syapse

Review: Trends in Oncology & Precision Medicine

syapse.com

Disclosures

- **Salary & Equity:** Syapse
- **Funding & Equity Holders:** Amgen, Merck, Roche
- **Honoraria:** Genentech

Syapse Mission

Enable healthcare providers to deliver the best cancer care for every patient through precision medicine

Syapse Overview

- **Founded:** 2008
- **Employees:** 125
- **Offices:** San Francisco (HQ), Philadelphia
- **Mission:** Improve cancer care today through precision medicine
- **Customers:** 12 health systems covering 285 hospitals, select pharmaceutical companies
- **Funding:** $70M
- **Investors:** Ascension Ventures, GE Ventures, Safeguard, Social Capital, Intermountain Healthcare, Amgen, Medidata Solutions, Merck, Roche

Oncology Practice is Entering a New Era

Cancer patients actively seek out care tailored to them

NGS is becoming a routine part of advanced cancer care

90% of cancer drugs in late phase trials target a molecular pathway

1st drug approval based on biomarker, instead of tumor site of origin

Targeted therapies require robust evidence to justify reimbursement

Value-based care models, like OCM, are shifting incentives

Barriers to Scaling Precision Medicine

Clinical data is siloed in multiple disparate systems

Molecular test results are stored as scanned images

Oncologists are unfamiliar with new targeted therapies and trials

Patient outcomes are not captured systematically

Payers may not reimburse for targeted drugs without strong evidence

Patients may refuse treatment due to high out-of-pocket costs

syapse

Syapse solves these challenges with a Provider-Driven Network

Provider Empowerment

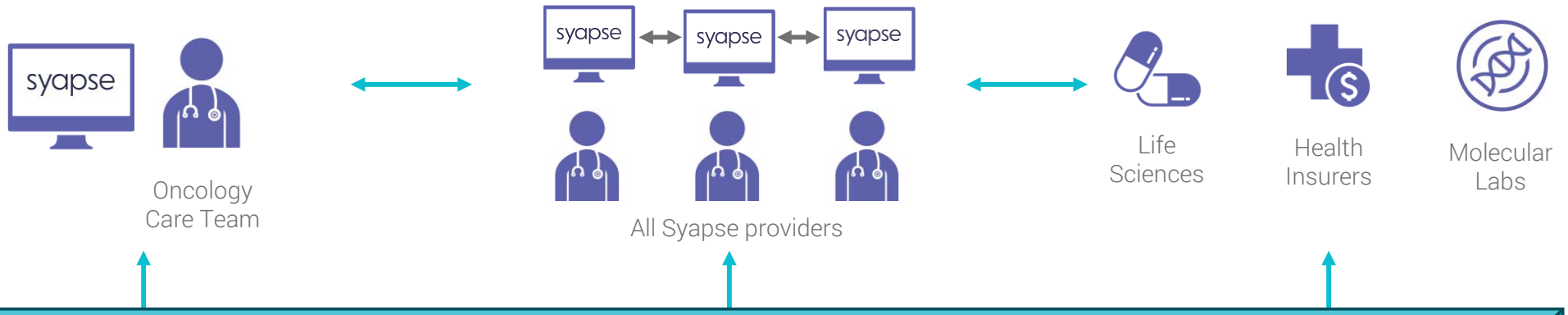
Care delivery & performance monitoring solutions empower providers

Learning Health Network

Networked providers share data and best practices across the network to improve clinical decisions

Ecosystem Partnerships

External partners connect to network to provide services and learn from real world outcomes



syapse

Cancer Moonshot: National Cancer Data Sharing Network

1,100 Oncology Providers

295 Hospitals

159,000 new cancer cases per year

syapse

ASCO 2017 State of Cancer Care in America:

AT A GLANCE

The U.S. cancer care delivery system is quickly transforming to better meet the needs of people with cancer. Advances in risk assessment, prevention, disease detection, drug development, and care delivery are leading to reduced rates of incidence and mortality for many common cancers, with more patients surviving their disease.

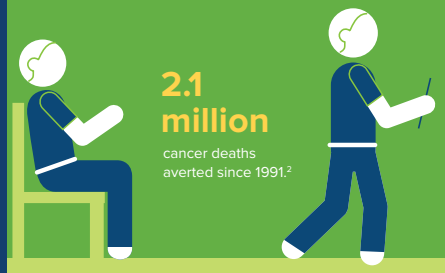
Despite these gains, more people will be diagnosed with common aging-associated cancers as the U.S. population continues to grow and age. Ensuring patients' access to affordable, high-quality care remains a critical challenge.

This "At A Glance" provides an overview of the American Society of Clinical Oncology's (ASCO) fourth annual State of Cancer Care in America report, which describes the progress in cancer care delivery and the challenges confronting the cancer care community.

The full-text version is published in the Journal of Oncology Practice at ascopubs.org/doi/10.1200/JOP.2016.020743.

A digital version of the "At A Glance" is available at asco.org/state-of-cancer-care.

20.3 million
cancer survivors predicted by 2026, a **31% increase** from 15.1 million survivors in 2016.[1]



2.1 million
cancer deaths averted since 1991.[2]

Progress & Opportunity

Tremendous activity is occurring across diverse stakeholders to improve the lives of patients with cancer.

52% of oncology practices share electronic health record (EHR) data with patients.

43% of physicians are already receiving some portion of their reimbursement under value-based systems.[8]

NEW APPROACHES: PRECISION MEDICINE AND IMMUNOTHERAPY

Greater investment in research is moving cancer care toward the full potential of precision medicine and treatment advances.

In 2016, the Food and Drug Administration approved:

- 16 new and expanded use cancer therapies[3]
- First liquid biopsy diagnostic test[4]
- First next-generation sequencing diagnostic test[5]

Meaningful improvements in survival for patients with some historically challenging diseases

34% of patients with metastatic melanoma **treated with new immunotherapy** in early clinical trial, alive after 5 years.[6]

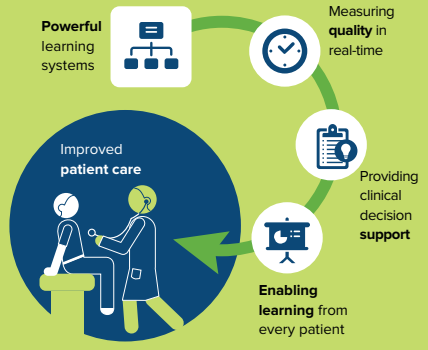
VS.

18% of U.S. patients **diagnosed with metastatic melanoma** between 2006 and 2012, alive after 5 years.[7]

By creating momentum among public and private enterprises, the **Beau Biden Cancer Moonshot Initiative** launched dozens of cutting-edge initiatives and cross-disciplinary partnerships. Congressional passage of the 21st Century Cures Act includes **$352 million** in supplemental National Institutes of Health funding to support the initiative.

CANCER MOONSHOT

REAL-WORLD EVIDENCE AND DATA SHARING



Rapid Learning Systems Driving Cancer Innovation

CancerLinQ® is the learning health system developed by ASCO to use the power of data analytics to 'learn' from each patient to improve cancer care delivery and patient outcomes.

70+ **vanguard practices** representing more than 2,000 physicians.

PRACTICE TRANSFORMATION

Innovative payment models promote and incentivize high-quality cancer care, while reducing costs and paving the way toward value-based reimbursement.

MACRA

The Centers for Medicare & Medicaid Services (CMS) triggered significant practice transformation through implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

Physicians may choose from **two options to derive their Medicare payments** starting in 2019

- **Advanced Alternative Payment Models** (APMs)
- **Merit-based Incentive Program** (MIPS)

Clinical Pathways

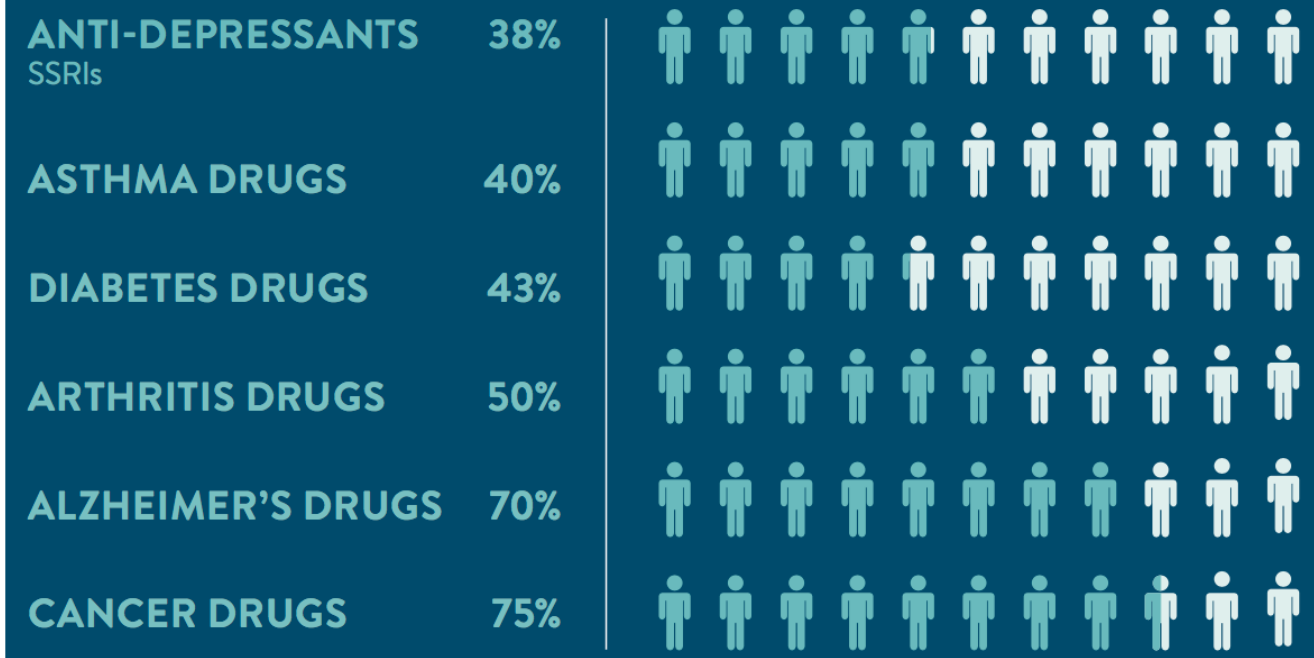
58% of surveyed oncology practices used clinical pathways in 2016.

Clinical pathways are increasingly used to **improve quality and reduce cost** by promoting adherence to evidence-based treatment plans.

- Standard figure in all precision medicine / oncology presentations, but this is from 2001!
- We've made some progress since then…

FIGURE 1: ONE SIZE DOES NOT FIT ALL

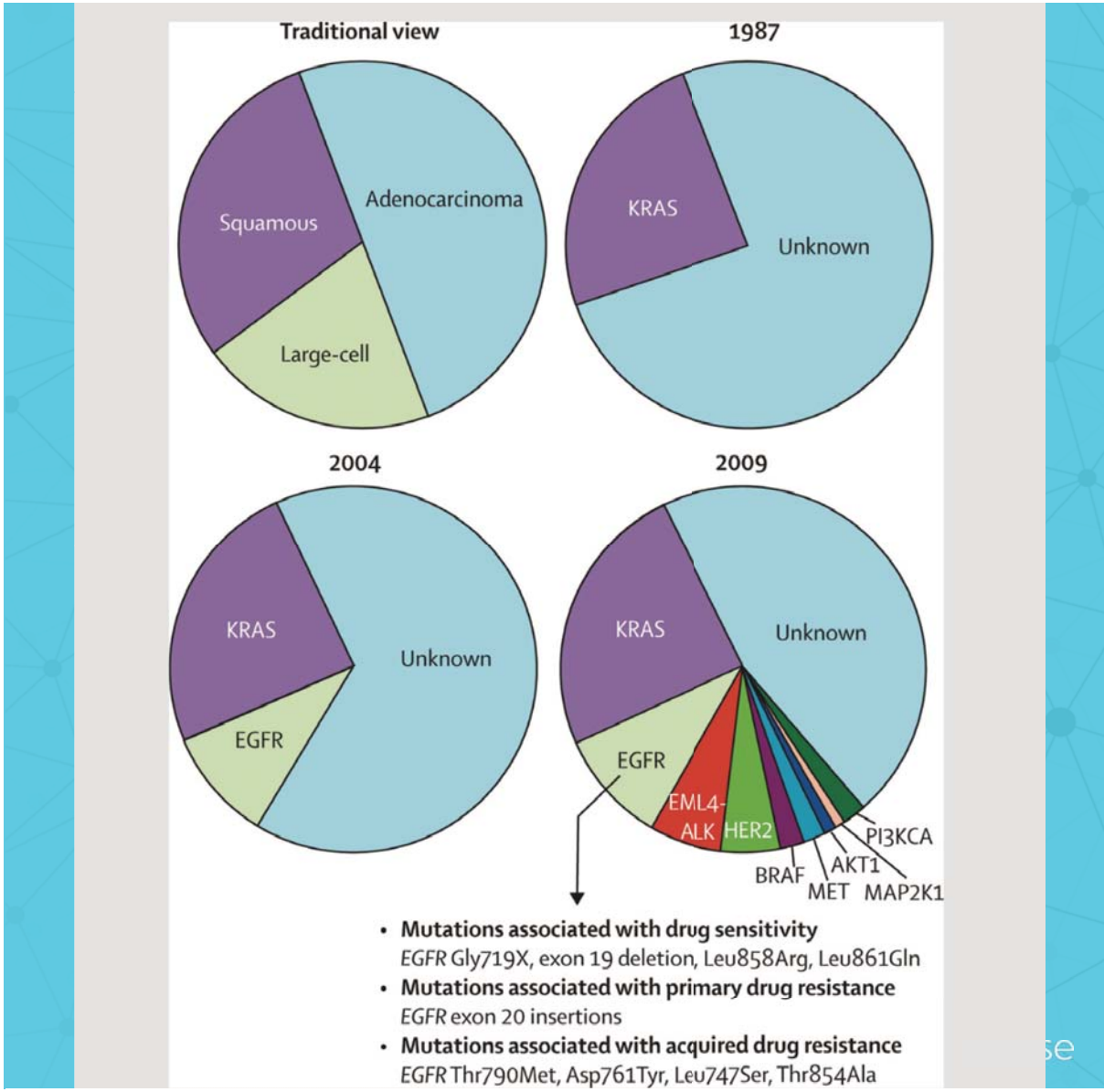
Percentage of the patient population for which a particular drug in a class is ineffective, on average.



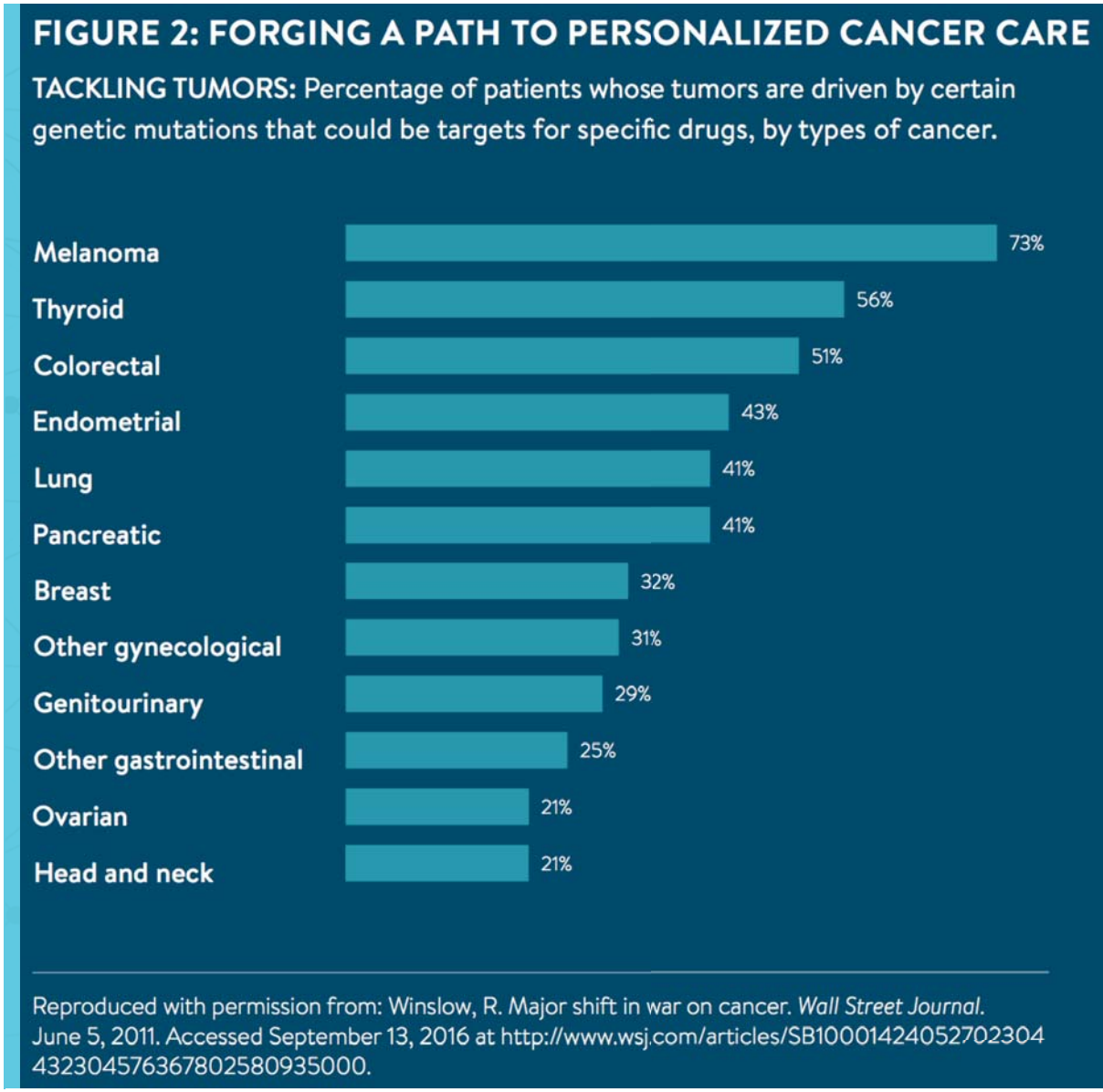
Reproduced with permission from: Spear, BB, Heath-Chiozzi, M, Huff, J. Clinical application of pharmacogenetics. *Trends in Molecular Medicine*. 2001;7(5): 201-204.

Non-Small Cell Lung Cancer

- Evolution from traditional histology-based view to molecular characterization



Pan-Tumor View



Luke Timmerman
@ldtimmerman

Following

Wrote about Vectibix for wild-type KRAS patients in 2008. Now FDA approved with next-gen sequencing Dx.

Xconomy: Amgen Cancer Drug Getting Personal, Which Ma...

Amgen is preparing to make an unusual argument to an FDA advisory panel tomorrow. The world's largest biotech company (NASDAQ:]), with research operations

xconomy.com

3:09 PM - 29 Jun 2017

syapse

Amgen Cancer Drug Getting Personal, Which May Be a Good Thing for Patients —and Sales

Luke Timmerman
December 15th, 2008

Xconomy Seattle — Amgen is preparing to make an unusual argument to an FDA advisory panel tomorrow. The world's largest biotech company (NASDAQ: **AMGN**), with research operations in Seattle and Cambridge, MA, plans to make a case that one of its drugs should be used by just a subgroup of patients with colorectal cancer who appear to be most likely to benefit from it.

Normally, drugmakers spend a lot of time and money trying to prove their products should be used by the broadest number of patients possible. This meeting will be closely watched by hundreds of cancer drugmakers, since it could be an important test case for the movement toward creating more personalized cancer medicines.

The hearing will focus on two colorectal cancer drugs that hit the same target that's a culprit in tumor proliferation, EGFR. The medicines, Amgen's panitumumab (Vectibix) and Eli Lilly's cetuximab (Erbitux), have both been shown in backward-looking statistical analyses to work much better for about 40 percent patients with a normal form of a gene called KRAS. If you're one of the unlucky others with a mutant form of KRAS, which makes cancer more aggressive, the drugs won't work. Since these treatments are hugely expensive, at $10,000 a month for the Lilly product and $8,000 a month for the Amgen version, there's a societal interest in genetic testing of these patients before they get treatment. It also could spare a whole lot of people the nasty skin rash and other side effects that come with the drugs, if they have little chance of benefit.

- “Amgen has concluded that the benefit/risk profile of panitumumab will be improved by restricting monotherapy use to those patients whose tumors have the wild-type (normal) KRAS gene,” the company said Friday in briefing **document** posted online.

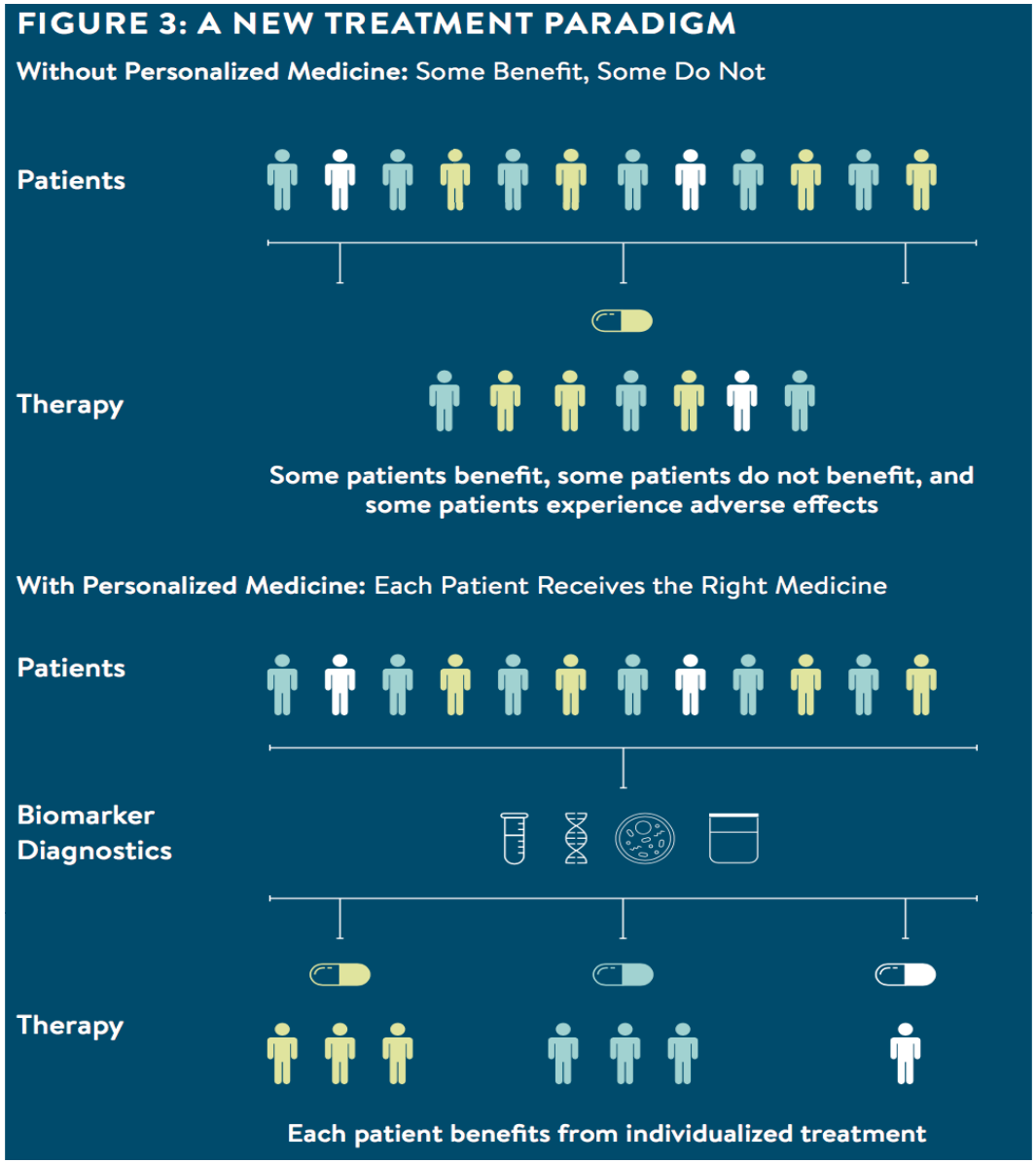
Luke Timmerman
@ldtimmerman

Following

Sure has. Precision medicine was mainly just a concept. DNA seq was expensive. Immuno-oncology was fringe idea. Totally different world now.

> **Jonathan Hirsch** @JonathanHirsch
> Wow, the cancer world has changed in the past 9 years !! #PrecisionMedicine twitter.com/ldtimmerman/st…

3:19 PM - 29 Jun 2017



syapse

Toward Precision Medicine

Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease

The National Academies of | SCIENCES ENGINEERING MEDICINE

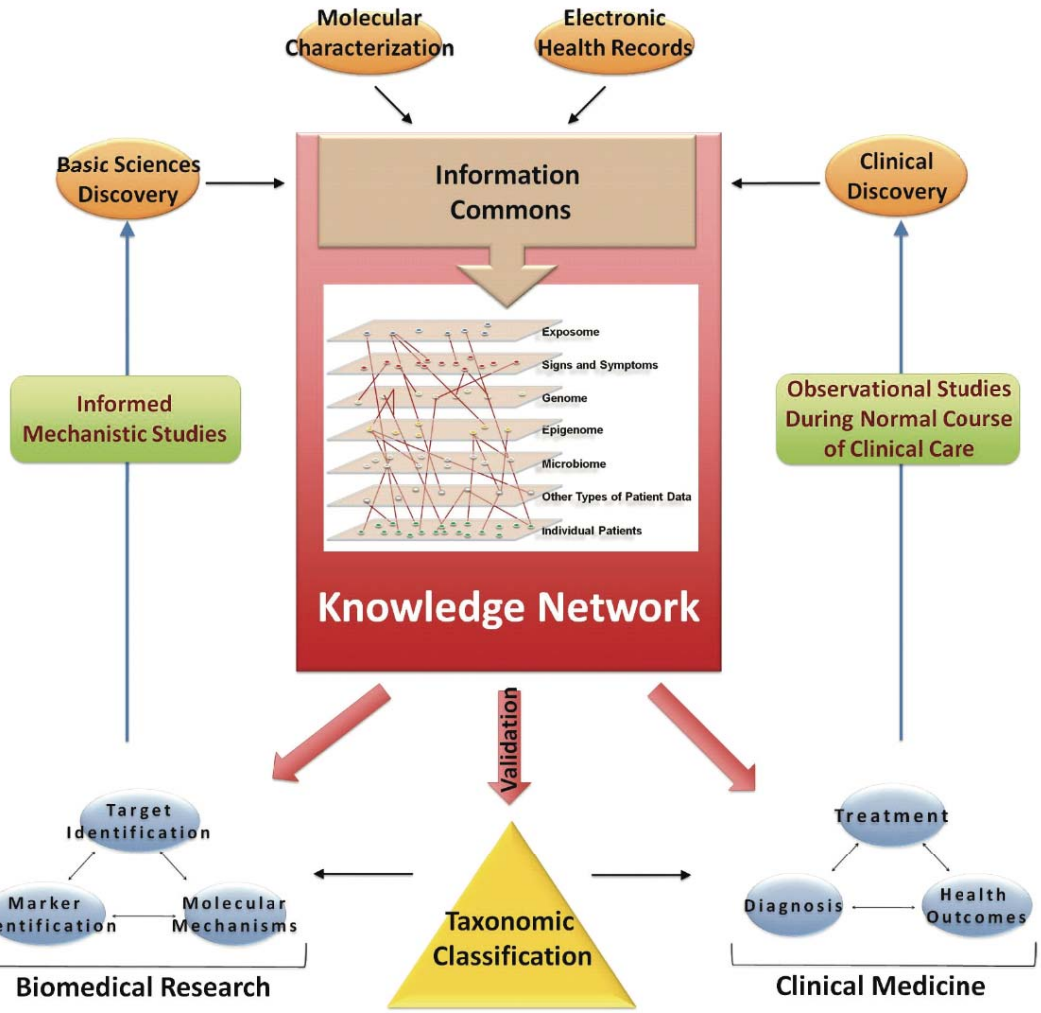
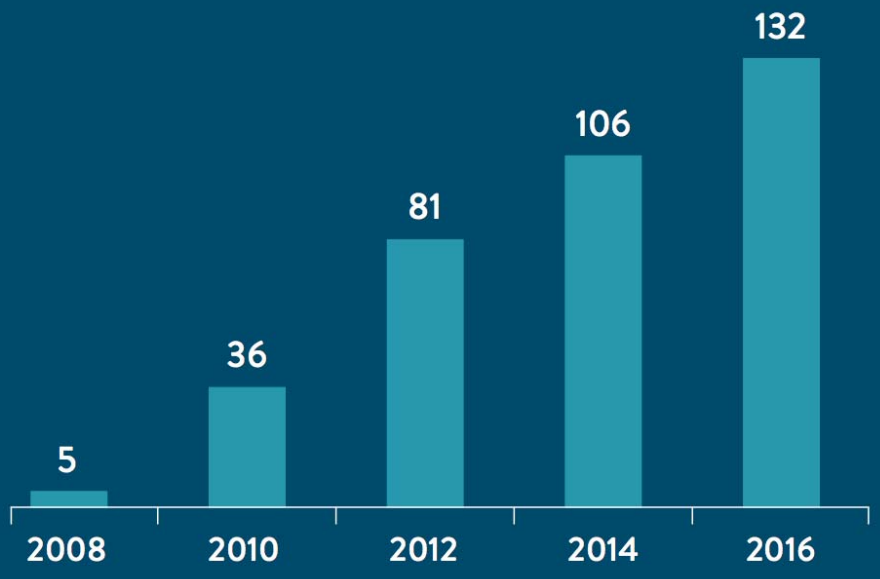


FIGURE 3-1 Building a biomedical Knowledge Network for basic discovery and Medicine.

FIGURE 4: COMING OF AGE

Number of Personalized Medicines Has Increased Steadily Since 2008*



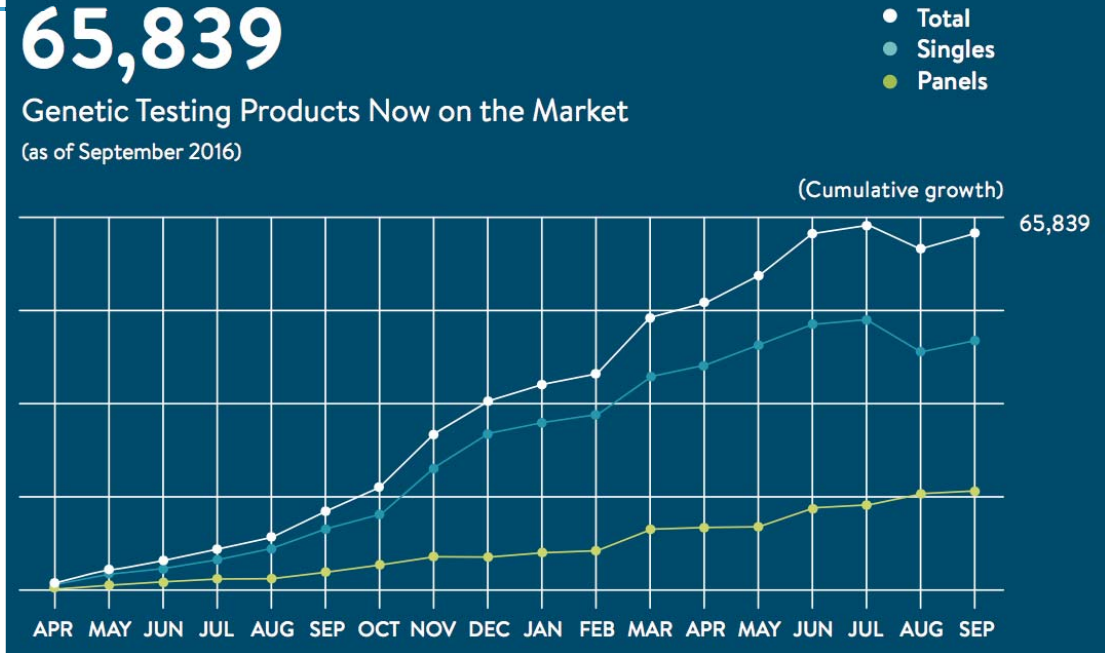
Personalized Medicine Coalition. *The Case for Personalized Medicine* (eds. 1–4). 2008–2014; Personalized Medicine Coalition. *Applications: Therapies.* Accessed October 31, 2016 at http://www.personalizedmedicinecoalition.org/Education/Therapies.

FIGURE 5: PROGRESS BY THE THOUSANDS

65,839

Genetic Testing Products Now on the Market

(as of September 2016)

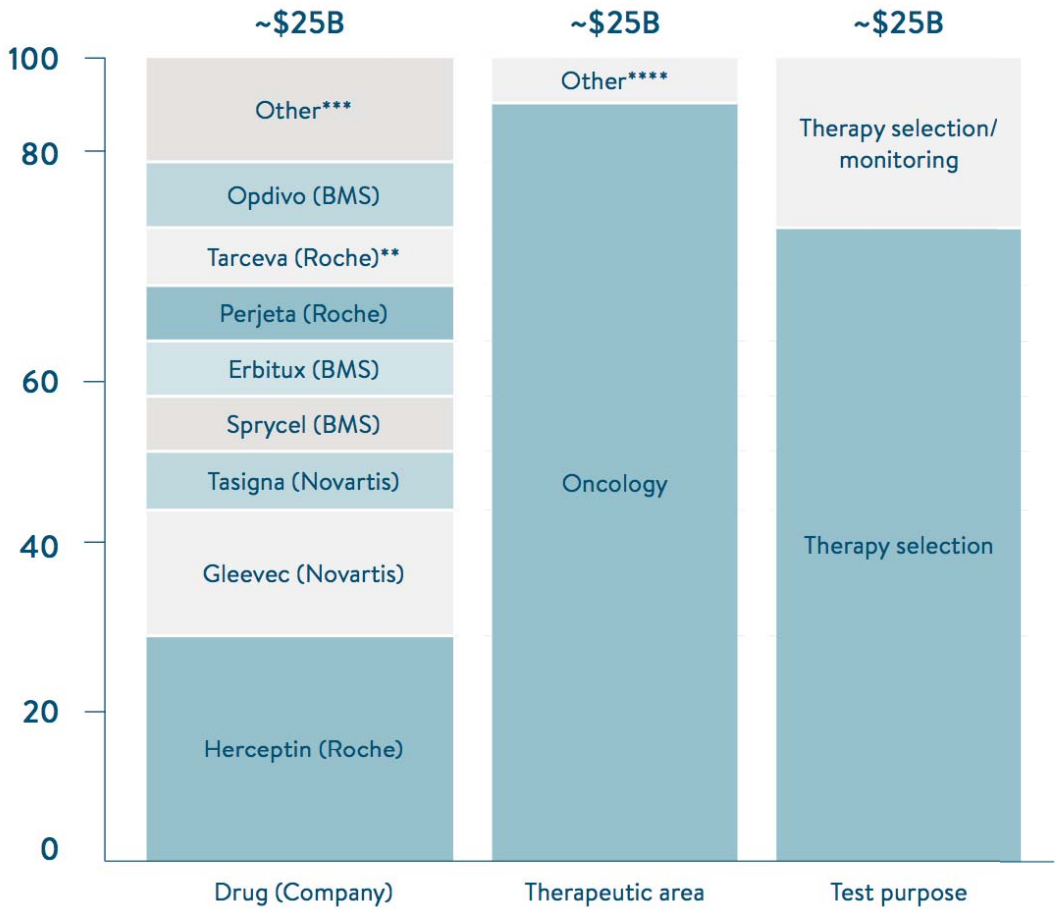


More Than 5,500 New Genetic Testing Products Came to Market Between April 2015 and September 2016*

syapse

FIGURE 6: MARKETED THERAPEUTICS RELIANT ON A CDx GENERATED ~$25 BILLION IN THERAPEUTIC REVENUES IN 2015

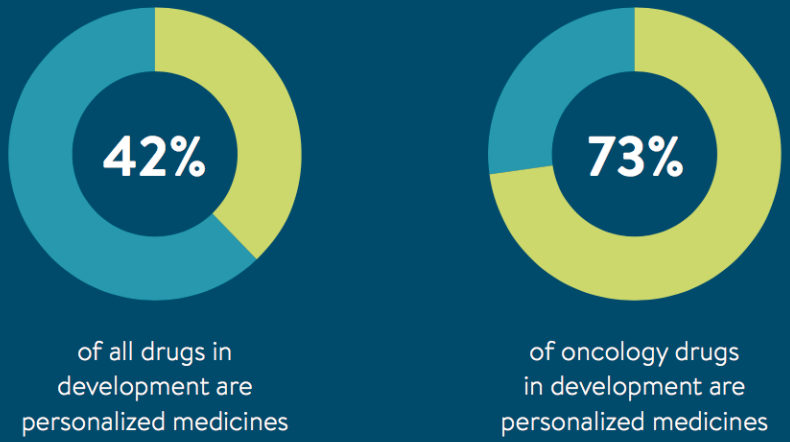
Biopharma worldwide marketed CDx drug revenue segmentation (2015)*
Percent of revenues



syapse

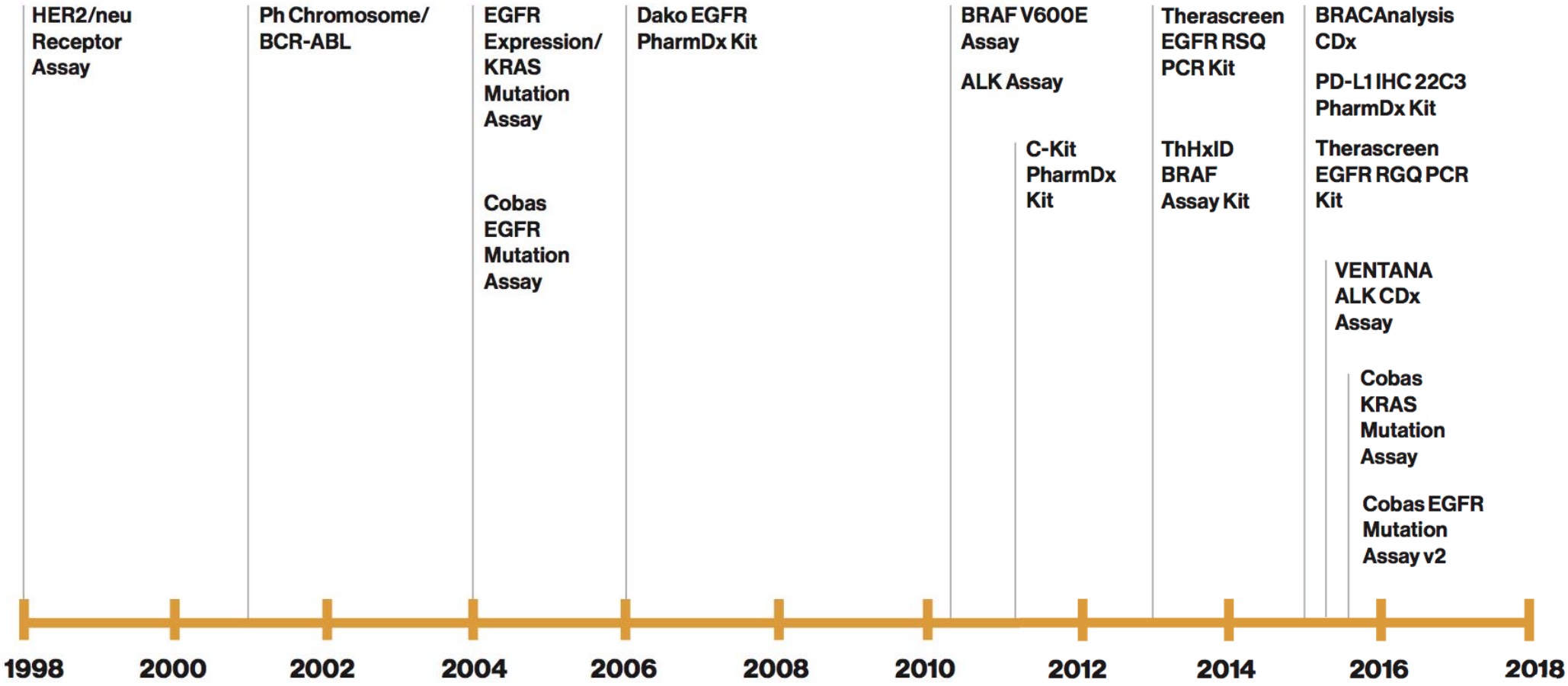
FIGURE 7: THE BIOPHARMACEUTICAL INDUSTRY IS COMMITTED TO PERSONALIZED MEDICINE

Drug development pipelines are full of targeted treatments that offer new hope for patients.



- **42%** of all compounds and **73%** of oncology compounds in the pipeline have the potential to be personalized medicines
- Biopharmaceutical companies **nearly doubled** their R&D investment in personalized medicines over the past five years, and expect to increase their investment by an additional 33 percent in the next five years
- Biopharmaceutical researchers also predict a **69%** increase in the number of personalized medicines in development over the next five years

Figure 6 | **Introduction of Cancer-Related Biomarker Tests and Companion Diagnostics Into the Market**



Initiatives Advancing Precision Medicine

In the last 4 years, numerous government and industry initiatives have fueled the growth and excitement about precision medicine (Figure 7)[21,24-32]:

- **March 29, 2012:** President Obama launches the Big Data Research and Development Initiative
- **July 15, 2012:** ASCO begins first phase of CancerLinQTM development
- **January 30, 2015:** President Obama launches the Precision Medicine Initiative (PMI)
- **July 10, 2015:** US House of Representatives passes the 21st Century Cures Act, a bill to accelerate the discovery, development, and delivery of 21st century cures
- **August 2015:** NCI Molecular Analysis for Therapy Choice (NCI-MATCH) trial opens for enrollment
- **December 15, 2015:** FDA launches the precision FDA Web platform to foster innovation and develop the science behind NGS
- **February 1, 2016:** Vice President Biden launches the Cancer Moonshot initiative
- **March 14, 2016:** ASCO Targeted Agent and Profiling Utilization Registry (TAPUR) trial opens for enrollment
- **May 27, 2016:** National Institutes of Health funds biobank to support PMI Cohort Program
- **June 6, 2016:** Cancer Moonshot task force launches the Genomic Data Commons database, which allows cancer researchers from anywhere in the world to upload data
- **December 7, 2016**: Senate passes the 21st Century Cures Act
- **December 13, 2016**: 21st Century Cures Act signed into law

ɔse

FDA News Release

FDA approves first cancer treatment for any solid tumor with a specific genetic feature

For Immediate Release May 23, 2017

Release

The U.S. Food and Drug Administration today granted accelerated approval to a treatment for patients whose cancers have a specific genetic feature (biomarker). This is the first time the agency has approved a cancer treatment based on a common biomarker rather than the location in the body where the tumor originated.

Keytruda (pembrolizumab) is indicated for the treatment of adult and pediatric patients with unresectable or metastatic solid tumors that have been identified as having a biomarker referred to as microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR). This indication covers patients with solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options and patients with colorectal cancer that has progressed following treatment with certain chemotherapy drugs.

DRUG	COMPANY	TARGETED MOLECULAR ALTERATION	STATUS
Pembrolizumab (Keytruda)	Merck	Mismatch repair deficiency	Approved 23 May
Larotrectenib (Loxo-101)	Loxo Oncology	TRK fusions	Phase II
Entrectenib	Ignyta	TRK, ALK, and ROS1 fusions	Phase II
Loxo-195	Loxo Oncology	Loxo-101 resistant TRK fusions	Phase I
Loxo-292*	Loxo Oncology	RET fusions and activating point mutations	Phase I
RXDX-105*	Ignyta	RET alterations	Phase I
TPX-0005	TP Therapeutics	TRK, ALK, and ROS1 fusions	Phase I/II
BLU-667*	Blueprint Medicines	RET alterations	Phase I/II

*Agnostic indication contingent on early trial data

DRUG	COMPANY	TARGETED MOLECULAR ALTERATION	STATUS
Pembrolizumab (Keytruda)	Merck	Mismatch repair deficiency	Approved 23 May
Larotrectenib (Loxo-101)	Loxo Oncology	Positive Ct Results; Bayer	Phase II
Entrectenib	Ignyta	Roche	Phase II
Loxo-195	Loxo Oncology	Loxo-101 resistant TRK fusions	Phase I
Loxo-292*	Loxo Oncology	RET fusions and activating point mutations	Phase I
RXDX-105*	Ignyta	Roche	Phase I
TPX-0005	TP Therapeutics	TRK, ALK, and ROS1 fusions	Phase I/II
BLU-667*	Blueprint Medicines	RET alterations	Phase I/II

*Agnostic indication contingent on early trial data

FDA News Release

FDA approval brings first gene therapy to the United States

CAR T-cell therapy approved to treat certain children and young adults with B-cell acute lymphoblastic leukemia

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

For Immediate Release August 30, 2017

syapse

FDA News Release

FDA approval bring United States

CAR T-cell therapy approved to treat c lymphoblastic leukemia

SHARE | TWEET | LINKEDIN | PIN IT

For Immediate Release

August 30, 20

The U.S. Food and Drug Administration issued a historic action today making the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases.

The FDA approved Kymriah (tisagenlecleucel) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL).

"We're entering a new frontier in medical innovation with the ability to reprogram a patient's own cells to attack a deadly cancer," said FDA Commissioner Scott Gottlieb, M.D. "New technologies such as gene and cell therapies hold out the potential to transform medicine and create an inflection point in our ability to treat and even cure many intractable illnesses. At the FDA, we're committed to helping expedite the development and review of groundbreaking treatments that have the potential to be life-saving."

Kymriah, a cell-based gene therapy, is approved in the United States for the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse.

Kymriah is a genetically-modified autologous T-cell immunotherapy. Each dose of Kymriah is a customized treatment created using an individual patient's own T-cells, a type of white blood cell known as a lymphocyte. The patient's T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains a specific protein (a chimeric antigen receptor or CAR) that directs the T-cells to target and kill leukemia cells that have a specific antigen (CD19) on the surface. Once the cells are modified, they are infused back into the patient to kill the cancer cells.

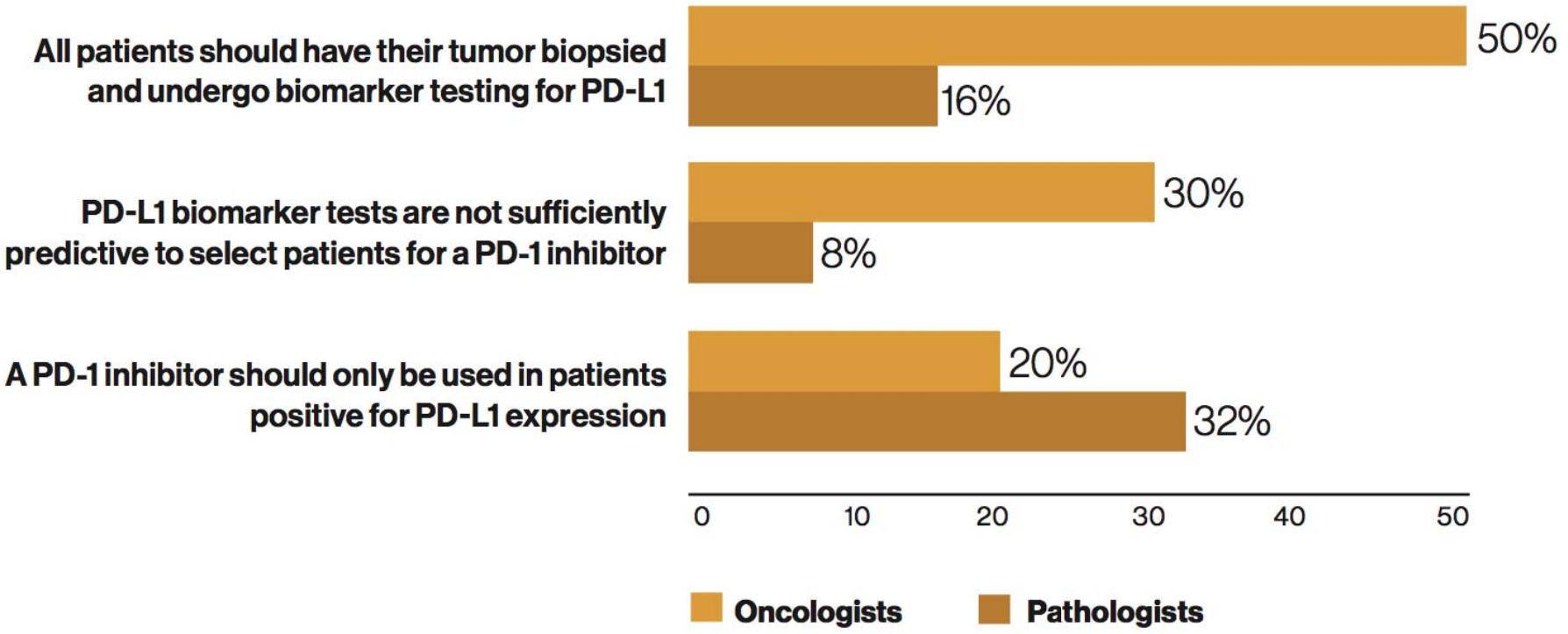
Closing the Knowledge Gap

- How do we arm physicians, health systems, and payers to deal with this wave of precision oncology?

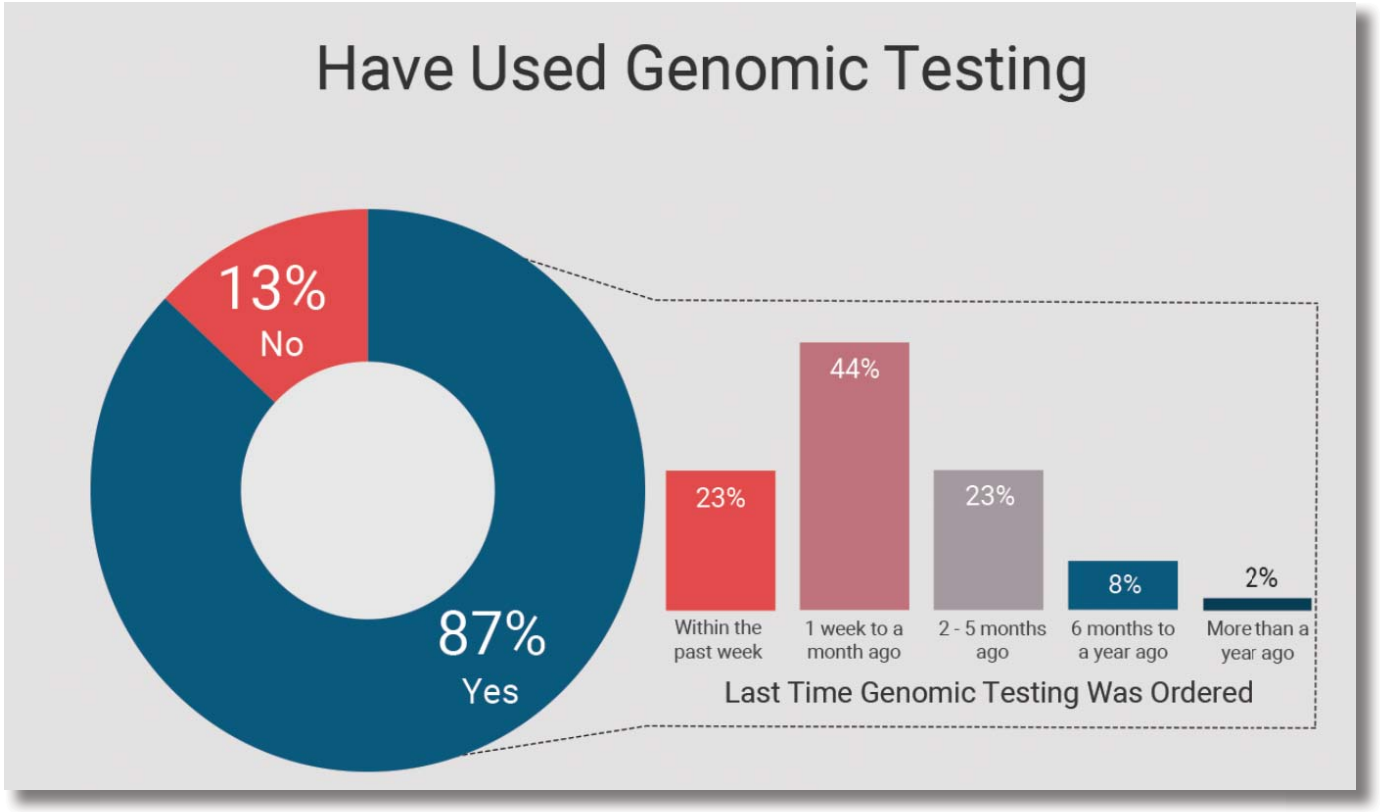
PD-L1 Biomarker Testing for Patients With NSCLC

Almost one-third of oncologists expressed concerns with PD-L1 biomarker testing and using it to select patients for a PD-1 inhibitor who fail first-line therapy (Figure 8).

Figure 8 | **Providers Who Strongly Agree With the Following Statements Regarding PD-1 and PD-L1 Biomarkers**



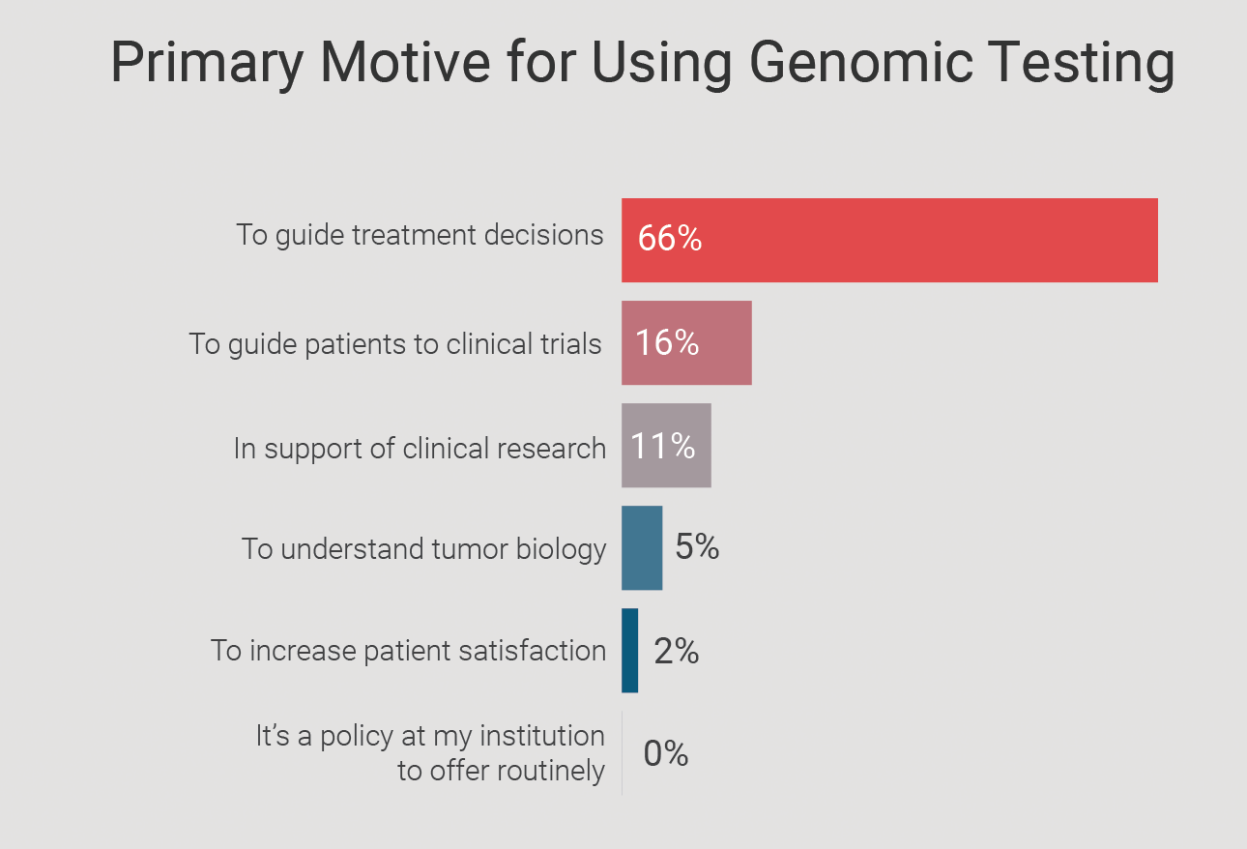
Most oncologists are ordering some molecular testing…



1 West and Miller, 2017, Medscape. "Genomic Testing and Precision Medicine in Cancer Care"

syapse

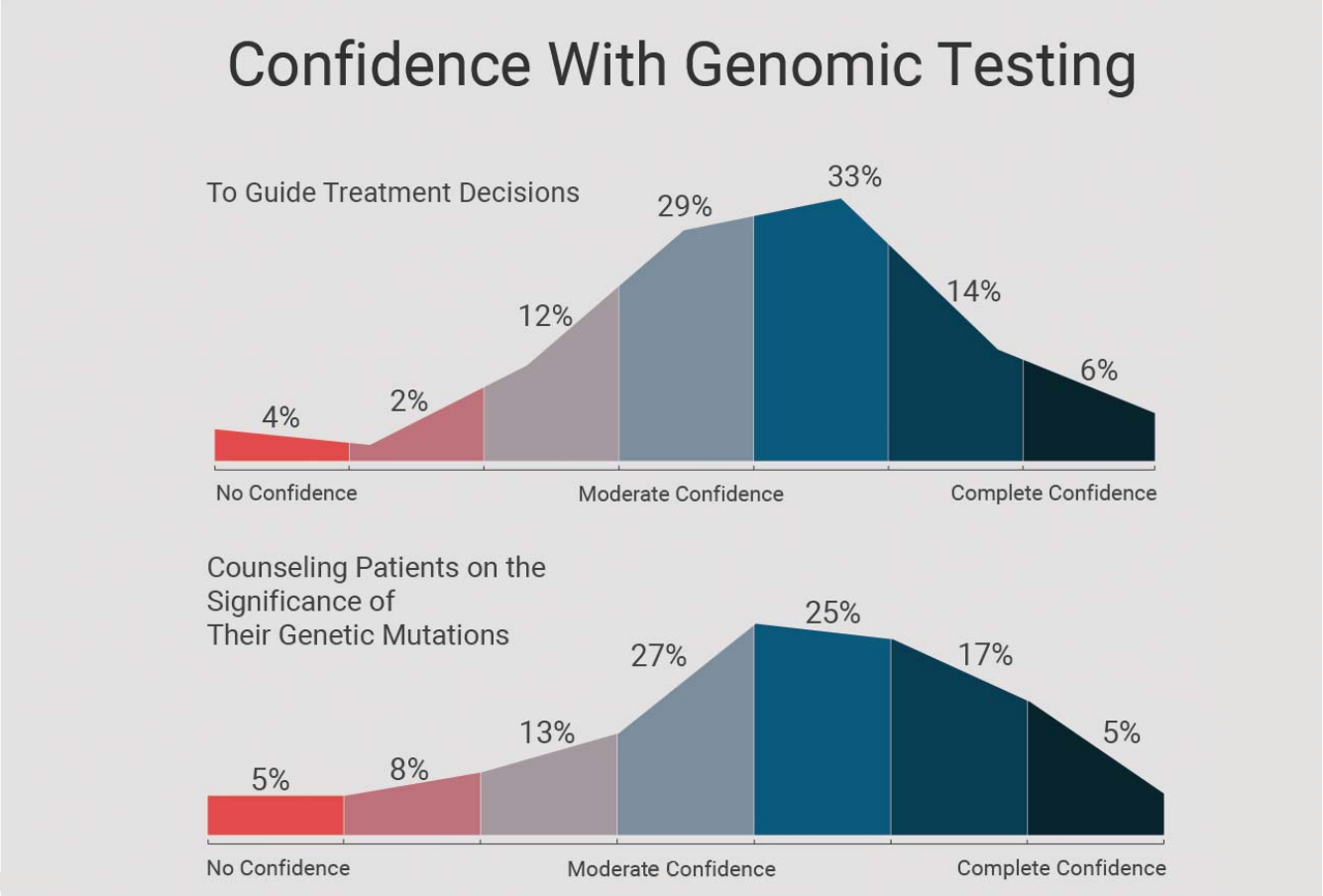
And ordering it to guide treatment decisions…



1 West and Miller, 2017, Medscape. "Genomic Testing and Precision Medicine in Cancer Care

syapse

But they're not fully prepared to use the information to make treatment decisions



syapse

Overall Concerns With Genomic Testing

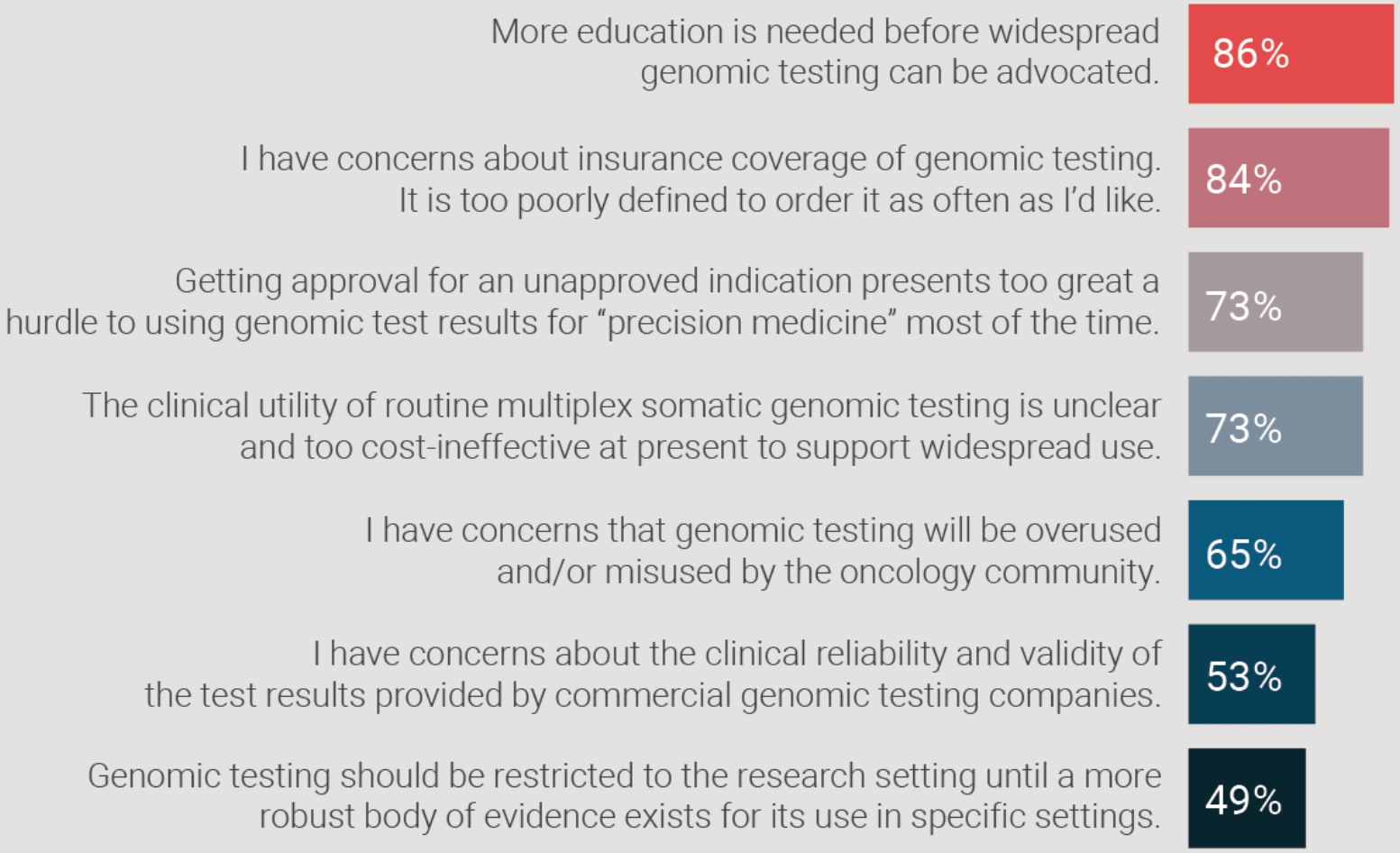


Figure 11 | **Oncologists' Concerns When Ordering a Biomarker Test: 2016 vs 2015**

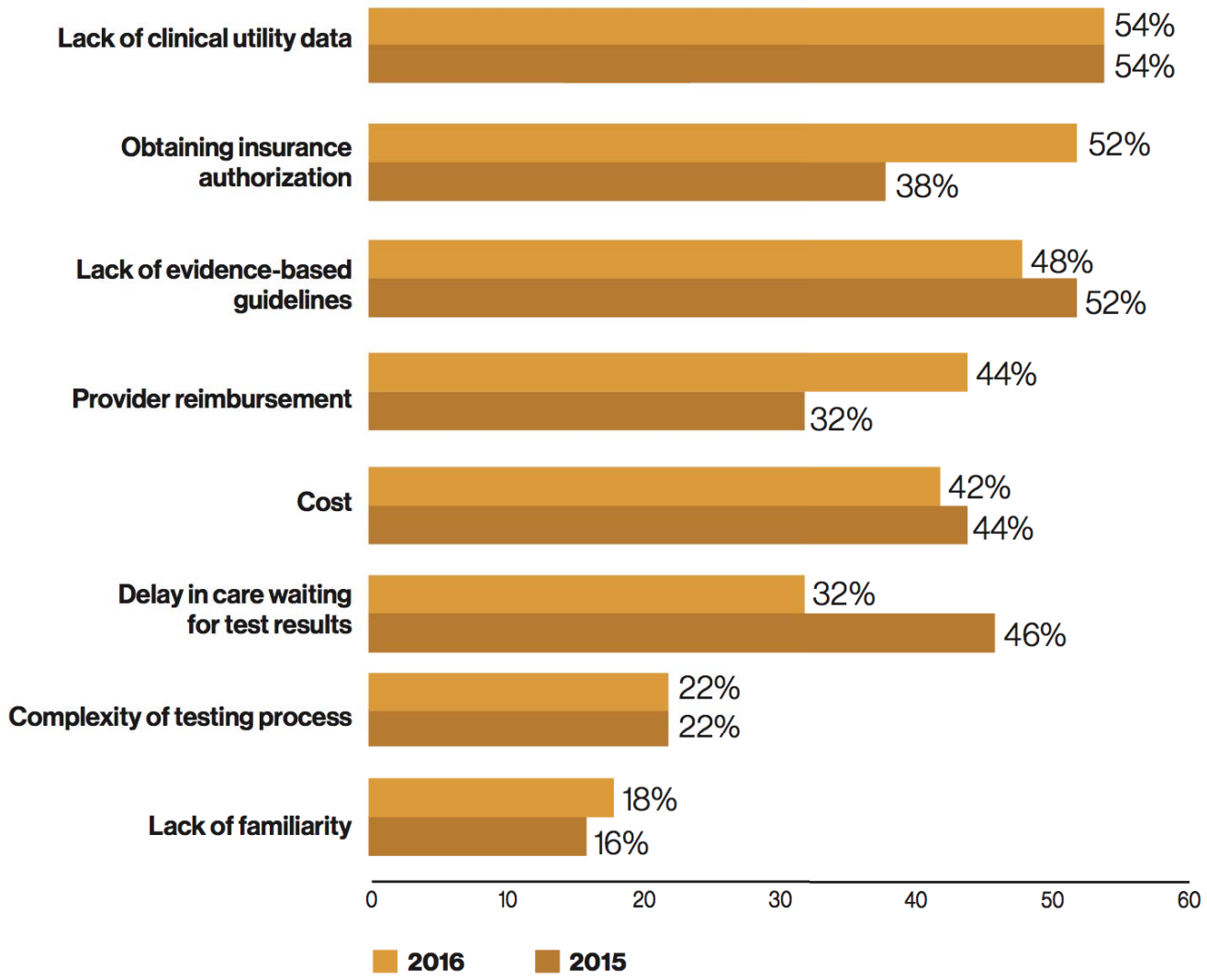


Figure 14 | **Percent of Providers Using Pathways and/or Guidelines from Payers**

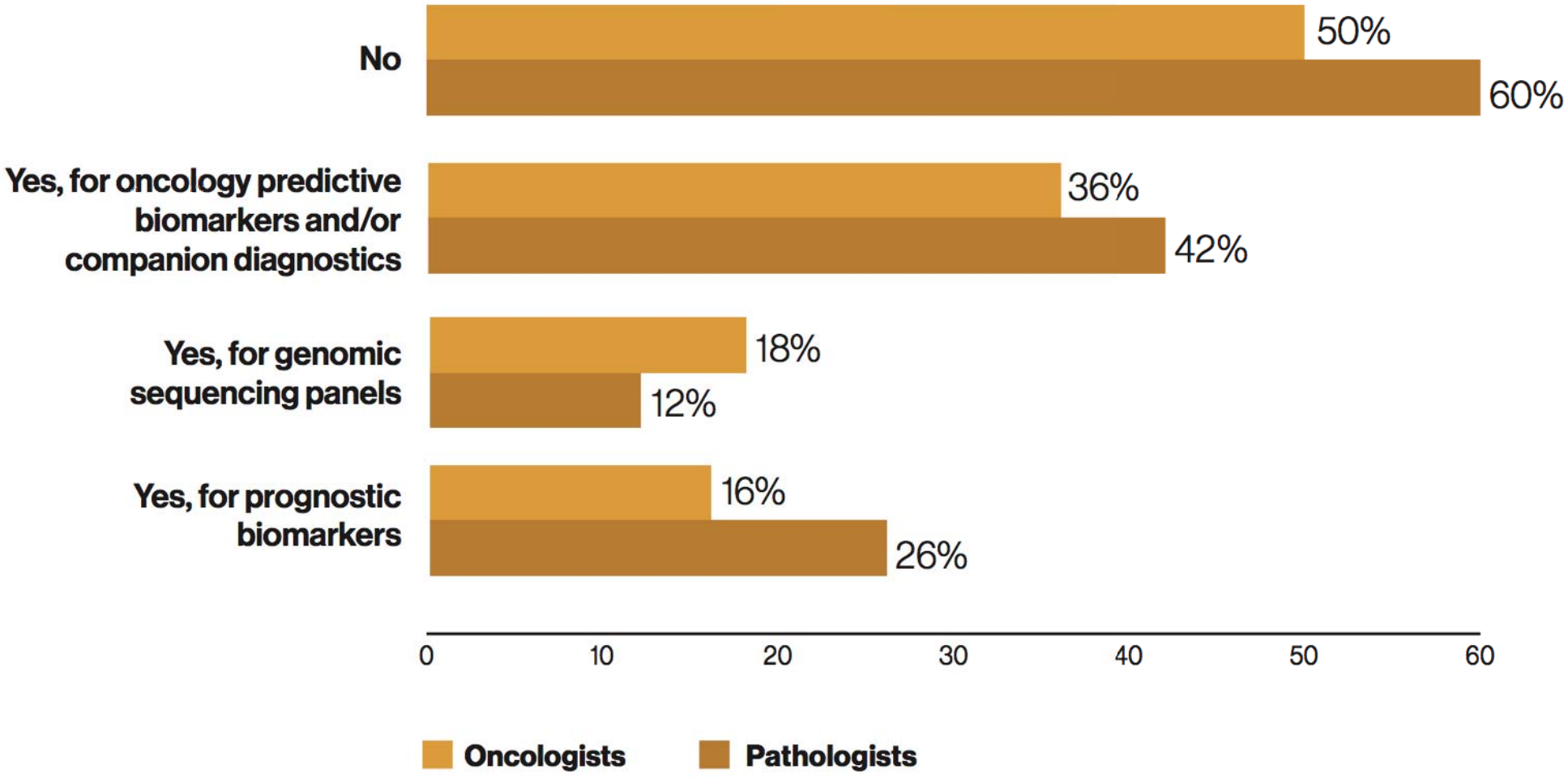


Figure 20 | **Most Important Factors for Payers When Making Coverage Decisions for Targeted Therapies**

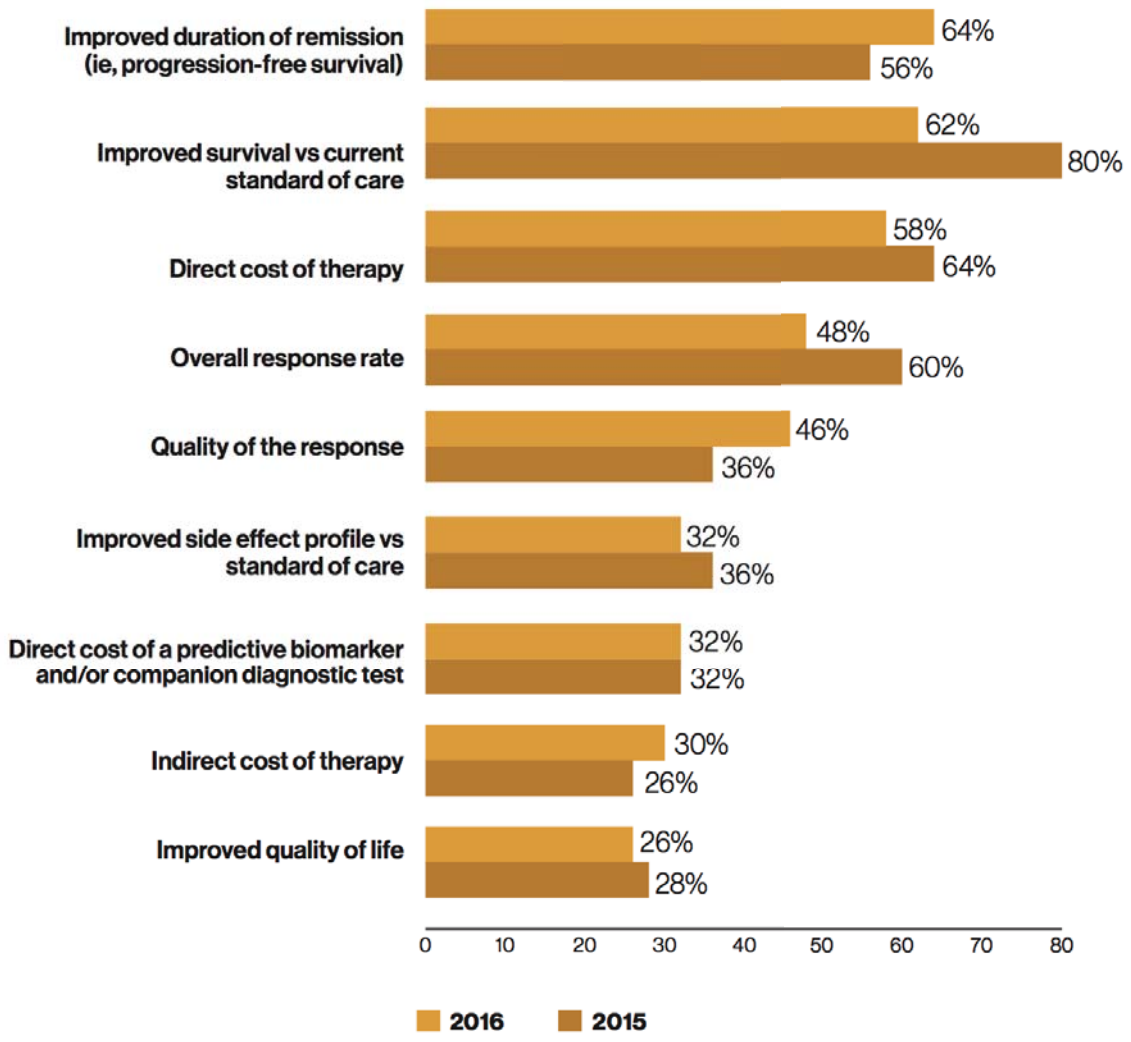
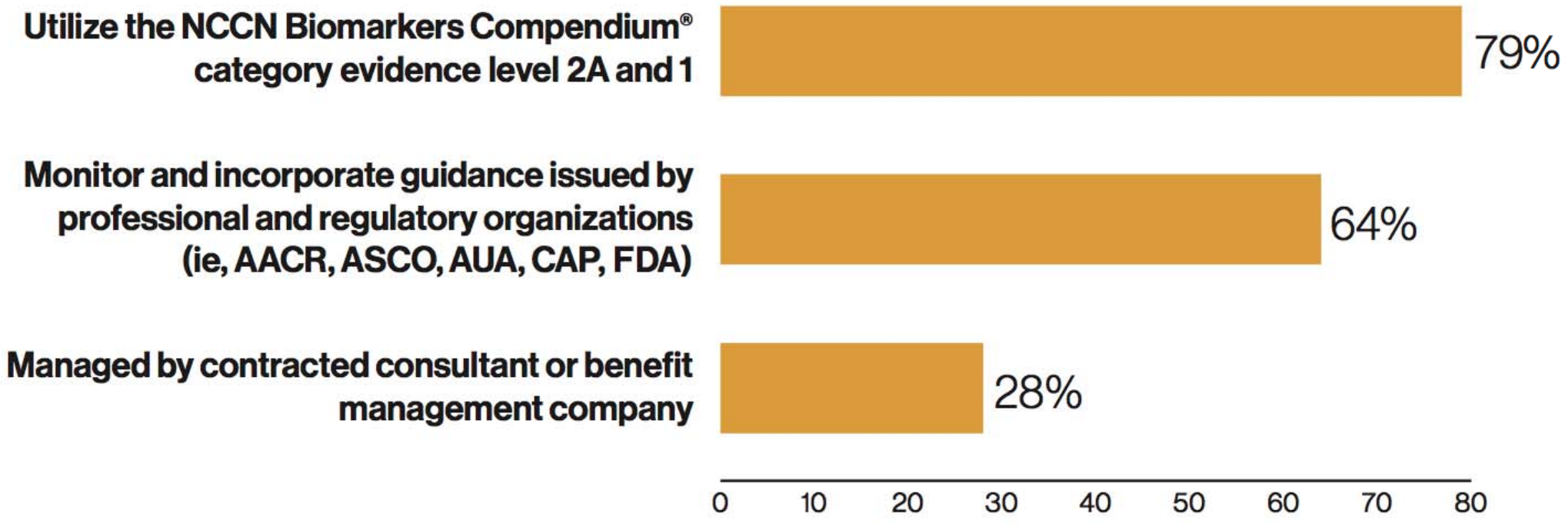


Figure 30 | **Payers' Use of Third Parties to Guide Coverage Decisions for Oncology Predictive Biomarkers**



syapse

POLICY FORUM

HEALTH POLICY

Insurance for broad genomic tests in oncology

Insurance coverage should precede rather than follow clinical validation of broad genomic testing in oncology

By **Rebecca Eisenberg**[1] *and* **Harold Varmus**[2] | needed to evaluate clinical utility of such test-

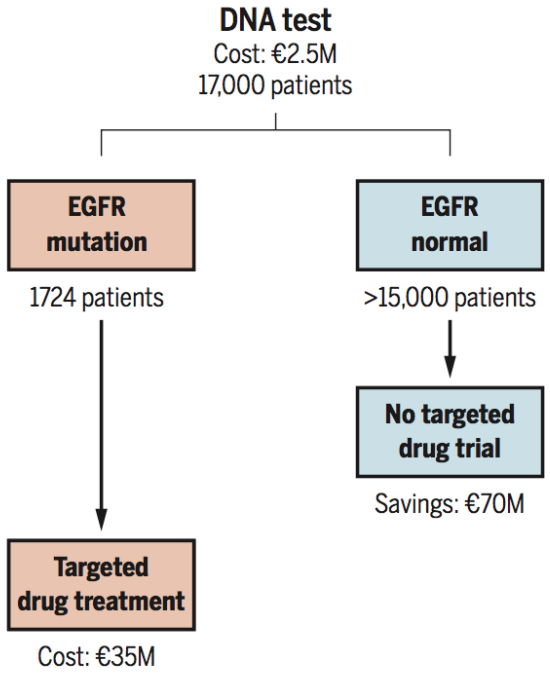
Science

Insurance for broad genomic tests in oncology
Rebecca Eisenberg and Harold Varmus

Science **358** (6367), 1133-1134.
DOI: 10.1126/science.aao6708

The economic benefit of testing for somatic mutations in cancers

Without testing for mutation in the gene encoding the epidermal growth factor receptor (EGFR), all patients with lung adenocarcinoma would receive an 8-week trial of a drug targeting the EGFR and continue with treatment only if they showed an image-validated response. Patients in this 2010 study (*19*) whose tumors were found to have a mutation in the EGFR-encoding gene were treated with the targeted drug; the other patients were spared the costs and delay of an 8-week trial for a drug that would not work for them.



syapse

Analysis of Reimbursement for Next Generation Sequencing (NGS) on Patients' Tumors in the Context of a Personalized Medicine Program

Brown TD[1], Tameishi M[1], Liu X[1], Scanlan JM[2], Beatty JD[1], Drescher CW[1], Pagel JM[1], Gold PJ[1], Alexander S[1], Summers LK[1], Brindle M[1], Varghis N[1], Yates J[1], Fondren KN[3], Birchfield GR[1], Dong DE[1], Benkers TL[1,4], Wahl TA[1], Ramsey SD[5], Berry AB[1,3].

[1]Swedish Cancer Institute, Seattle, WA; [2]Swedish Medical Center, Seattle, WA; [3]CellNetix Pathology & Laboratories, Seattle, WA; [4]Swedish Neuroscience Institute, Seattle, WA; [5]Fred Hutchinson Cancer Research Center, Seattle, WA

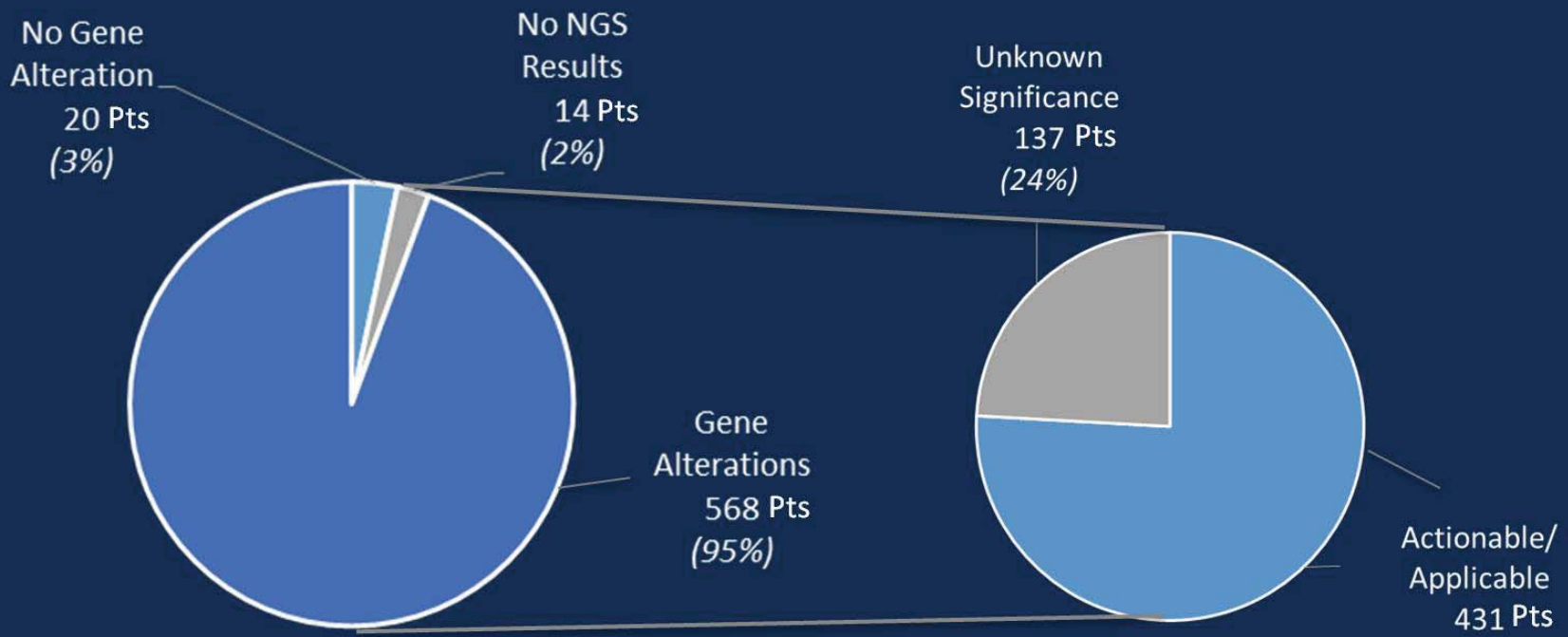
PRESENTED AT: ASCO ANNUAL MEETING '17 | #ASCO17

Presented by: Thomas D. Brown, MD, MBA

Abstract #6506

SCI PMRP: NGS Results

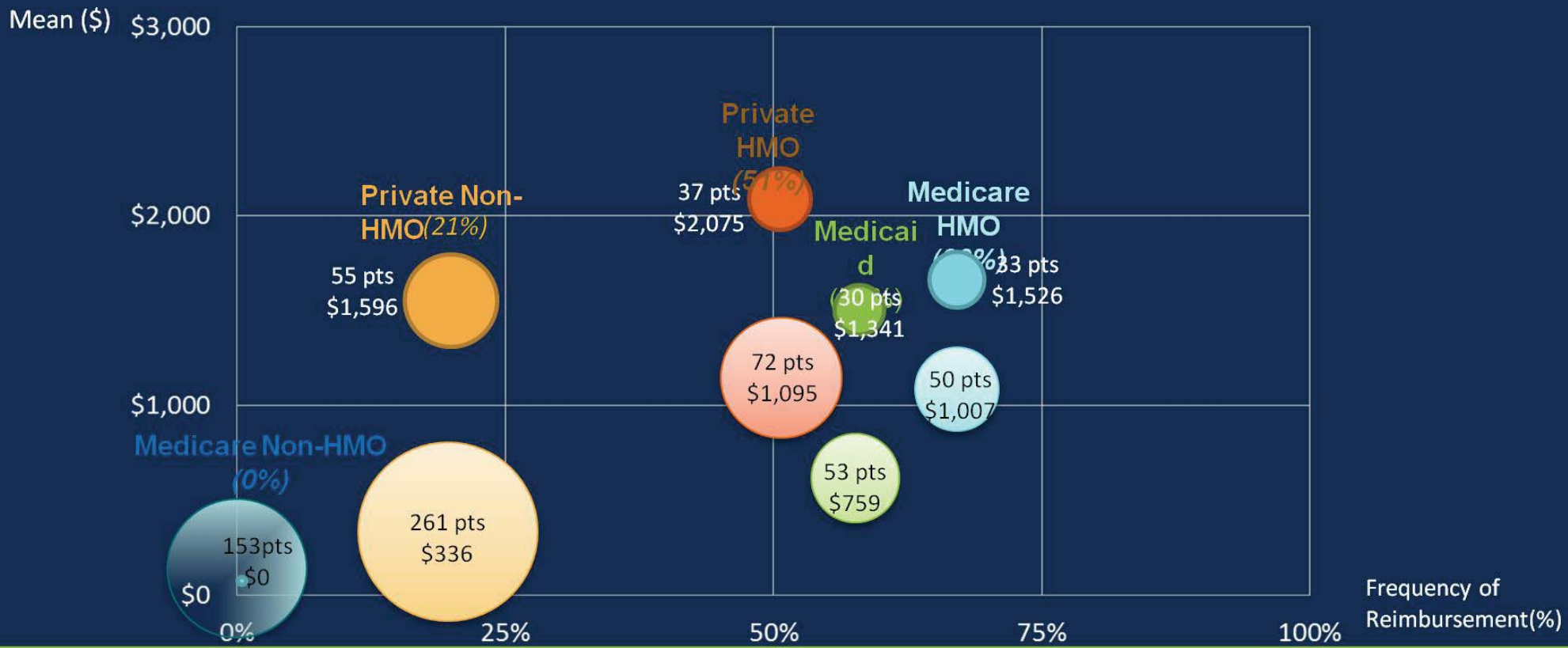
Evaluable 602 Pts with NGS Cases



# of Pts
(%)

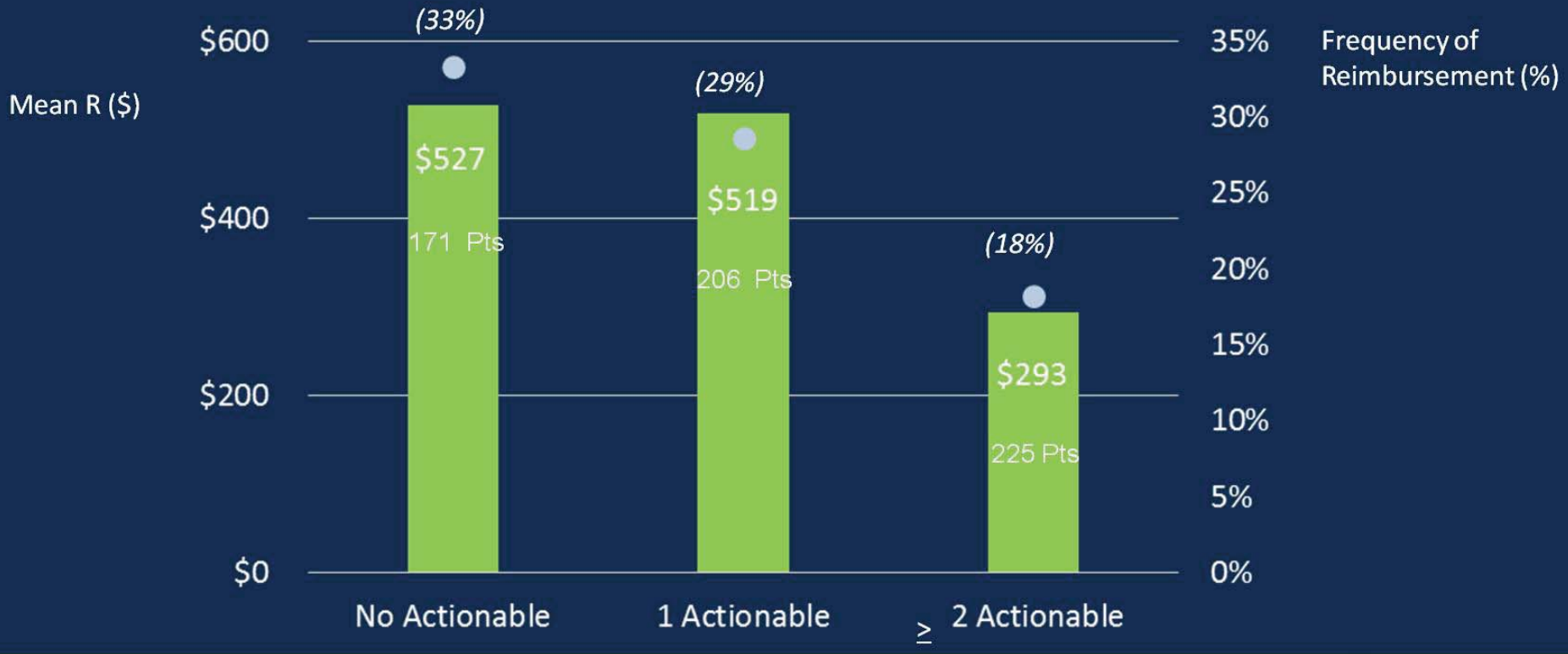
Reimbursement Frequency and Payment by Payer

- Medicare HMO has higher frequency of reimbursement than Private HMO (p<.04).
- Payments by both Private and Medicare HMOs were higher than other payers (p<.001).



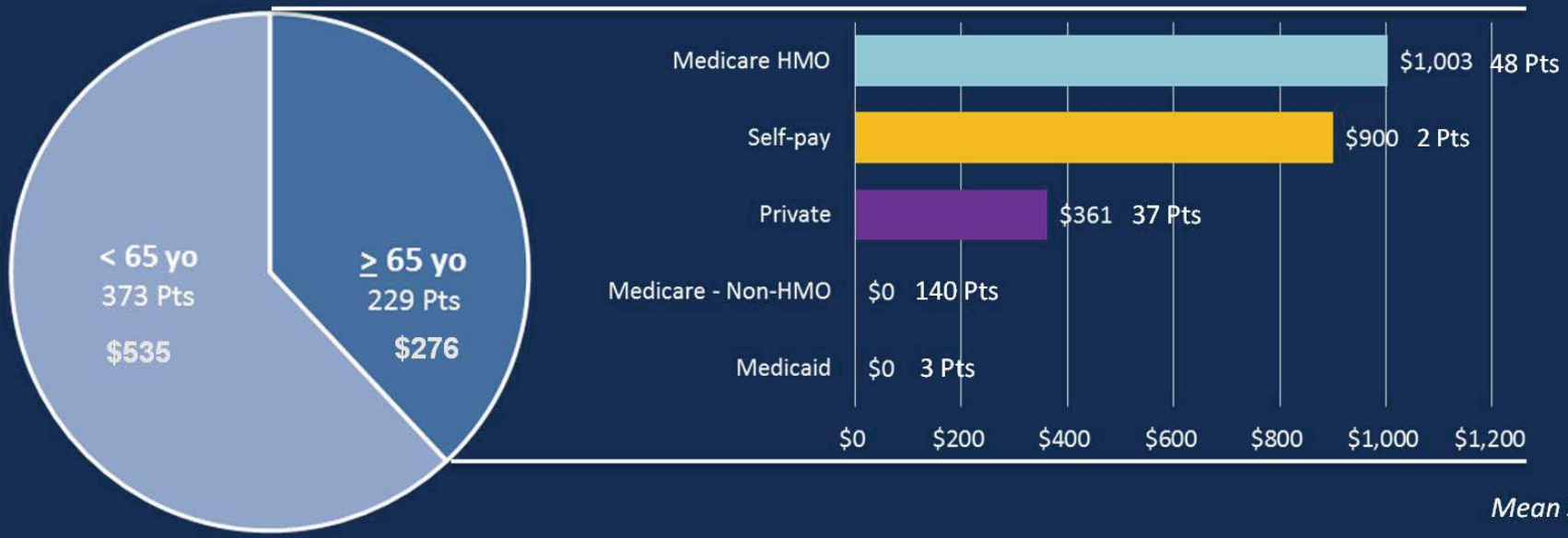
Association of Actionability with Reimbursement

- Frequency of reimbursement and payment for pts with ≥ 2 actionable mutations were significantly lower than for pts with 0 or 1 actionable mutations ($p < .01$) .



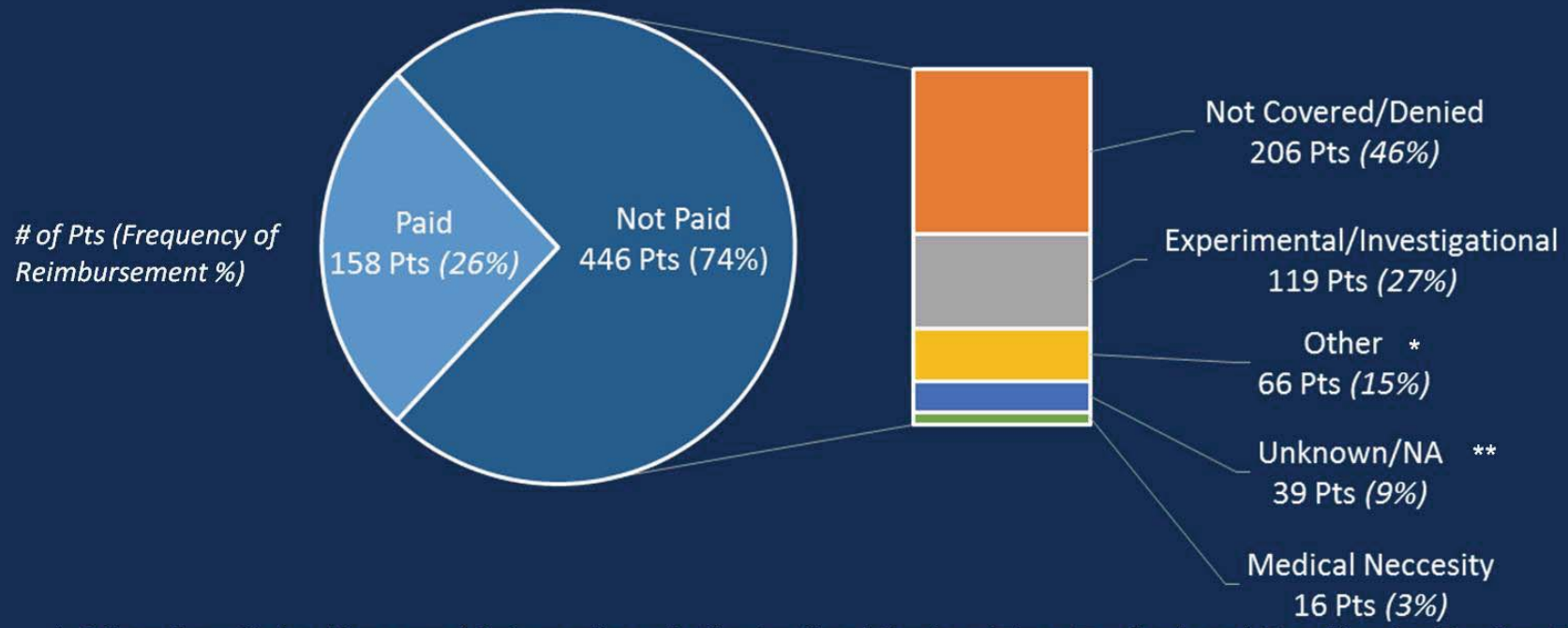
Association of Age with Reimbursement

- Younger age was associated with more frequent and higher reimbursement (31% in pts < 65 years, 17% in pts ≥ 65 yo) (p < .001).
- Among pts ≥ 65 yo, frequency (p < .001) and payments (p < .005) by Medicare HMO (69%; $1,003) were higher than Private payers (19%; $361).



NGS Reimbursement Denial Based on Denial Codes

- Denials based on "not covered," and "investigational therapy" were the most common reasons for lack of reimbursement.



** Other: Insufficient/Incorrect Information; Authorization Missing; Time Expired and Pending for Further Review, etc.*

*** Unknown/NA: Denial Codes Not Documented.*

Conclusions

- One third of patients received some reimbursement for NGS testing.
- Reimbursement was more frequent and higher in managed care programs, both Private and Medicare. No reimbursement was received from non-HMO Medicare.
- Reimbursement was more likely for younger age patients.
- Actionable NGS results were associated with less frequent and lower reimbursement.

Conclusions (Cont'd)

- Neither cancer diagnosis nor stage were significantly associated with reimbursement.
- "Not covered" and "Investigational" were the most common reasons for denial.
- These data demonstrate the need for rational, transparent, and consistent reimbursement policies, along with a value-based reimbursement model for NGS across all payer groups.

Figure 31 | **Providers' Report on Specificity of Typical Biomarker Utilization Guidance/Pathway**

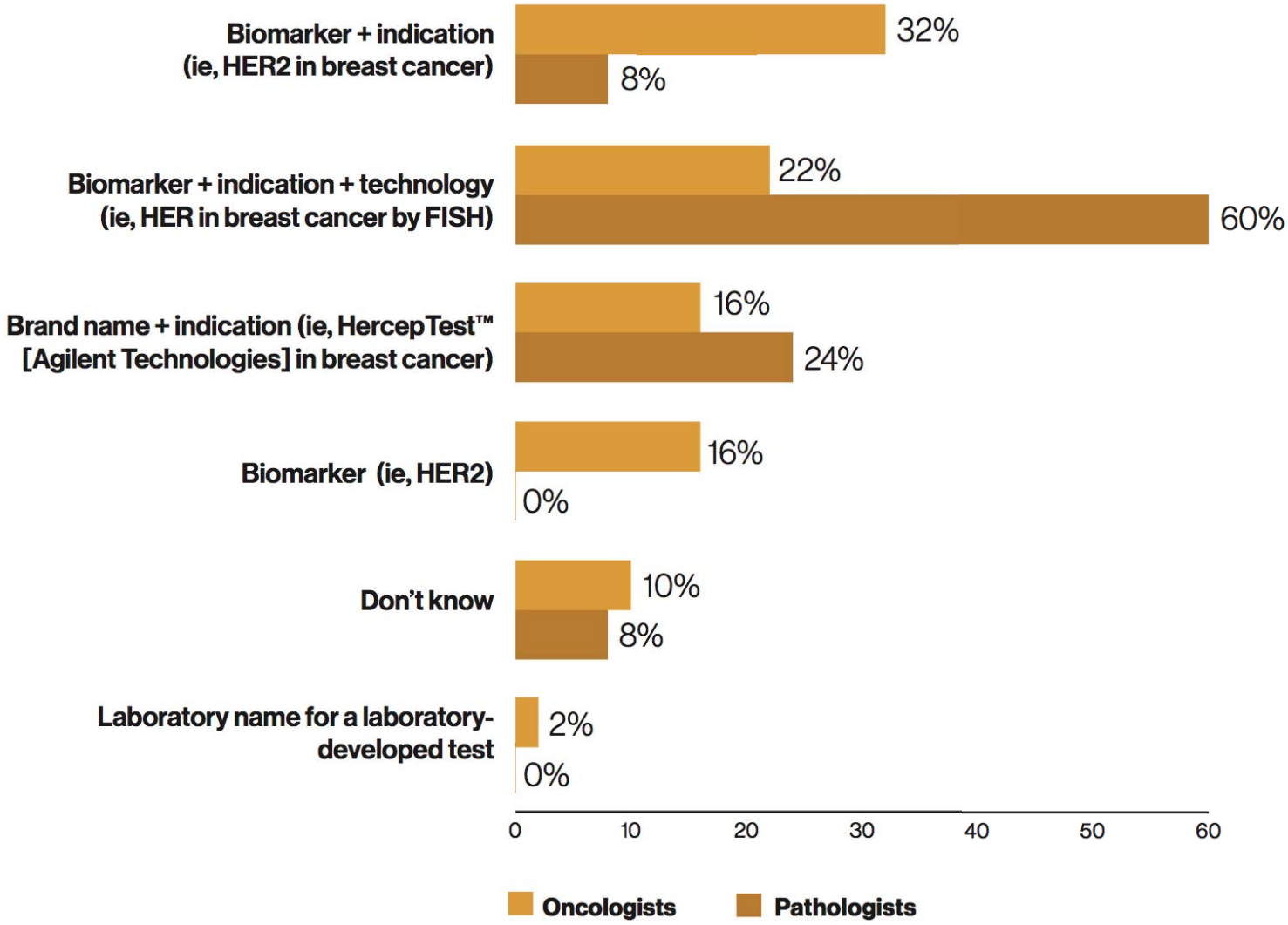
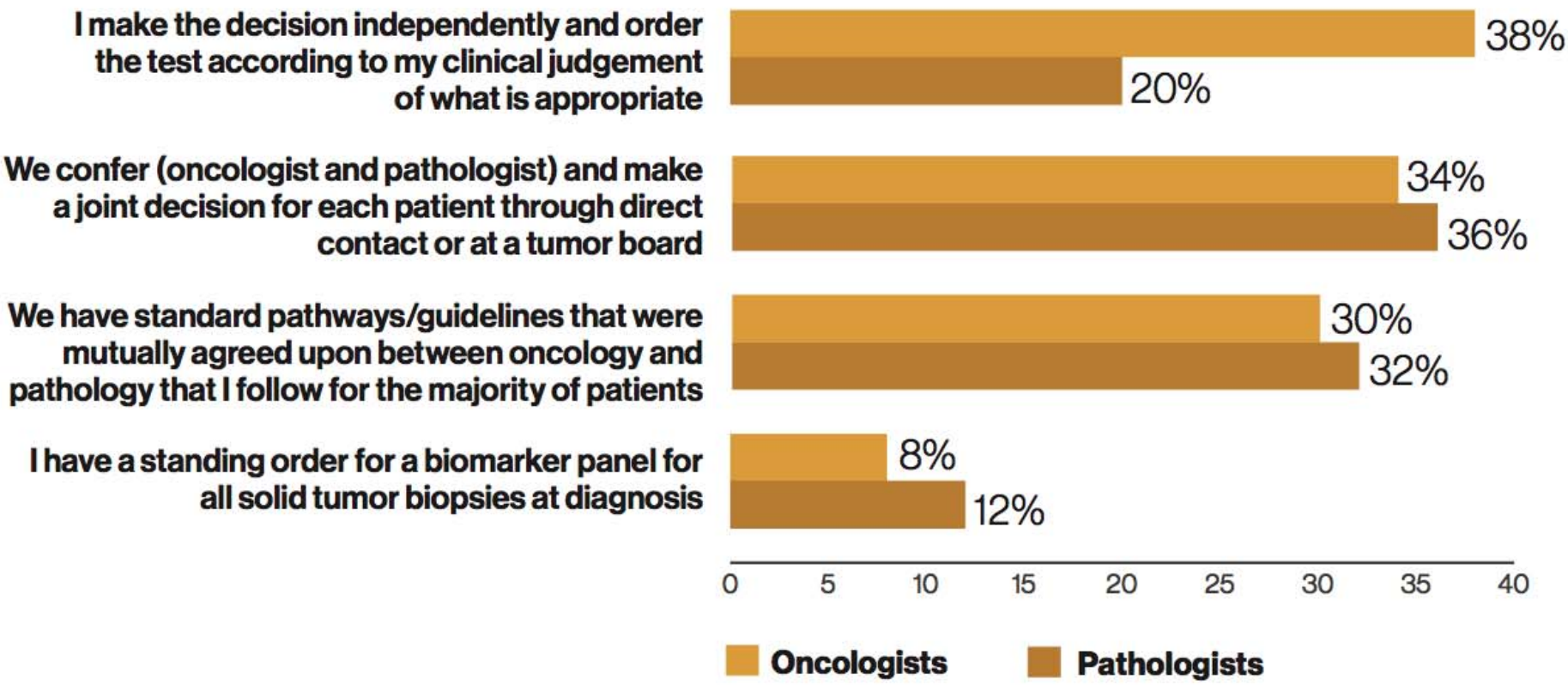


Figure 42 | **Process for Determining Biomarker Choice for Solid and Liquid Tumors**

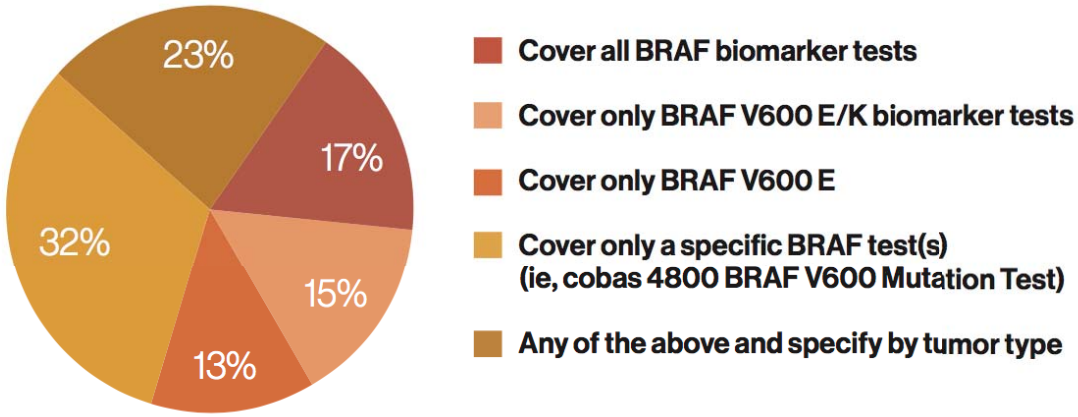


Few payers cover a specific BRAF test for melanoma.

FDA approvals of 3 agents that target V600E or V600K mutations in the BRAF gene of patients with advanced melanoma include a companion diagnostic assay as a requirement for use. One of these agents is only approved for patients with the BRAF V600E mutation, while the other 2 agents are approved for BRAF V600E and V600K.[48]

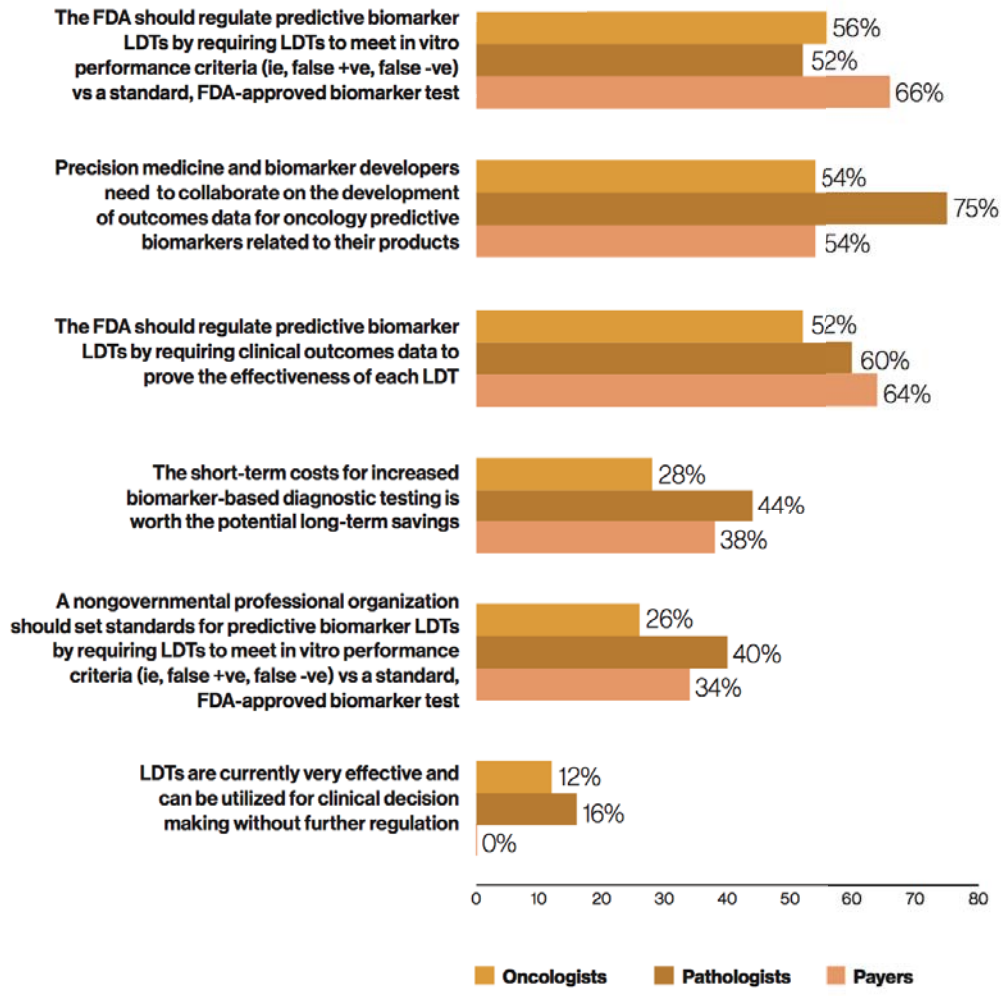
At the time of printing, 4 agents were approved by the FDA for the treatment of patients with advanced melanoma and a BRAF V600E or V600K mutation (2 BRAF inhibitors and 2 MEK inhibitors). Just 32% of payers reported only covering a specific BRAF test, such as the cobas® 4800 BRAF V600 Mutation Test (Roche Molecular Systems Inc). Two of the 3 agents that include a companion diagnostic assay as a requirement for use are approved with both BRAF V600 E and K mutations yet only 50% of payers specify coverage for BRAF tests that capture both mutations. Payer policy decisions to not provide coverage for the BRAF V600K mutation appears to be adversely impacting testing for the other agents.[48]

Figure 35 | **Payers' Coverage Policies for BRAF Biomarker Test in Melanoma**



Providers and payers strongly agree that LDTs require regulation and oversight of their effectiveness.

Figure 38 | **Providers Who Strongly Agree With the Following Statements**



syapse

Be careful what you ask for…

Landmark Approval: The Path Forward

FDA
CMS

FDA Approval and Preliminary NCD
November 30, 2017

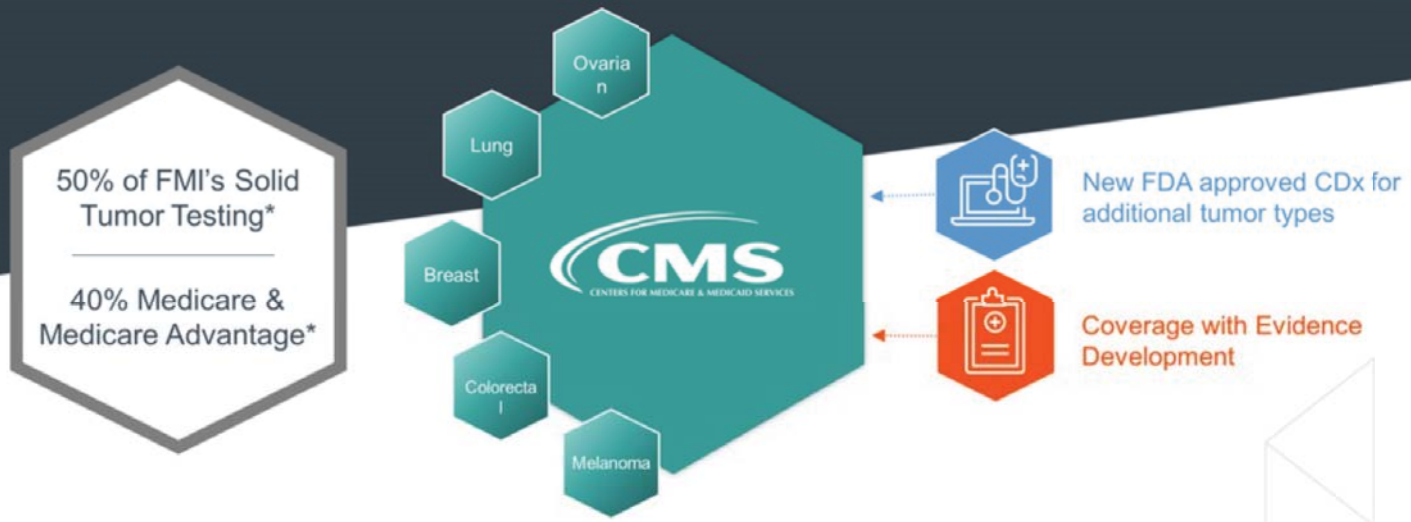
90
DAYS

Comment Period and Administrative Window to Finalize NCD
February 28, 2018

FoundationOne CDx Launch

syapse

FoundationOne CDx: Meaningful Medicare Coverage through a National Coverage Determination (NCD)



*Estimates are projections based on historical data contained in a genomic database of patients with NSCLC, melanoma, colorectal cancer, ovarian cancer or breast cancer who received CGP testing from Foundation Medicine

CMS.gov
Centers for Medicare & Medicaid Services

View Public Comments for Next Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (CAG-00450N)

Commenter: **Segal, Jeremy**

Title: Director, Genomic and Molecular Pathology

Organization: University of Chicago

Date: 12/02/2017

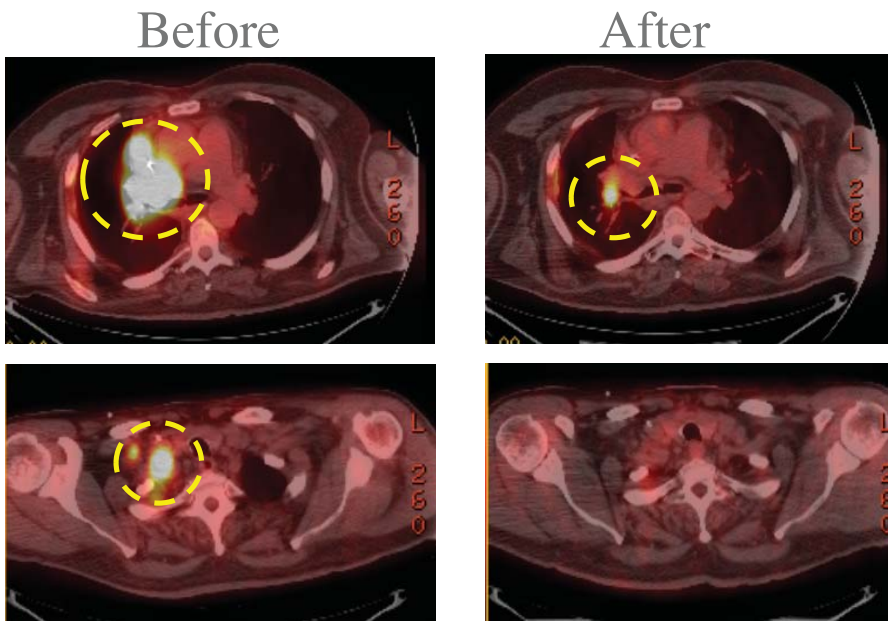
Comment:

What on earth are you thinking? 99% of all clinical diagnostic laboratories in the country doing NGS oncology are not FDA approved. Paying only FDA approved labs will destroy almost the entire academic laboratory molecular diagnostics community! It will also kill most of the commercial laboratories. You will be making the FDA the ultimate king-makers and monopolists. Of all of the awful decisions I've seen our government make, I've spent the last four years of my life building a vibrant laboratory at our University and you are just going to step in and destroy it without a single thought! No decision could be worse for patients and payers or for academic medical centers and for academic translational research. I am stunned and horrified reading this, of everything I've ever seen our government do to our field, this is the worst. The most absolutely thoughtless and negligent destruction of an industry you could imagine. My laboratory performs the highest quality testing and will continue to do so until the day you shut us down out of plain ignorance and greed.

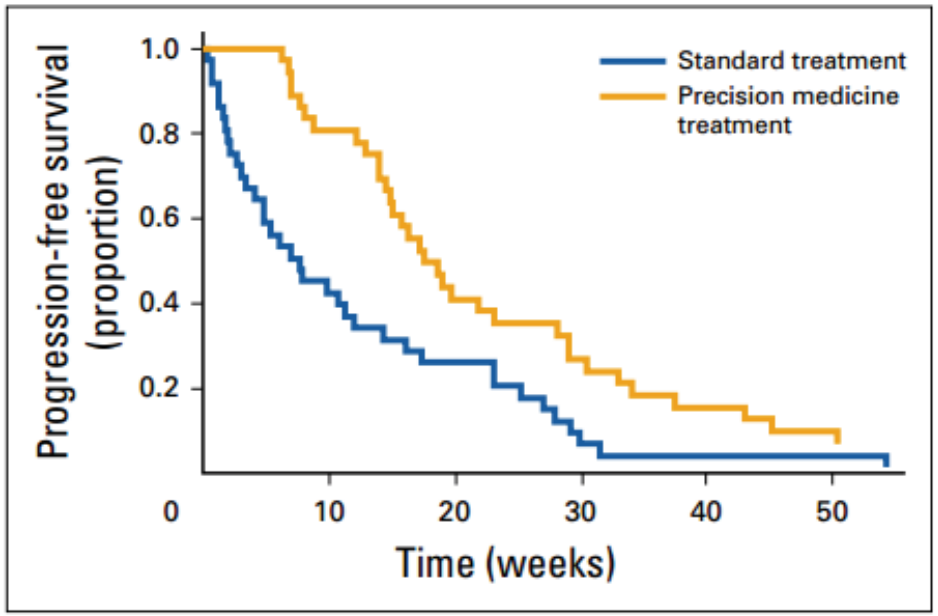
In spite of this, there is positive news…

Patient Case: Lung Cancer

- 56 year old man with metastatic lung cancer
- Progressed through standard chemotherapy regimen
- Genomic analysis: BRAF mutation (not V600E)
- Targeted treatment x 9months



Syapse & Intermountain Healthcare Clinical Utility Study



Progression Free Survival:

Standard: 12.0 weeks

Targeted: 22.9 weeks

HR: 0.53, p<0.002

Better outcomes[1]

23 PFS weeks on precision medicine vs 12 PFS weeks on standard of care

Lower costs[1]

$4,665 per PFS-week per patient on precision medicine vs $5,000 on standard of care

More drugs reimbursed[2]

82% of targeted therapy orders successfully obtained through insurance approval or clinical trials

MTB efficiencies

4-fold increase in molecular tumor board review throughput

[1]Haslem, Derrick S., et al. "A Retrospective Analysis of Precision Medicine Outcomes in Patients With Advanced Cancer Reveals Improved Progression-Free Survival Without Increased Health Care Costs." *Journal of Oncology Practice* (2016): JOPR011486.

[2]Nadauld, Lincoln, et al. "Implementation of a precision cancer program in an integrated health care system." (2015): e17647-e17647.

syapse

Health Systems See the Future

Cancer patients actively seek out care tailored to them

NGS is becoming a routine part of advanced cancer care

90% of cancer drugs in late phase trials target a molecular pathway

1st drug approval based on biomarker, instead of tumor site of origin

Targeted therapies require robust evidence to justify reimbursement

Value-based care models, like OCM, are shifting incentives

The Academy
The Health Management Academy

FIGURE 1. AMONG YOUR ORGANIZATION'S STRATEGIC AIMS, WHAT LEVEL OF PRIORITY IS DEVELOPING A PRECISION MEDICINE PROGRAM?

Survey of 43
leading health systems

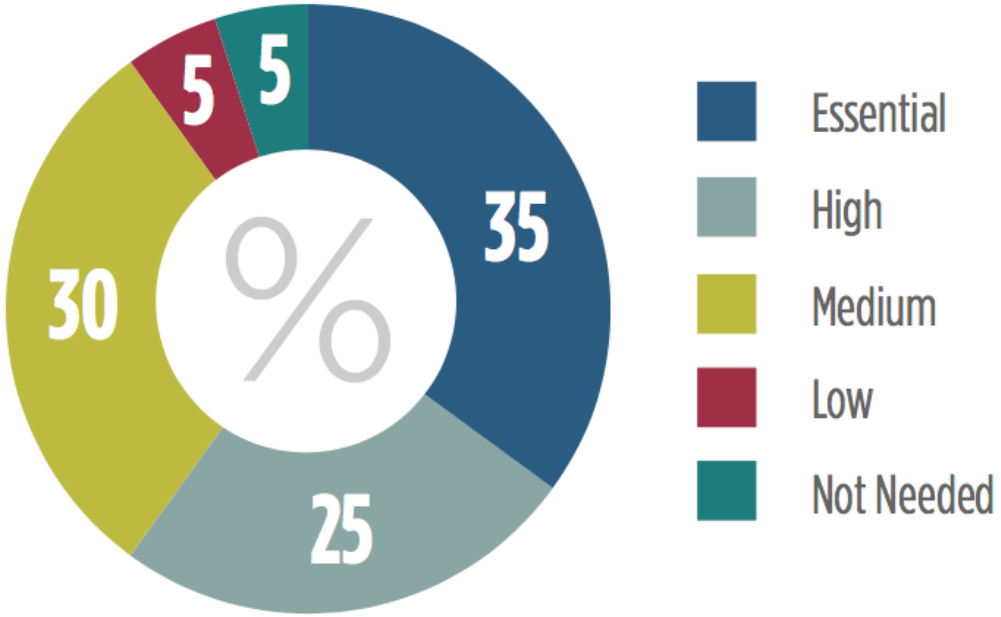


FIGURE 2. WHAT STAGE IS YOUR ORGANIZATION IN DEVELOPING A PRECISION MEDICINE PROGRAM?

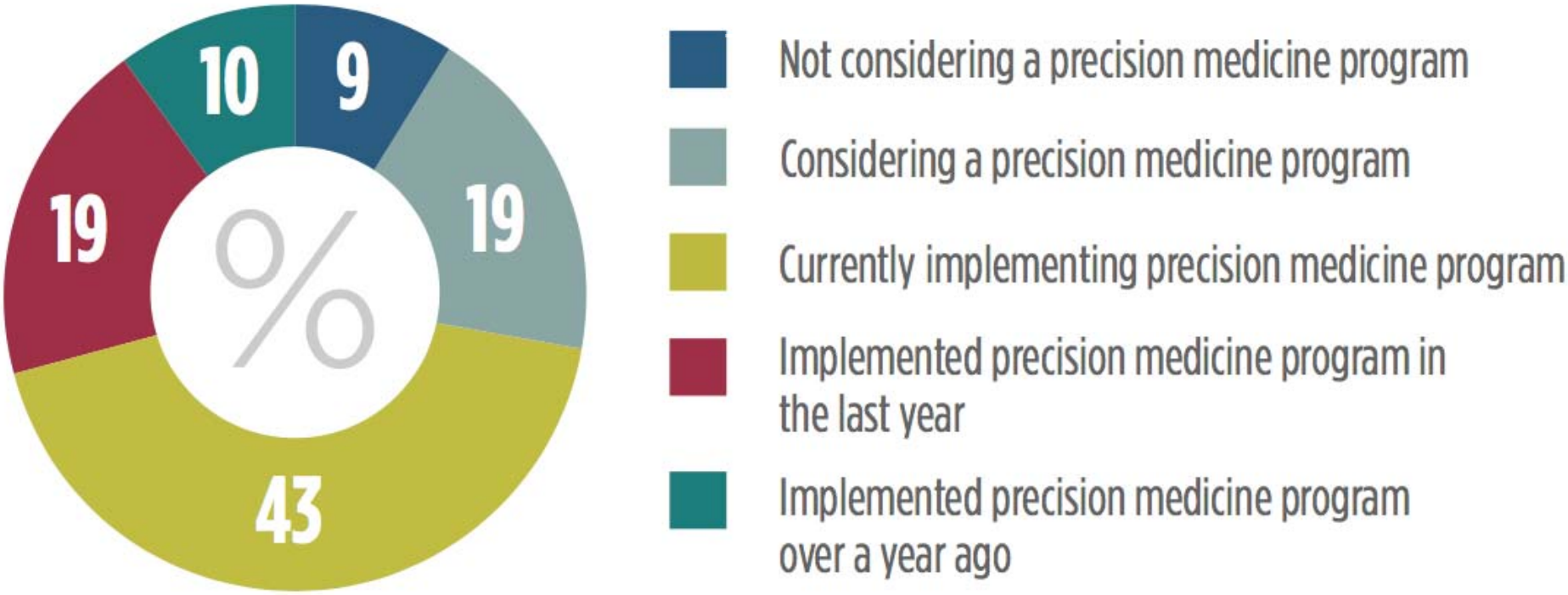


FIGURE 4. WITH WHAT FREQUENCY DO YOUR INSTITUTION'S ONCOLOGISTS ORDER LARGE-PANEL NEXT GENERATION SEQUENCING (NGS) FOR STAGE IV CANCER PATIENTS?

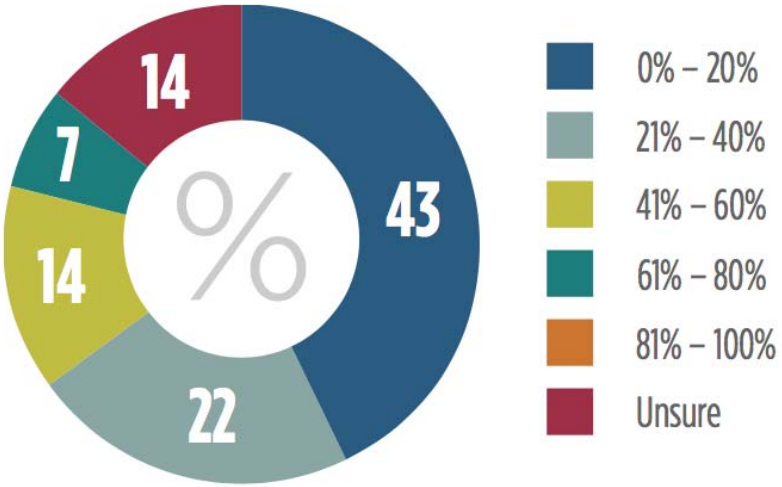


FIGURE 5. WHAT IS THE FREQUENCY WITH WHICH YOUR INSTITUTION'S ONCOLOGISTS PRESCRIBE MOLECULARLY TARGETED THERAPIES FOR STAGE IV CANCER PATIENTS?

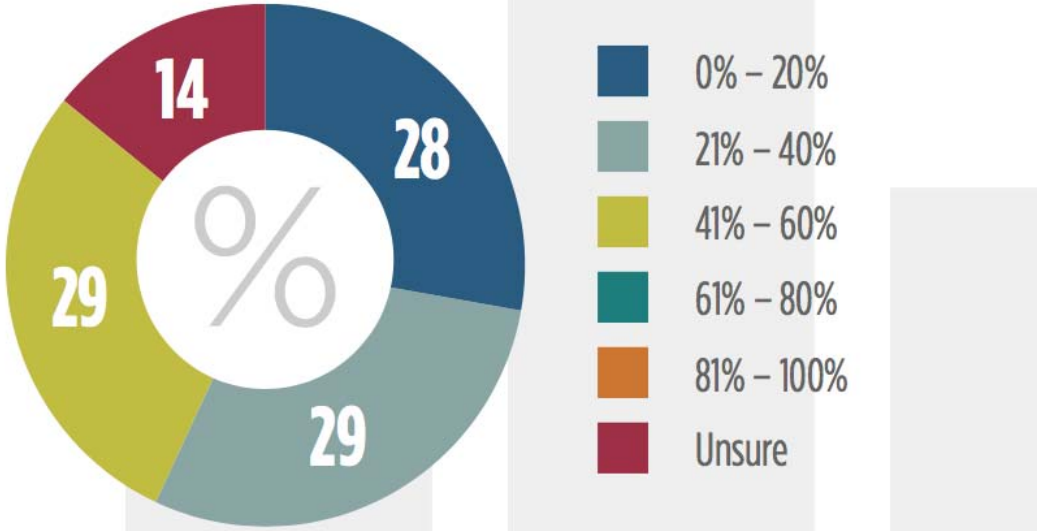
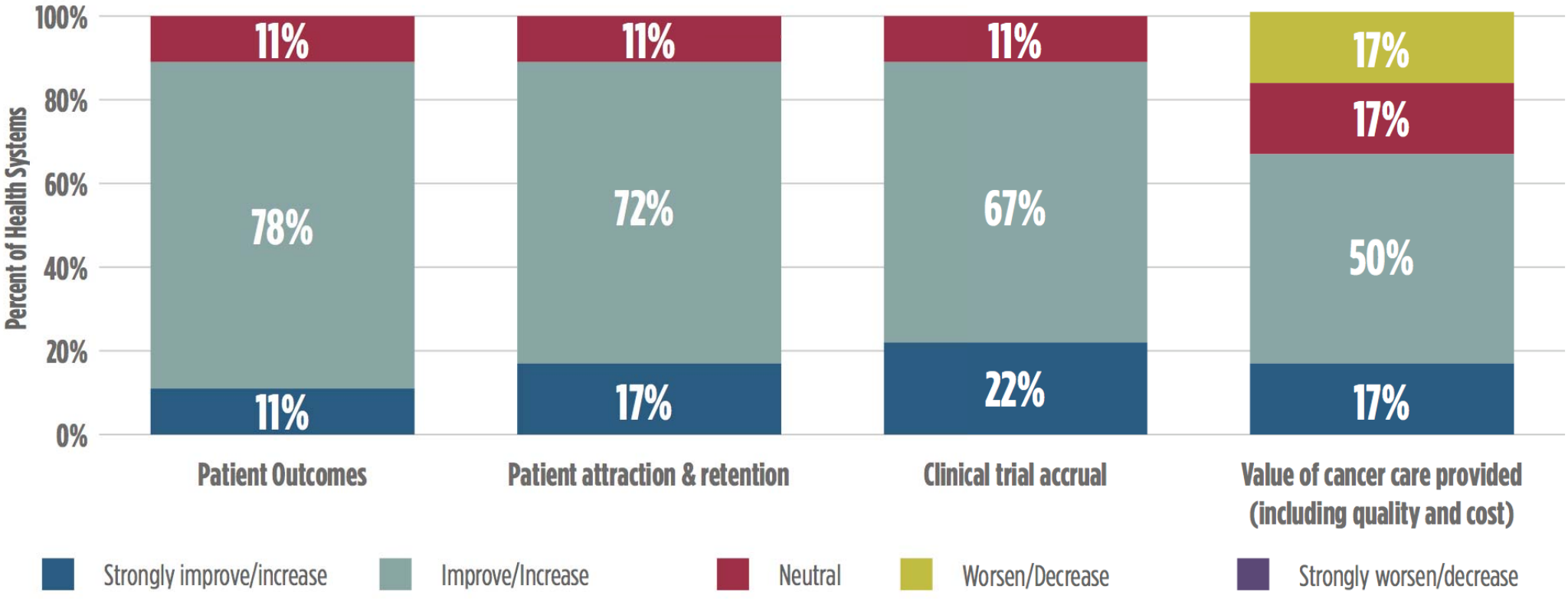
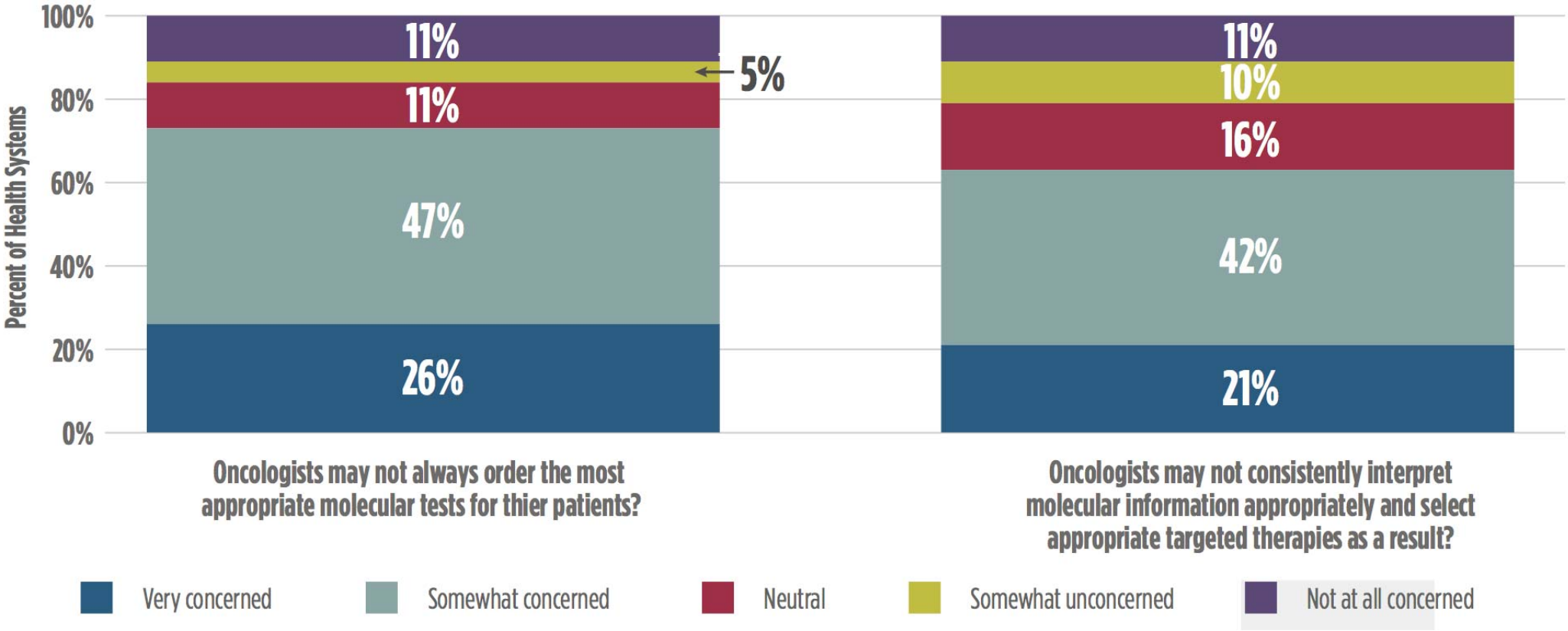


FIGURE 6. HOW MUCH HAS/ WOULD YOU EXPECT A PRECISION MEDICINE PROGRAM TO IMPACT THE FOLLOWING?



syapse

FIGURE 9. HOW CONCERNED ARE YOU REGARDING THE FOLLOWING:



syapse

FIGURE 10. WHAT IS INCLUDED IN YOUR ORGANIZATION'S PLAN FOR TUMOR SITE AGNOSTIC DRUGS? (PLEASE CHECK ALL THAT APPLY.)

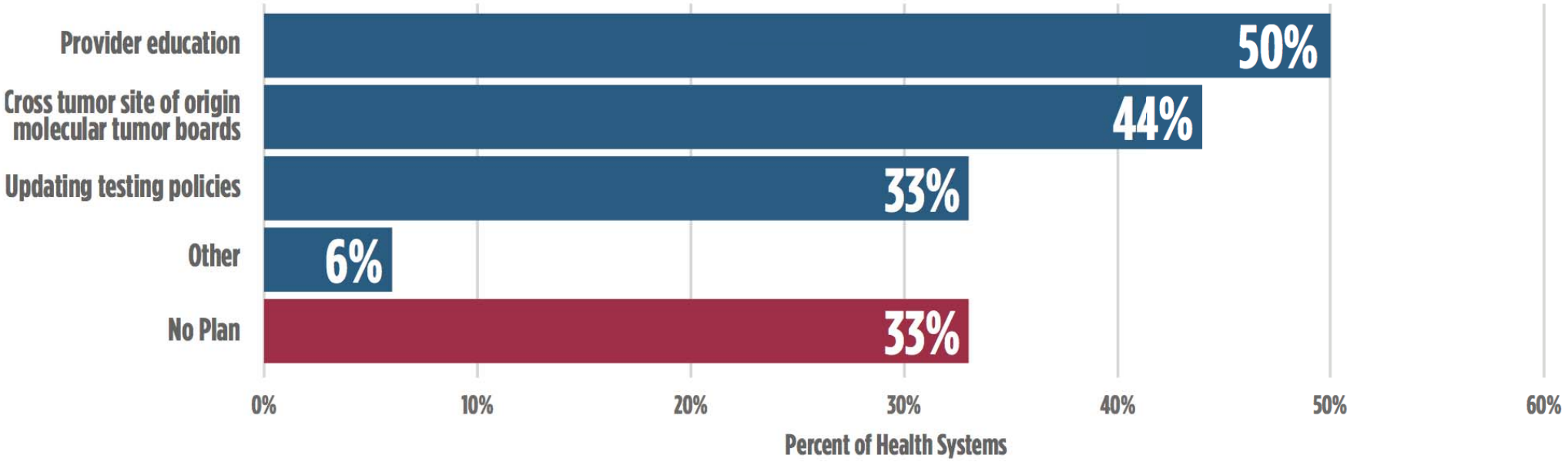


FIGURE 11. HOW IMPORTANT DO YOU THINK IT IS TO PROVIDE GUIDANCE TO ONCOLOGISTS TO HELP THEM NAVIGATE MOLECULAR DIAGNOSTIC AND TARGETED THERAPIES

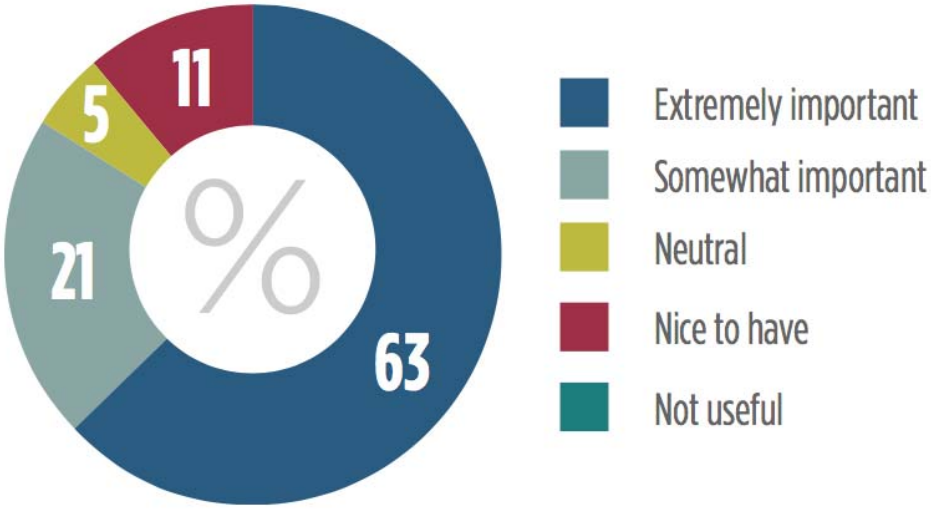


FIGURE 13. IN THE FUTURE, HOW IMPORTANT WILL REAL WORLD OUTCOMES FROM AGGREGATED DE-IDENTIFIED DATA BECOME IN GUIDING PHYSICIAN DECISION MAKING IN COMPLEX CASES?

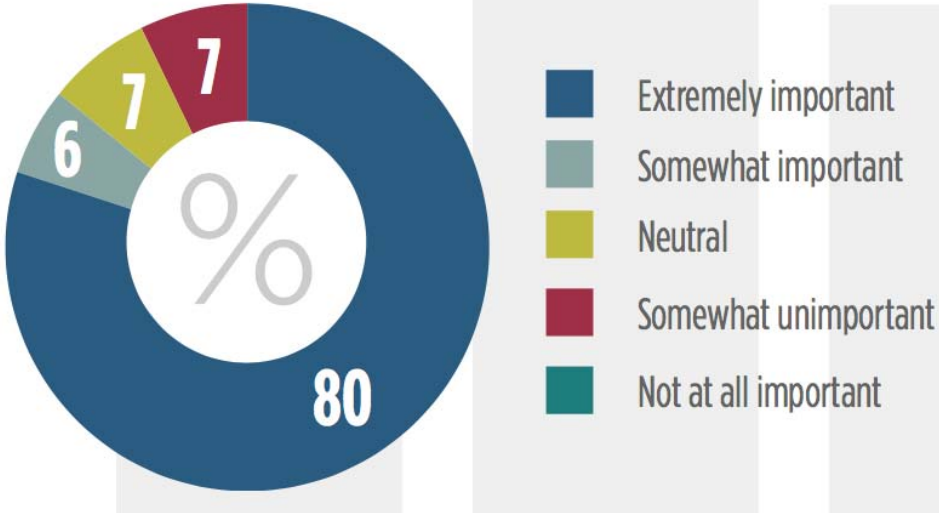
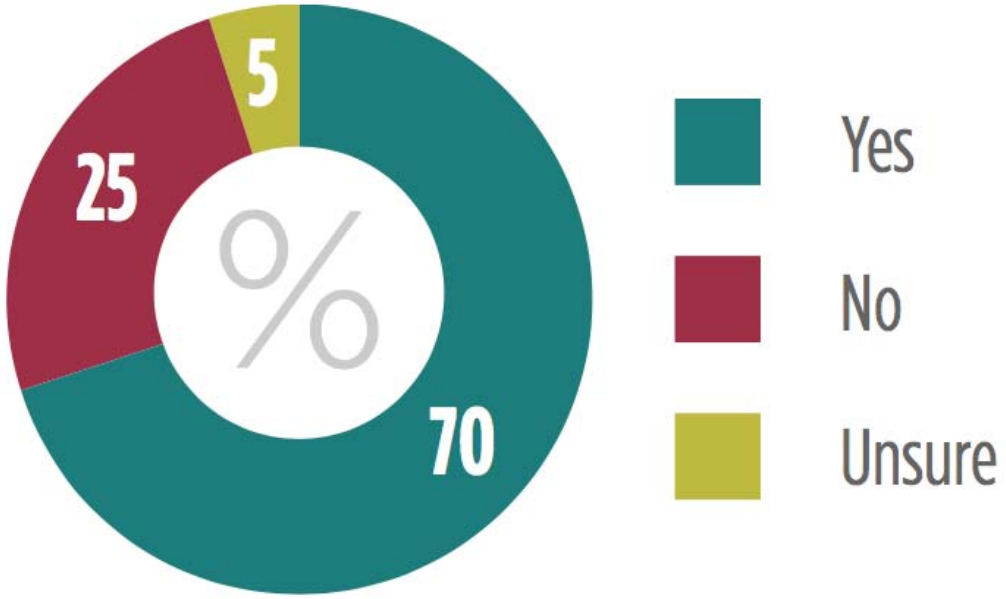


FIGURE 7. DO YOU BELIEVE THAT YOU MUST INVEST IN SOFTWARE TO POWER A PRECISION MEDICINE PROGRAM? (NOTE: PLEASE EXCLUDE ANY SOFTWARE NEEDED TO SUPPORT IN HOUSE SEQUENCING ANALYTICS.)



The Path Forward

ASCO is optimistic about the future of the cancer care delivery system, but recognizes the challenges of delivering the highest quality care for all patients with cancer. Building on efforts currently underway, the following ASCO recommendations set forth a framework to strengthen the current system and ensure patients' access to cancer care well into the future.

Ensure Access to Affordable, High-Quality Cancer Care

All people with cancer should have health insurance that ensures access to high-quality cancer care delivered by a cancer specialist and provides the full range of services patients need in a timely manner.

Develop Patient-Centered Payment Models

As the nation moves from a volume-based to value-based healthcare reimbursement system, public and private payers should work with oncology providers and patients to develop new payment models that support patient-centered cancer care across healthcare teams and care delivery settings. Furthermore, the Centers for Medicare & Medicaid Services should support testing of multiple payment models in oncology, including ASCO's Patient-Centered Oncology Payment model.

30%

of Medicare payments tied to alternative payment models (APMs) in 2016.[21]

Support Development of Cancer Treatments

To ensure the ongoing development and delivery of promising new treatments for patients with cancer, the federal government should provide adequate funding and infrastructure support for cancer research, continue funding the Cancer Moonshot Initiative, and provide adequate resources to the Food and Drug Administration to review and approve the safety and efficacy of cancer therapies and diagnostics efficiently and quickly.

Promote EHR Interoperability

To reach the full potential of cancer-specific rapid learning health systems and accelerate the pace of cancer research, it is essential to speed implementation of the 21st Century Cures Act provisions to promote interoperability of electronic health records (EHRs) and prevent information blocking.

42%

of surveyed oncology practices cannot integrate patient information from other EHR systems into their own.

Reduce Administrative Burden

As regulatory changes have significantly increased the administrative burdens providers face, policymakers and payers should streamline and standardize documentation and reporting requirements so that oncology professionals are able to focus adequate time and resources on their patients.

Top 3 strains on oncology practices

- Increasing expenses
- Drug pricing
- Implementing EHRs

A Transformed Cancer Care System on the Horizon

All stakeholders have a role to play – capitalizing on these opportunities and addressing challenges will take greater commitment and collaboration than ever before. ASCO remains dedicated to supporting the efforts of policymakers to strengthen the nation's cancer care delivery system on behalf of all patients with cancer and their providers. For more information, please contact **policy@asco.org.**

syapse

Syapse Network is the largest precision oncology data-sharing consortium in the world

Syapse Network was founded by Syapse and our partner health systems in 2016, and endorsed by Vice President Biden as key part of Cancer Moonshot, to use real-world evidence to improve care today

Providence St. Joseph Health

Dignity Health

Aurora Health Care

Henry Ford Health System

Catholic Health Initiatives

hoag

syapse

Thank you!

syapse.com