in which clinical trials are conducted and help to achieve the vision above:

Prioritize trials with the greatest potential

benefits for patients: The cancer research community should shift away from trials that promise only marginal improvements in care, and prioritize development of treatments, diagnostics and prevention strategies that represent significant advances for patients. Trials should focus on demonstrating meaningful patient outcomes, including both significant reductions in mortality and improvements in quality of life.

- ASCO will partner with patient advocates to convene a working group of experts in the field (including industry, investigators from multiple areas of biomedical research, NCI, FDA and insurers) to develop consensus on the specific benefits that constitute "meaningful patient outcomes."
- The working group will develop proposals to encourage broad adoption of meaningful patient outcomes – for example, working with insurers to ensure these outcomes are linked to eventual coverage of new treatments, and encouraging peer-reviewed journals and medical meetings to adopt policies that prioritize publication and presentation of trials that demonstrate such outcomes.

Select study populations based on molecular

characteristics: To the greatest extent possible, clinical trials should be conducted in populations based on their molecular characteristics. At the same time, researchers should decrease use of other, less meaningful exclusionary criteria, such as having had prior cancers or having brain metastases. In addition, clinical trial populations should better reflect the racial, ethnic, age and gender diversity of people with cancer.

- ASCO will partner with NCI, Cooperative Groups and



industry to convene stakeholders in trial development to examine current exclusionary criteria and determine which criteria are scientifically required and which can be eliminated as we move more completely into the era of targeted treatment and prevention strategies.

Employ flexible, efficient trial designs: ASCO will bring together government agencies, academia and public and private trial sponsors to develop shared standards for new and flexible trial designs that allow researchers to achieve results efficiently with smaller, molecularly-defined sub-populations of patients. These new trial design standards should promote the use of surrogate study endpoints that represent meaningful measures of benefit to patients and will require less time to achieve.

- Building on past work with FDA and professional societies, ASCO will hold a state-of-the-science workshop on surrogate endpoints to catalog successful

approaches, identify new standards and develop strategies to improve their use and promote their recognition by regulatory agencies.

- ASCO will create educational modules to enable researchers and biostatisticians to make greater use of innovative clinical trial designs.

Streamline data requirements for new uses of existing treatments: In regulatory applications for additional uses of already approved cancer drugs, FDA and industry should streamline data reporting by recognizing and building from the safety data that already exists for the treatment. Collection of new data should be focused only on those scientific questions that are directly relevant to clinical decision making. Such applications today require collecting information on known, low-grade safety risks and complete records of other medications being taken by individual study participants. However, these data do

not routinely inform regulatory or clinical practice decisions and consume significant time and resources.¹⁶

Train health care providers in clinical research:

Medical societies and educational institutions should encourage and train cancer care providers to conduct clinical research as an integral component of patient care.

- ASCO will develop and disseminate educational modules and materials to teach core concepts of clinical research. These will be designed for use during training across all medical disciplines. The educational content will address the conduct of clinical research in both academic and community-based settings.
- ASCO will convene a working group with investigators and leaders from academic and medical institutions to discuss ways to recognize and reward physician participation in research, with a particular focus on team-oriented research.

Improve prioritization of NCI-sponsored trials:

ASCO supports the efforts of NCI and the research community to prioritize NCI-sponsored clinical trials.¹⁷ Policymakers and the research community should work together to increase support for high-priority, NCI-sponsored clinical trials while streamlining regulatory and logistical processes to expedite this vital research.⁶

- ASCO will partner with patient advocates, NCI, federally funded research institutions and industry to develop consensus on criteria for prioritizing cancer trials. The discussion should address the concepts of greatest public health need, meaningful patient benefit and scientific opportunity.
- NCI and private research sponsors should use these consensus criteria when determining which research to initiate.

Revitalize the NCI Cooperative Group program:

ASCO will continue its partnership with stakeholders to ensure full implementation of recommendations issued by the IOM in April 2010 (see box).

Institute of Medicine (IOM) Recommendations to Revitalize the NCI Clinical Trials Cooperative Group Program

In April 2010, the Institute of Medicine (IOM) released its report, *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program*. The report makes comprehensive recommendations to modernize and strengthen this vital component of the federally-funded clinical cancer research system, which has contributed many of the most important advances against cancer in recent decades.

The major IOM recommendations are as follows:

- Improve the speed and efficiency of the design, launch and conduct of Cooperative Group trials
- Incorporate innovative science and trial design into cancer clinical trials
- Improve the prioritization, selection, support and completion of trials
- Incentivize the participation of patients and physicians

Additional, detailed recommendations are made in each of these areas. (The full report is available at <http://www.iom.edu/Reports.aspx>.)

ASCO supports full implementation of the IOM report and is working with NCI, the IOM, Cooperative Groups, patient advocates and other stakeholders to advance key elements of the recommendations.

For information about ASCO's efforts, visit <http://www.asco.org/GroupReorganization>.

III. HARNESSING HEALTH INFORMATION THROUGH TECHNOLOGY

FUTURE PATIENT PERSPECTIVE Health Information Technology

ASCO envisions that within a decade, the following experience will be routine:

It used to be that all my doctors kept separate records and I was the only one trying to track everything. Now that all my health care providers are using systems that communicate with each other, they can see and update my information on the same file. I can also review all my information (diagnosis, treatment options and side effects to expect) anytime I want on my smartphone. I can record how I'm feeling so that my doctors know what we should talk about before I arrive for my next visit, and they can call me between visits if there's something I should take care of myself – like taking fewer pills or picking up some medicine from the drug store.

I also receive important information electronically – last year I got an email when a clinical trial opened up that I qualified for, based on the information about my cancer in my EHR. My cancer doctor got the same message, so we talked about it at my next visit and I signed up. I had to go for treatment at a different location, and they pulled up my records and we were ready to go; no hours wasted filling out the same forms over and over again or retaking tests that I had already done. The EHR even updated my primary care doctor and my diabetes doctor.

THE SITUATION TODAY

Health information technology (HIT) has the potential to transform clinical cancer research and improve patient care. Yet this potential is only beginning to be realized.

New HIT tools are urgently needed to help synthesize the wealth of information that should inform patient care and research: physicians need better tools to help them stay abreast of rapidly evolving research and make increasingly complicated treatment decisions; patients need better tools to minimize the burden of coordinating their own care and to easily provide their doctors with information that could inform their care; and researchers need better access to clinical data and tissue samples to be able to identify research opportunities and emerging trends in real time.

Today, we are only beginning to develop the capability to process large amounts of data and use it to inform cancer research and care. This is due to several factors:

- Many health care providers are just beginning to use electronic health records (EHRs), which are key to securely collecting, analyzing and sharing patient information. In addition, standard formats for recording patient information are lacking, making it difficult or impossible to compare data from different providers or health systems for research purposes.
- There is no widely-used system that allows investigators to access information from EHRs for research purposes, while also protecting sensitive patient information.

- EHRs are not currently designed to alert patients and physicians to newly approved prevention methods, treatment options and clinical trials as they become available.
- Data on patient biospecimens (tissue and blood samples) is limited by the lack of standardized methods for biospecimen collection, storage, analysis and cataloging. This limits researchers' ability to determine patient eligibility for clinical trials and to identify new research ideas.
- Debates about intellectual property rights and the limited availability of secure systems to ensure privacy of patient information limit the ability of patients to contribute biospecimens and information to inform clinical and translational research.
- Patient awareness of research will have increased thanks in part to novel strategies like online recruiting databases (see box, p. 23). Patients interested in participating in trials will be able to securely enroll in universal notification services that alert them when trials relevant to their cancer's molecular characteristics become available. Investigators will be able to use these notification services to send information to appropriate patients and clinicians when they launch a new trial.
- Access to real-time clinical data will greatly enhance insight into how patients respond to therapies and why. For example, it may help identify distinct groups of patients who are more likely to respond to a specific drug or are in need of other treatment options. These insights will help drive clinical research.

ASCO'S VISION FOR THE NEXT DECADE

ASCO envisions that within a decade, advances in HIT will make it possible to dramatically improve patient care and will allow researchers to draw upon the wealth of real-world patient and physician information to speed research. To help achieve this vision, ASCO is leading the development of a Rapid Learning System for Cancer Care, which will harness cutting-edge HIT to connect cancer patients, their health care providers and researchers to a central knowledge base; to synthesize information from millions of physician and patient experiences; and to deliver up-to-the-minute, personalized information that allows every patient to receive the highest quality care (see sidebar, p. 22).

Key elements of ASCO's vision are as follows:

- Researchers and clinicians will develop consensus on baseline demographic and treatment information to collect from all patients with cancer. HIT developers will build these standardized data fields into all EHR products. In addition, IT professionals will develop secure systems in which investigators can conduct health services and outcomes research without compromising patient confidentiality.
- All patients will have the option to contribute to clinical research by confidentially sharing information from their EHR for research purposes. A secure HIT environment will enable patients to permit their clinical information to flow securely and freely among oncologists, primary care providers and researchers.
- Patients and clinical trial participants will be able to access a secure portal where they can enter information about symptoms, side effects and health status in real time. This information will not only provide their oncologists with information needed to quickly resolve the patient's symptoms, but will also provide more detailed, reliable information for researchers about the real-world benefits and complications of treatments.
- Data obtained from biospecimens will be electronically linked in a secure environment to patients' clinical information, allowing physicians to easily explore relationships between the molecular characteristics of a patient and their cancer – in order to choose the best treatment, as well as identify the most promising clinical trial opportunities. In addition, researchers will be able to use information in a

secure way to test hypotheses. This will also enable a wide range of research from population-level effectiveness modeling to quality improvement and monitoring for the safe use of approved treatments.

RECOMMENDATIONS

In order to accelerate research and improve cancer care through health information technology, ASCO recommends the following actions be implemented over the next three years:

Standardize oncology EHRs: ASCO will continue its work with clinical, research and HIT stakeholders to define the functional requirements and clinical and research data elements needed for HIT products. The elements should include:

- All relevant information in a consistent format, including the cancer’s molecular characteristics, site and prior treatments received by the patient.
- Information from ClinicalTrials.gov about available clinical trials and eligibility standards. This will ensure that physicians and patients are alerted to clinical trials that may apply to the patient as they become available.

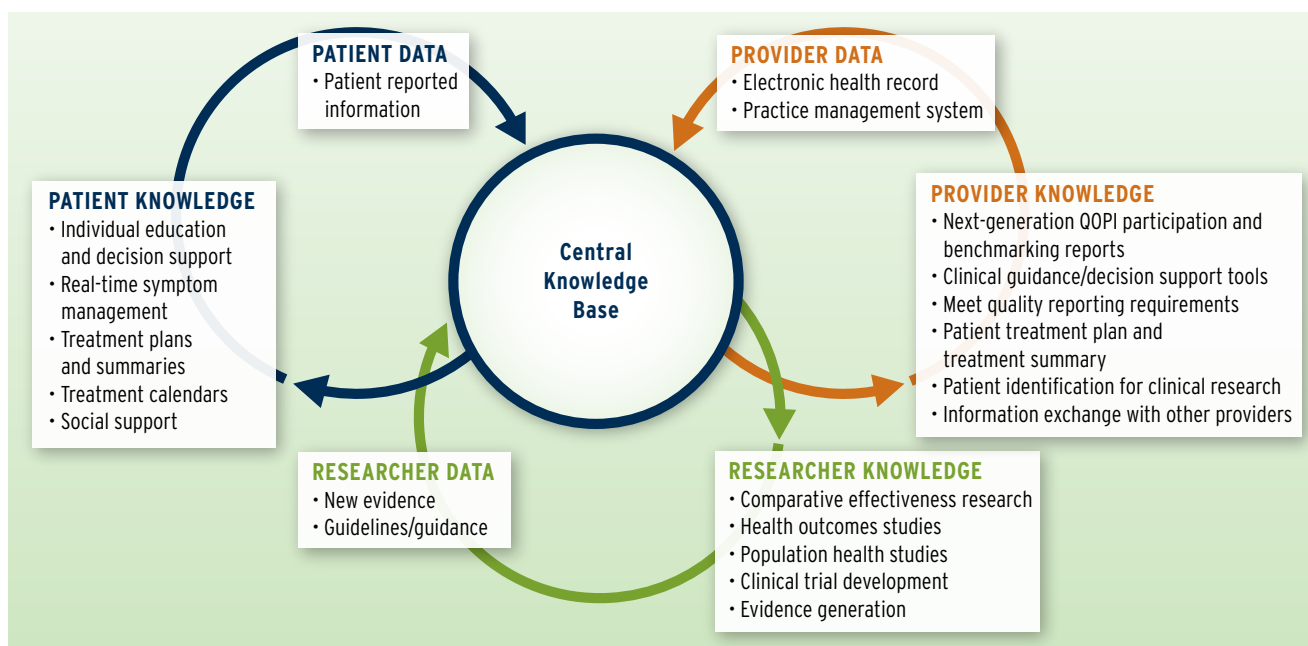


ASCO's Rapid Learning System for Cancer Care

This innovative, HIT-enabled rapid learning system environment will help to improve the quality of cancer patient care and accelerate research by forming a continuous cycle of learning: capturing evidence-based guidelines, evaluating quality of care against those recommendations, and creating insights through analysis of data from every patient experience.

To advance research, in particular, the system will:

- Provide a secure way to generate understanding of the outcomes of cancer patients. This will provide the research community with an unparalleled, high quality dataset to speed research
- Empower patients by providing personalized information, including clinical trials for which they are eligible based on their cancer type



- The ability to transfer data between clinical trial databases and patients' medical records to avoid discrepancies.
- Standardized fields for entering information about biospecimens, to help facilitate treatment decisions, determine patient eligibility for clinical trials, and ensure that researchers can analyze and draw conclusions from larger numbers of patients.
- Secure web-based and mobile applications that allow patients to provide information about symptoms and health status at any time.
- Terminology standards for demographic information and treatment outcomes that allow researchers to more effectively conduct health services and outcomes research.

Build ASCO's Rapid Learning System for Cancer Care:

To make this groundbreaking system a reality, ASCO is working with partners in the cancer, research and informatics communities to:

- Transform ASCO's Quality Oncology Practice Initiative (QOPI®) into a fully electronic system (<http://qopi.asco.org>). QOPI is the first and only nationwide system to help oncology practices monitor and improve the quality of care they provide. Once the system becomes fully electronic, practices will be able to share data in real time, enhancing insight into patient outcomes, improving quality and helping to inform clinical research questions. The continually expanding QOPI measures will be a core component of ASCO's Rapid Learning System for Cancer Care.
- Develop standards, applications and methods for collecting patient-reported outcomes (i.e., symptoms, side effects or quality of life indicators) in clinical care and clinical trial settings, as well as methods for notifying patients and doctors of relevant clinical trials.
- Partner with HIT developers to provide patients and physicians with the most up to date information and tools to guide decisions.

Using HIT to Increase Patient Involvement in Research

Several innovative HIT-based registries are helping to increase the number of people available for participation in cancer clinical trials. Examples include:

- **Love/Avon Army of Women:** An online registry working to recruit one million women willing to participate in breast cancer research. Women with and without breast cancer share contact information and basic demographic details, and agree to be contacted when new studies open. They are emailed when a new study becomes available, and are asked to respond if they are willing to participate. This approach has dramatically accelerated patient recruitment for some research studies – in one case, recruiting as many women in 10 months as it would have taken 3 years to recruit using a full-time recruiter (<http://www.armyofwomen.org>).
- **ResearchMatch.org:** An NIH-funded online registry for healthy individuals willing to take part in clinical research studies. Individuals fill out an online form, including basic health data. Researchers are able to search confidential volunteer data through the ResearchMatch website, and send a message to individuals who are an appropriate fit for the trial. Volunteers determine whether they are interested in participating (<https://www.researchmatch.org>).



Develop industry standards for working with biospecimens: ASCO will work with NCI and with colleagues in clinical research, pathology and epidemiology to develop more comprehensive standards and guidelines for biospecimen collection, storage and analysis. This work will build on successful molecular markers meetings and tutorials on biospecimens that have been sponsored by ASCO, NCI and the European Organization for Research and Treatment of Cancer.

Ensure that advances in HIT protect patients and researchers: ASCO will work with organizations in the oncology community and appropriate regulatory authorities (e.g., NCI, FDA and the HHS Office for Human Research Protections and Office for Civil Rights) to generate consensus on and support standards for patient privacy, information sharing and intellectual property protections to support HIT innovation.

CONCLUSION

The Way Forward

This report presents ASCO's vision for the future of translational and clinical research. ASCO's recommendations, when fully implemented, will help shorten the time between basic discoveries and development of new cancer therapies; focus efforts on therapies with the highest probability of success; and significantly improve the patient experience by enabling treatment to be better tailored to the needs of each individual.

We are not alone in our desire to revitalize clinical and translational research. Through our ongoing discussions with colleagues at research institutions, professional and patient organizations, federal agencies and industry, it is clear that others share many of the priorities laid out in this report – and all share our desire to accelerate the pace of research and offer patients more meaningful prevention, detection and treatment options.

This report lays out ASCO's initial recommendations and plans for implementation. We will build on these over the next decade, using this vision as a guidepost to map and evaluate our progress. As an organization representing cancer clinicians and researchers, ASCO plans to play a significant role in achieving the vision of this report. We are already working on several fronts to make this happen, and we hope to collaborate with many other stakeholders in the months and years ahead. Our major activities will include:

- **Building Consensus to Implement the Recommendations.** Over the next three years, ASCO plans to work with other stakeholders to convene working groups with experts from the scientific and regulatory communities, professional and patient advocate organizations and policymakers. The working groups will develop consensus recommendations on the topics identified in this report, including ways to develop biomarkers and surrogate endpoints, incentivize research collaboration, develop consensus on meaningful patient outcomes and research priorities, and increased use of innovative trial designs. ASCO will vet the consensus recommendations, seek peer-reviewed publication and work with advocacy partners to develop strategies for implementation.
- **Implementing ASCO Programs and Initiatives.** ASCO is engaged in and planning a number of activities to help improve clinical research. Several of these initiatives are noted in the Recommendations sections of this report. For example, ASCO is working to build a rapid learning system to improve cancer care and speed research. ASCO is also partnering with stakeholders to develop oncology-specific standards for HIT that are responsive to oncology practice, include quality measurement and improvement and integrate research. In addition, ASCO has conducted an analysis to determine how data sought in trials that study new uses for already-approved cancer treatments can be streamlined.¹⁶ Future activities will include ongoing educational resources and support to help oncologists adapt to new research approaches.
- **Advocating for Policy Changes.** In many ways, revitalization of clinical and translational cancer research will depend on action by policymakers, including regulatory agencies. ASCO will continue working to raise awareness and build support for needed policy changes through consensus development, research and modeling of the impact of policy changes, new publications, events and other advocacy over the coming years.

GLOSSARY

Clinical Cancer Research

The branch of medical science that tests the safety and effectiveness of promising new drugs, devices and diagnostic products in humans. This research is often conducted through clinical trials that involve human participants and serve as the vital link between discoveries in the lab and new treatments that improve the lives of patients.

Biomarkers

Substances or biological features arising in tumor tissue, blood or other bodily fluids that can be identified through tests and used to diagnose or monitor cancer and its response to treatment.

Cancer Stem Cells

A class of cells that gives rise to other forms of cancer cells, and are thought to be the most critical to attack in order to stop cancer's spread and recurrence.

Cancerous Cells

Cells that are at any stage of becoming a cancer, from pre-cancer states to advanced cancer.

Genomics

The study of how specific genes, and genetic mutations, work together to influence the function of a cell. In oncology, researchers focus on identifying and targeting the genes, proteins and molecular pathways that enable cancer cells to develop, replicate, spread and resist certain therapies.

Health Information Technology

Health information technology (HIT) describes the management of health data that is shared securely – among health care providers, patients, researchers and insurers – through electronic health records and other technologies. Recent advances in HIT promise to help dramatically improve the quality of health care and allow researchers to more quickly identify and share promising treatment approaches.

Molecular Characterization

The process of analyzing cancer cells to evaluate the genes, proteins and biological pathways that drive cancer growth.

Nanotechnology

A field of technology utilizing materials on a scale 10,000 times smaller than a human cell to treat disease or accomplish other tasks, e.g., nanoparticles. Because of their very small size, these technologies offer potential new ways to deliver treatments directly to cancer cells.

Panomics

Panomics refers to the interaction of all biological functions within a cell and with other body functions, combining data collected by targeted tests (such as a HER2 test) and global assays (such as genome sequencing) with other patient-specific information. By synthesizing this information, researchers gain a deeper understanding of how multiple defects at the molecular level combine with factors in the tumor's environment to drive tumor development and behavior. This understanding is increasingly guiding drug development and targeted cancer therapeutic and prevention strategies.

Pathway

A series of interconnected genes and proteins that together control a certain function within a cell, such as cell division or death. Mutations anywhere along a pathway have the potential to disrupt normal cell function and result in cancer cell development and proliferation. Targeted drugs block specific cancer-related pathways, with the goal of causing cancer cell death while leaving healthy cells intact.

Patient-Reported Outcomes

Self-reported data from patients, most commonly related to symptoms, quality of life and other general health perceptions experienced during a medical treatment.

QOPI

ASCO's Quality Oncology Practice Initiative (QOPI[®], see: <http://qopi.asco.org/>) is a physician-led, practice-based quality-improvement program used by oncology practices in the U.S. It measures practices' performance against evidence-based guidelines, and against other U.S. oncology practices, to give physicians detailed feedback and tools for improving the care they provide.

Rapid Learning System for Cancer Care

ASCO's proposed Rapid Learning System for Cancer Care will harness cutting-edge health information technology to connect cancer patients and their health care providers to a central knowledge base; synthesize information from millions of physician and patient experiences; and deliver up-to-the minute, personalized information to inform care for every patient. By collecting data in real time through electronic health records and other technologies, the system will also create a powerful new data source to generate new ideas for clinical research.

Surrogate Endpoint

As defined by the FDA, "A surrogate endpoint is a marker – a laboratory measurement, or physical sign – that is used in clinical trials as an indirect or substitute measurement that represents a clinically meaningful outcome, such as survival or symptom improvement. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval" (see: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/SpeedingAccess-toImportantNewTherapies/default.htm>). For example, researchers may focus on tumor shrinkage or various biomarkers that indicate a treatment is having an effect. By identifying and validating surrogate endpoints for use in future trials, researchers have the potential to gain faster answers about the value of new therapies.

Translational Cancer Research

Translational research transforms scientific discoveries arising from laboratory, clinical or population studies into clinical applications to reduce cancer incidence, morbidity and mortality.

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