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Improving Cancer Care through Precision Medicine

v|dsvh1frp

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

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

Luke Timmerman
@ldtimmerman

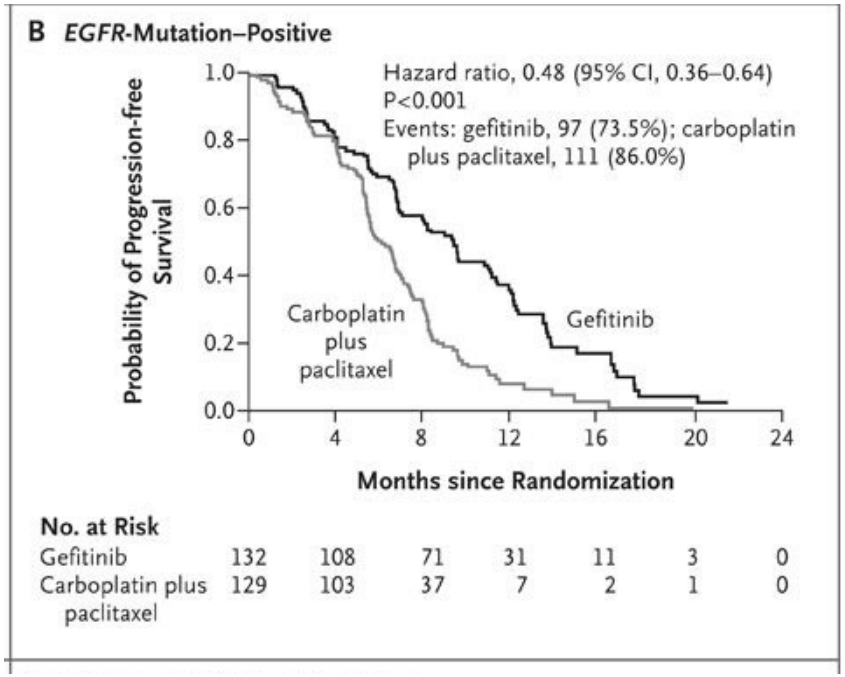
Following

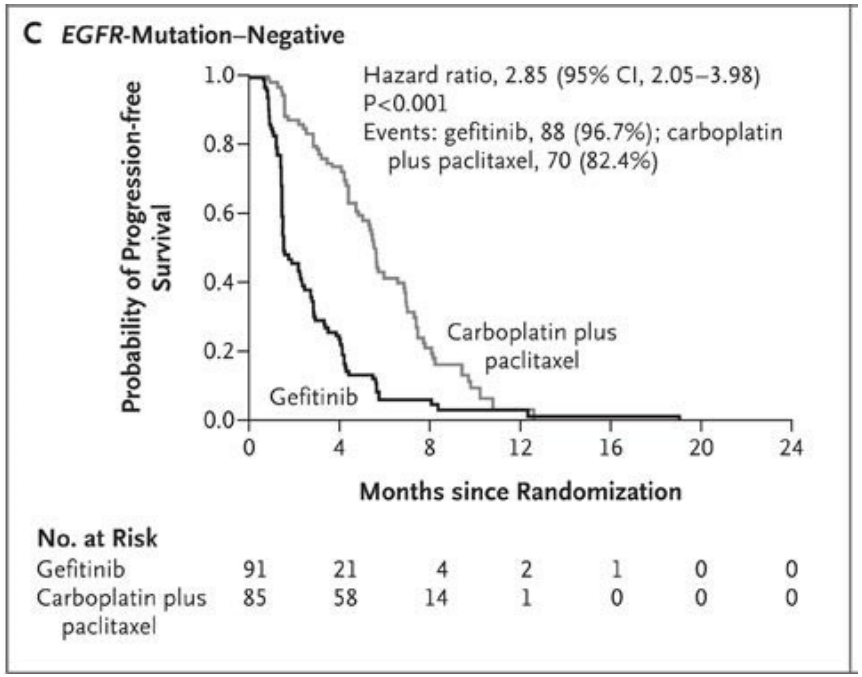
Sure has. Precision medicine was mainly just a concept. DNA seq was expensive. Immuno-oncology was fringe idea. Totally different world now.

> **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

IPASS: PFS in Advanced NSCLC
EGFR^{MUT} vs non-EGFR^{MUT} Patients





Mok TS et al. N Engl J Med 2009;361:947-957.

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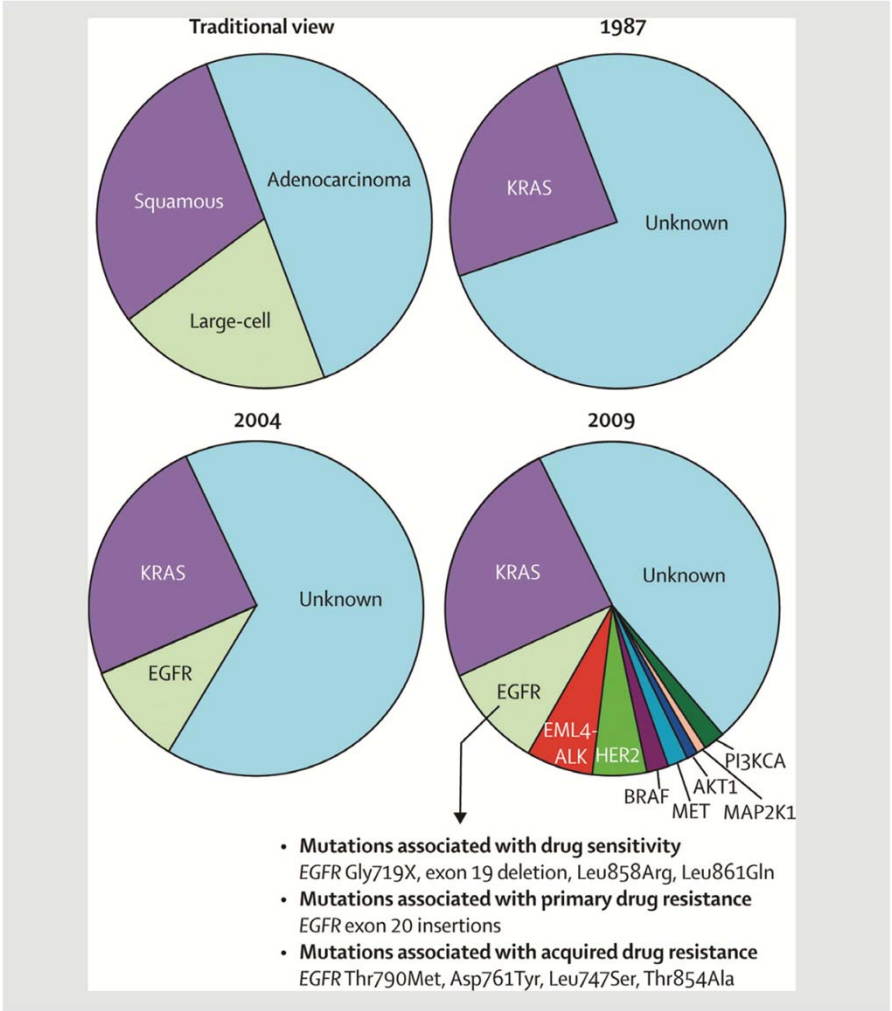

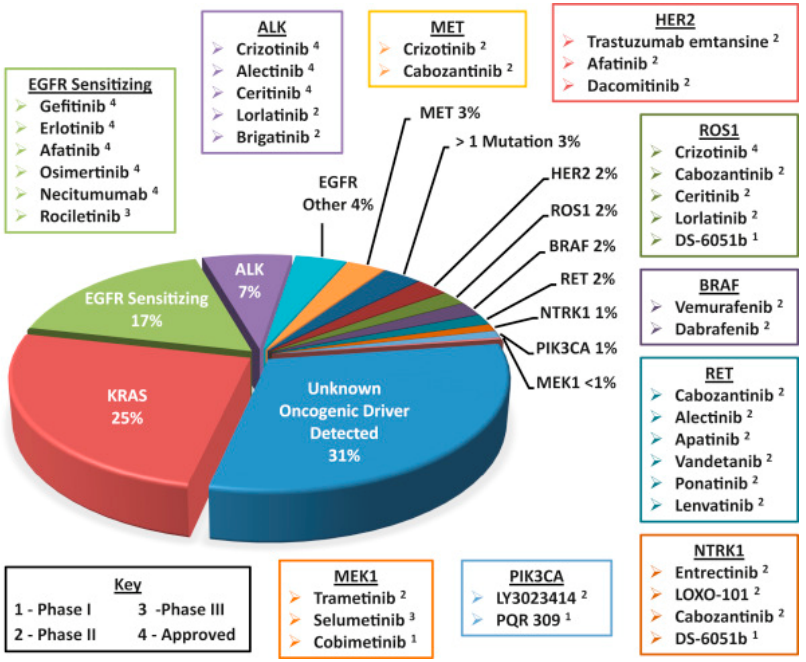

Journal of Thoracic Oncology 2016 11, 613-638DOI: (10.1016/j.jtho.2016.03.012)

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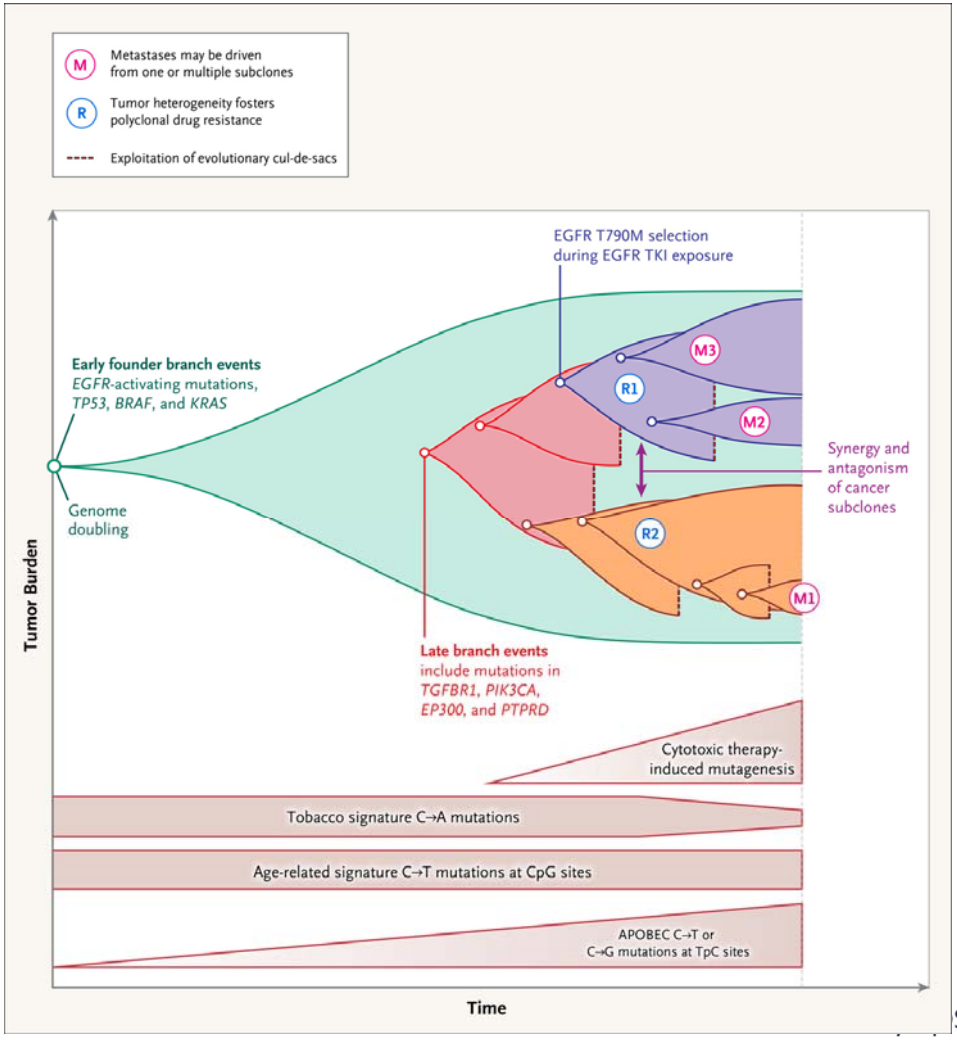
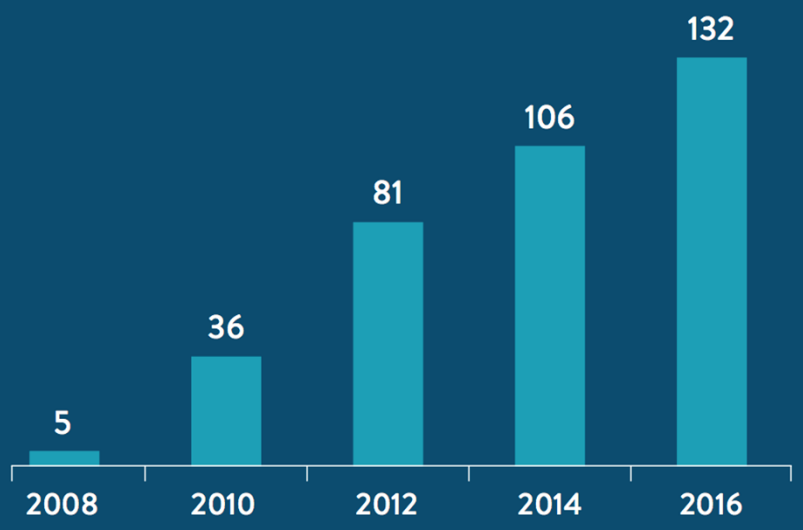
Clonal Evolution and Intratumor Heterogeneity



Swanton C, Govindan R. N Engl J Med 2016;374:1864-1873.

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*

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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

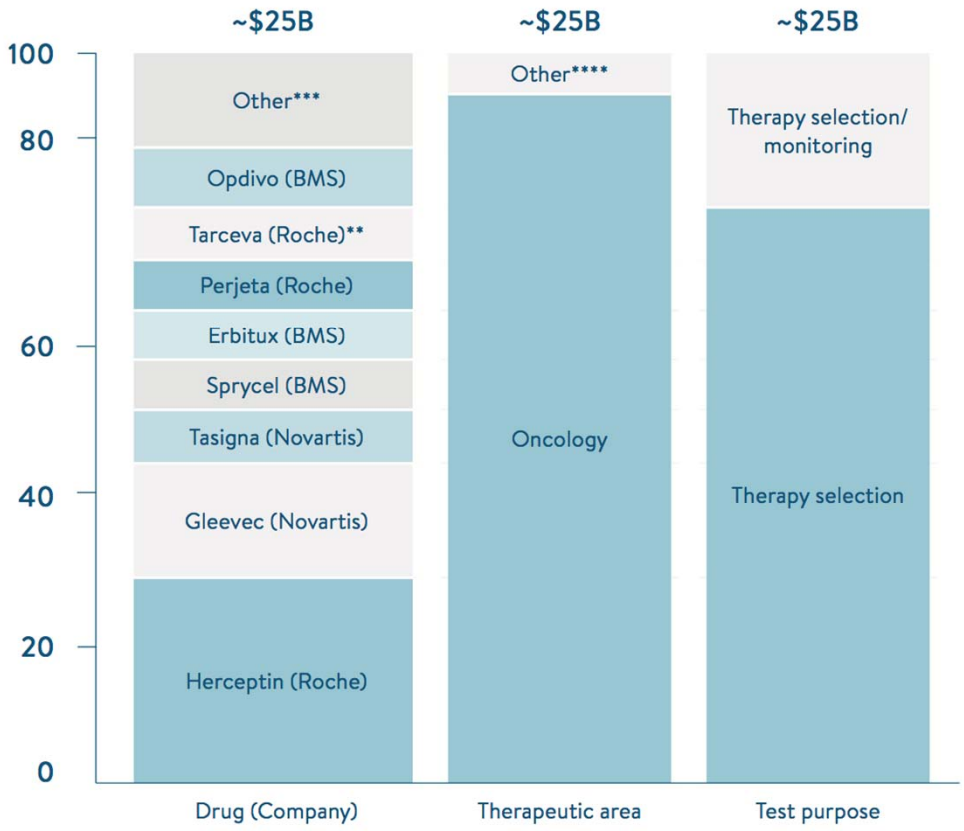

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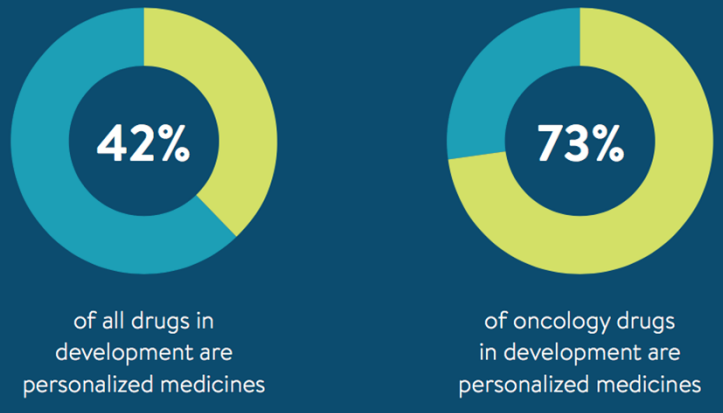
FIGURE 7: THE BIOPHARMACEUTICAL INDUSTRY IS COMMITTED TO PERSONALIZED MEDICINE

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

FDA News Release

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

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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

FDA News Release

FDA approval bring
United States

CAR T-cell therapy approved to treat ce
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.

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

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

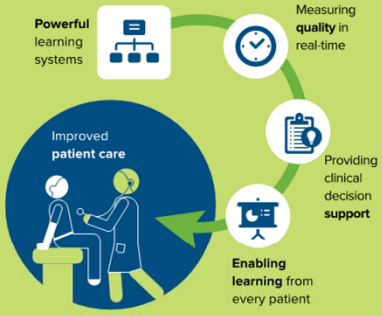
34% of patients with metastatic melanoma **treated with new immunotherapy** in early clinical trial, alive after 5 years.[6]

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.

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.

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

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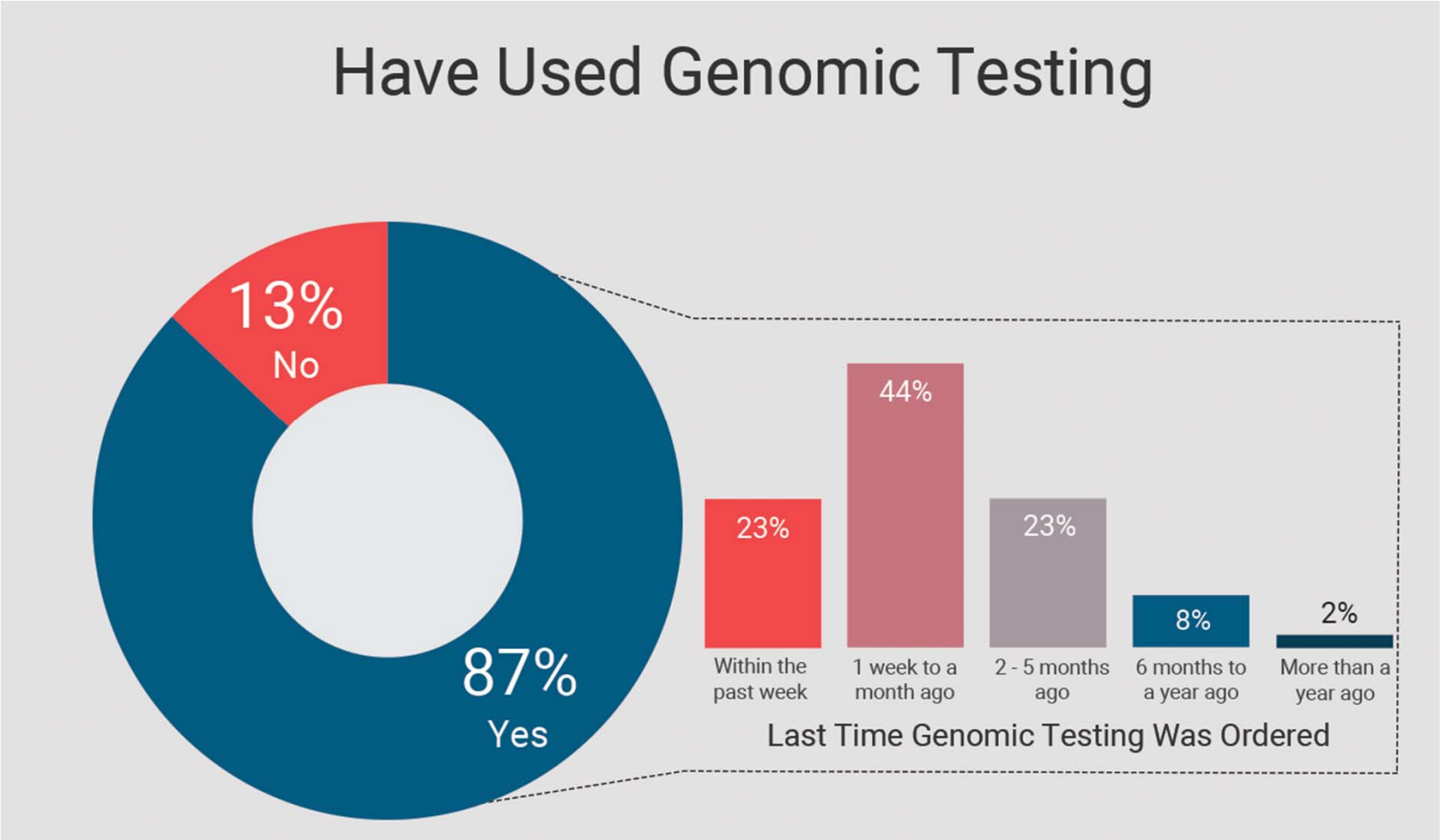

1 West and Miller, 2017, Medscape. “Genomic Testing and Precision Medicine in Cancer Care”

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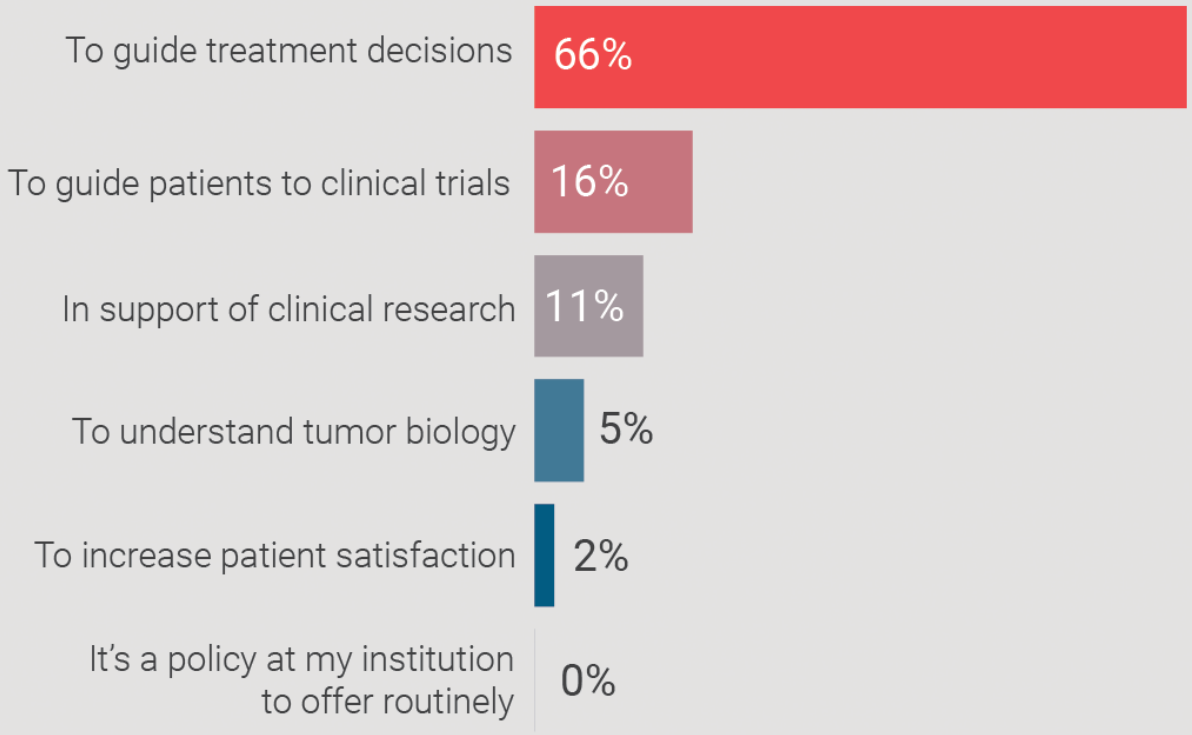
Primary Motive for Using Genomic Testing



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

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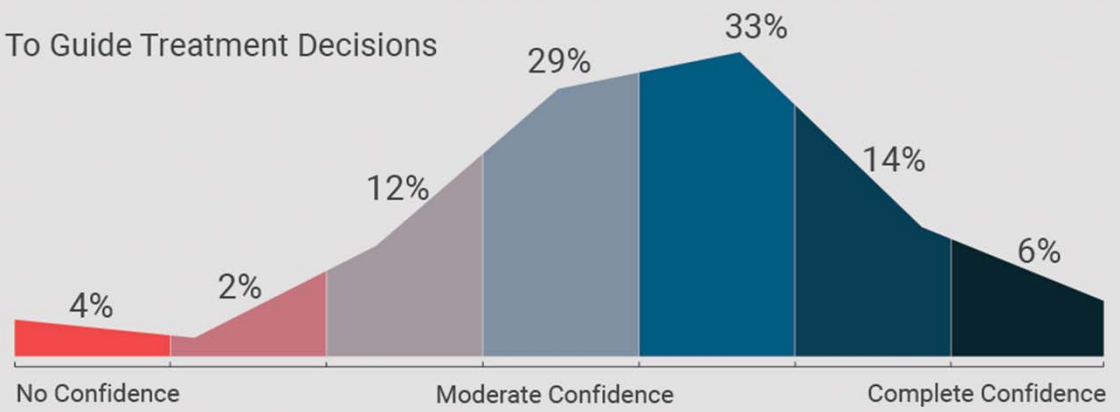
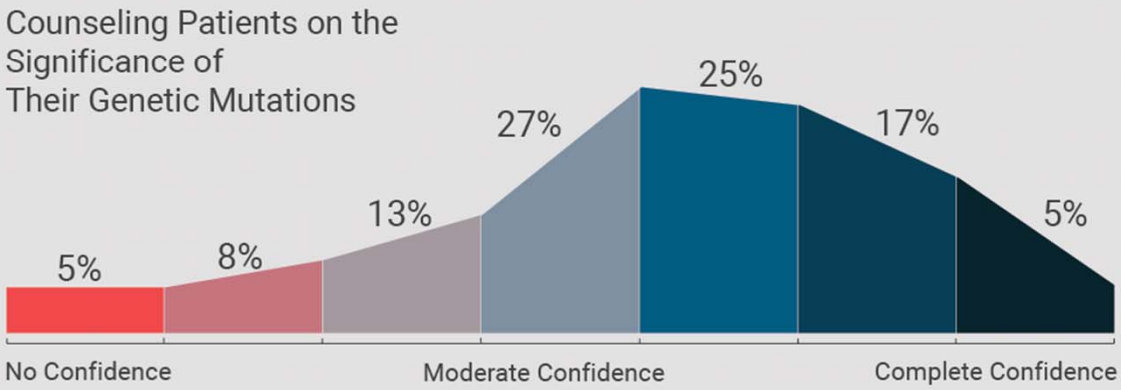
Confidence With Genomic Testing





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

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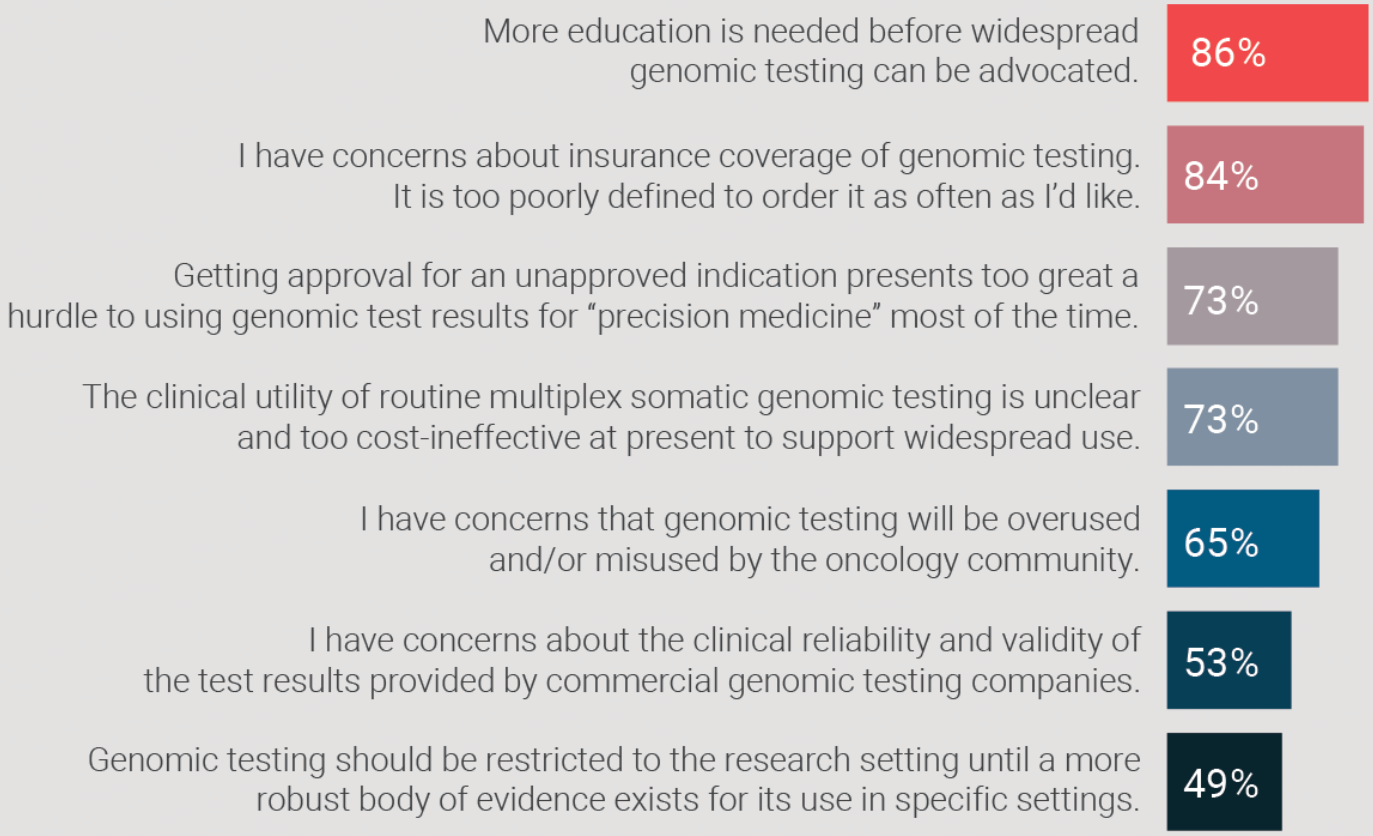
Overall Concerns With Genomic Testing



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

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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

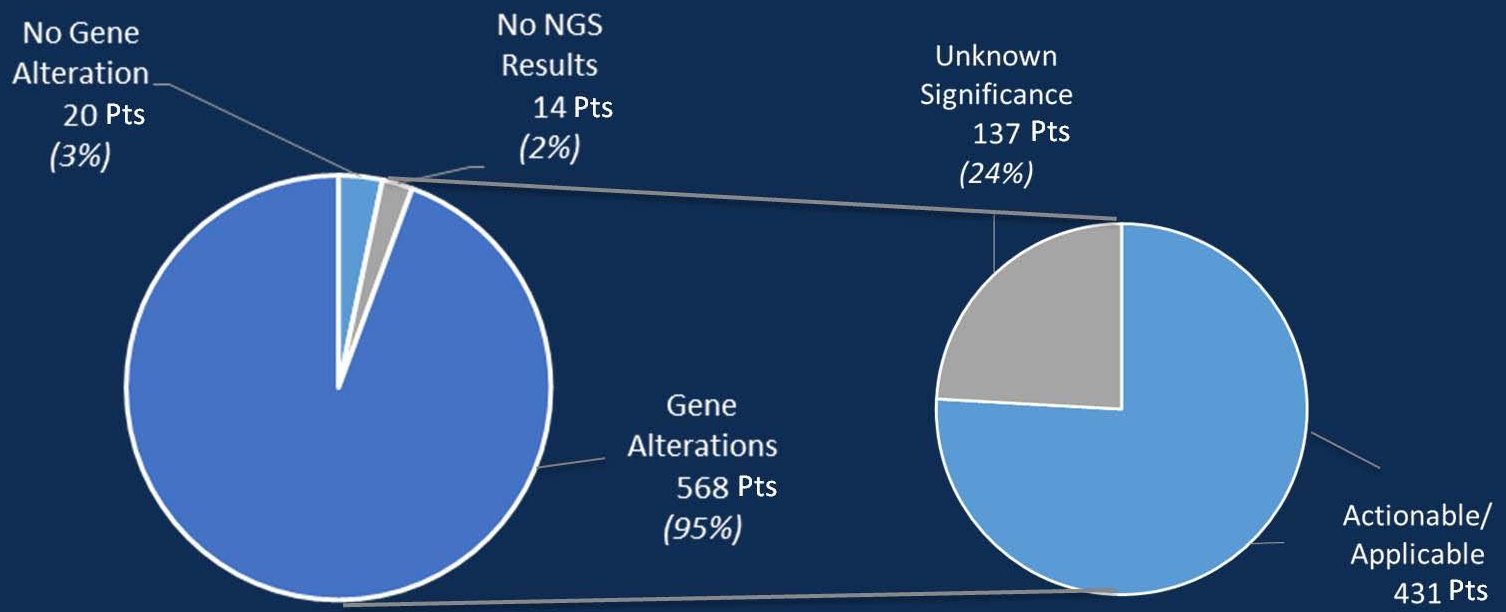
PRESENTED AT: ASCO ANNUAL MEETING '17 | #ASCO17

Presented by: Thomas D. Brown, MD, MBA

Abstract #6506

SCI PMRP: NGS Results

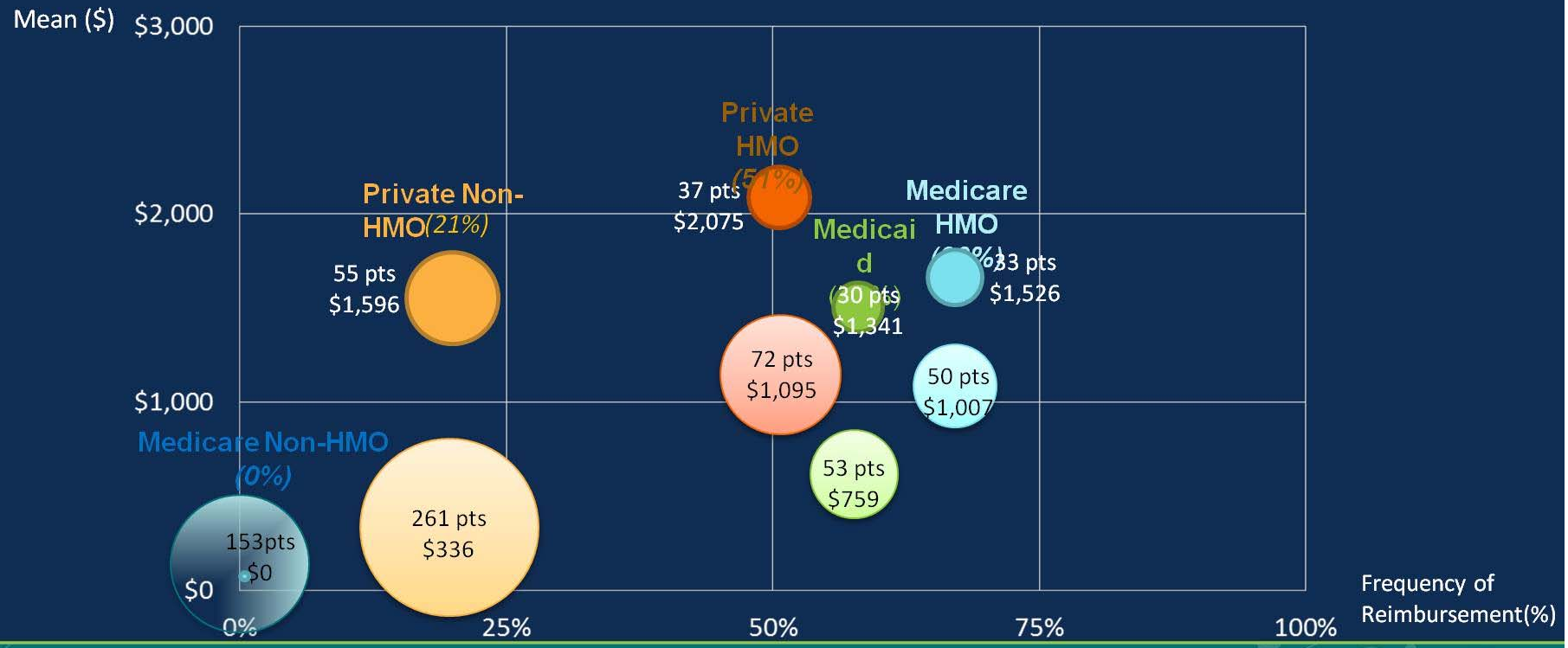
Evaluable 602 Pts with NGS Cases



# of Pts
(%)

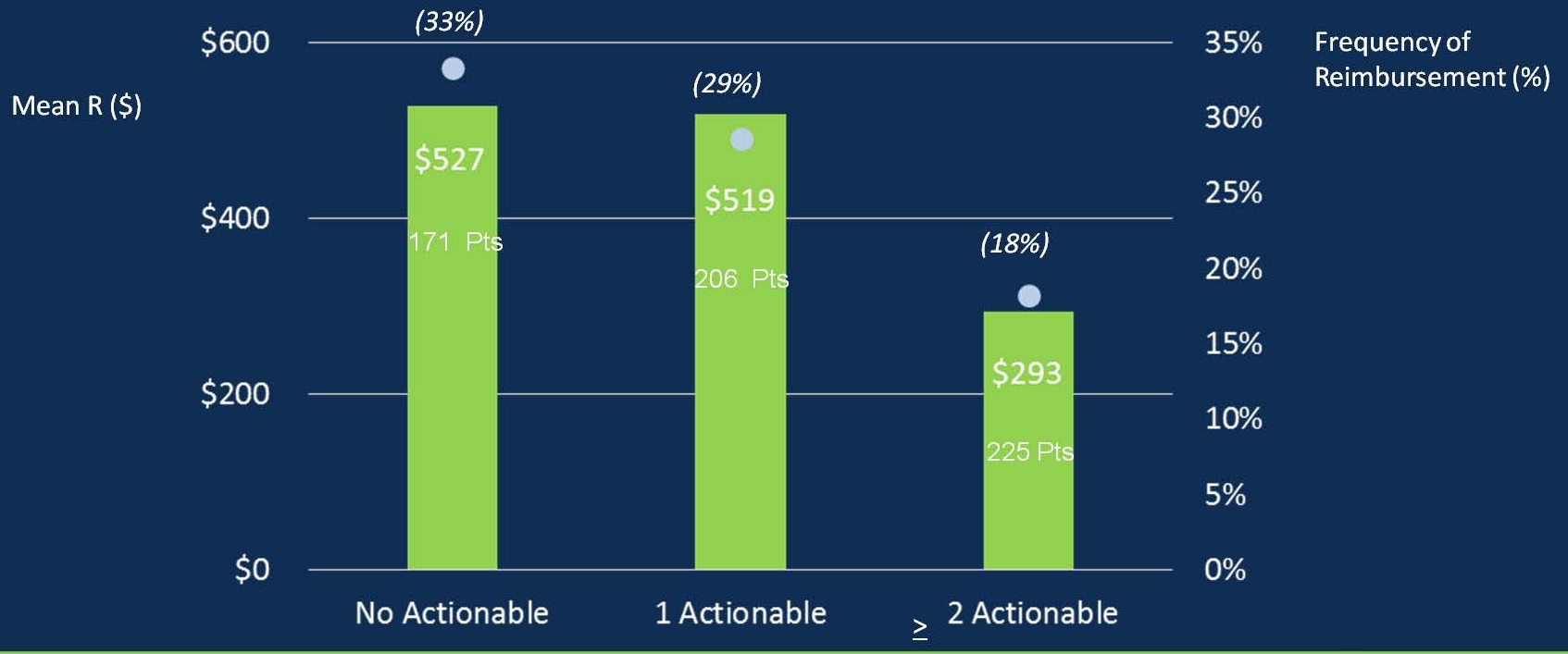
Reimbursement Frequency and Payment by Payer

- 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).



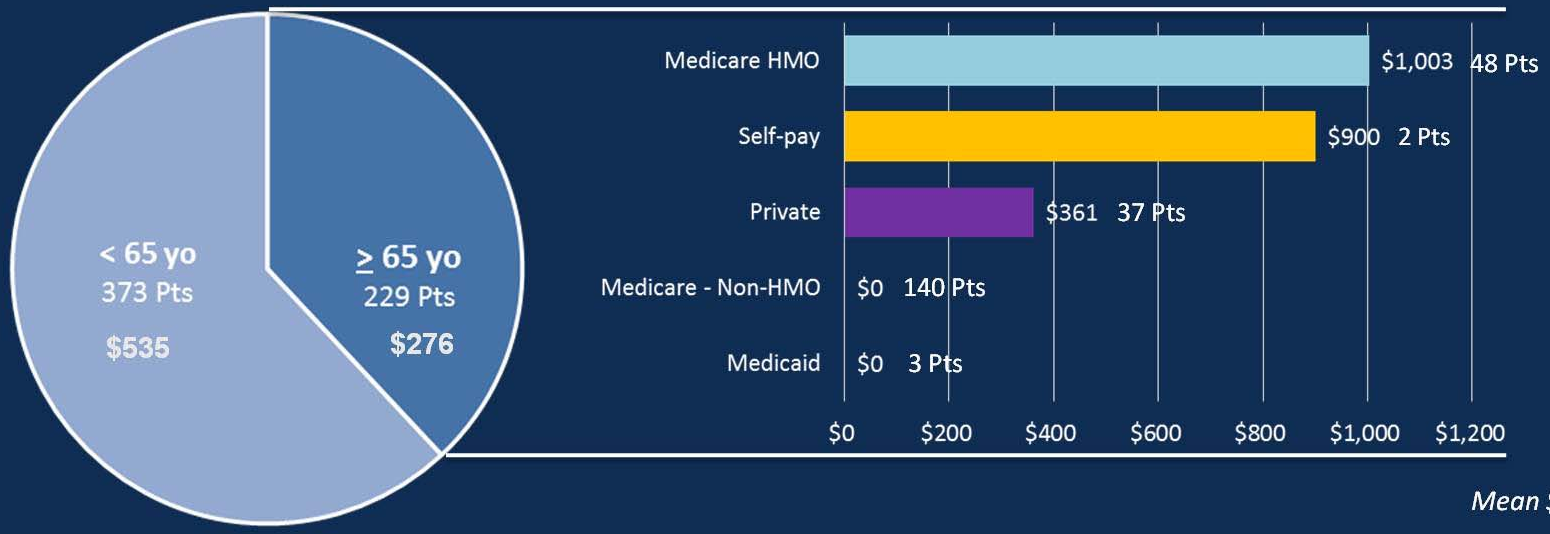
Association of Actionability with Reimbursement

- 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

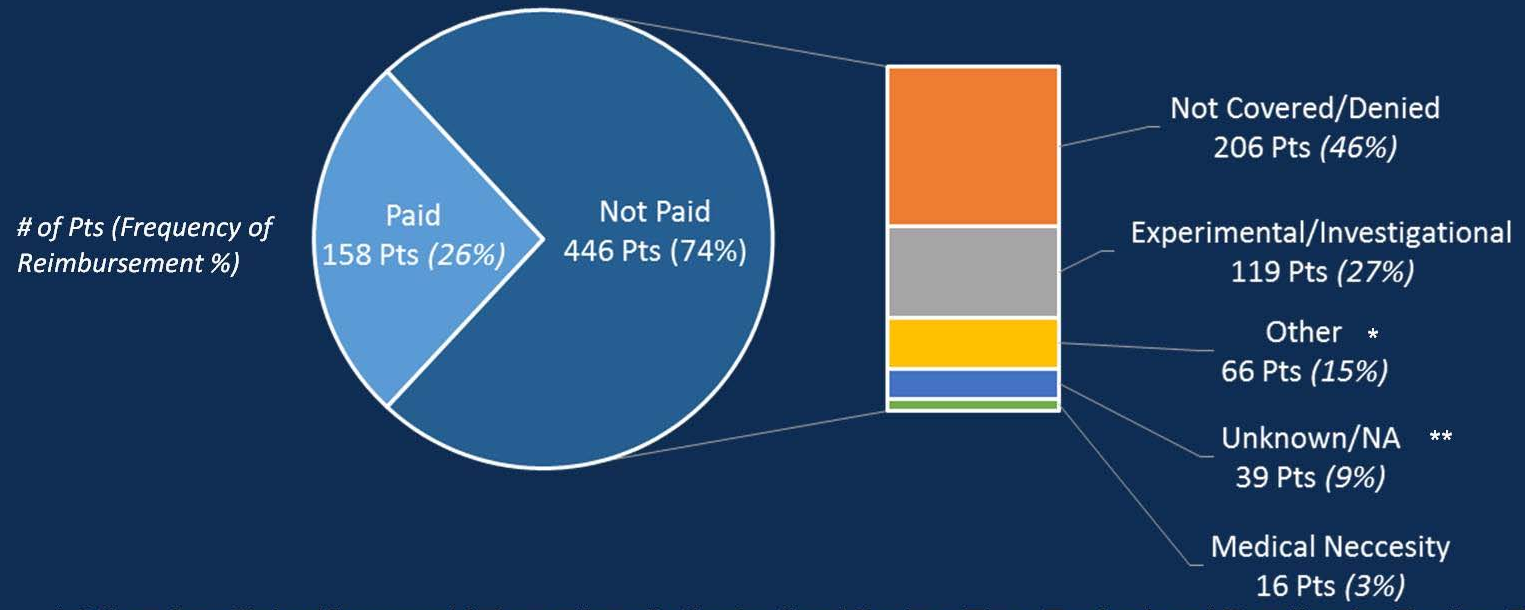
- Younger age was associated with more frequent and higher reimbursement (31% in pts < 65 years, 17% in pts ≥ 65 yo) (p < .001).
- Among pts ≥ 65 yo, frequency (p < .001) and payments (p < .005) by Medicare HMO (69%; $1,003) were higher than Private payers (19%; $361).



Mean $; # of Pts

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

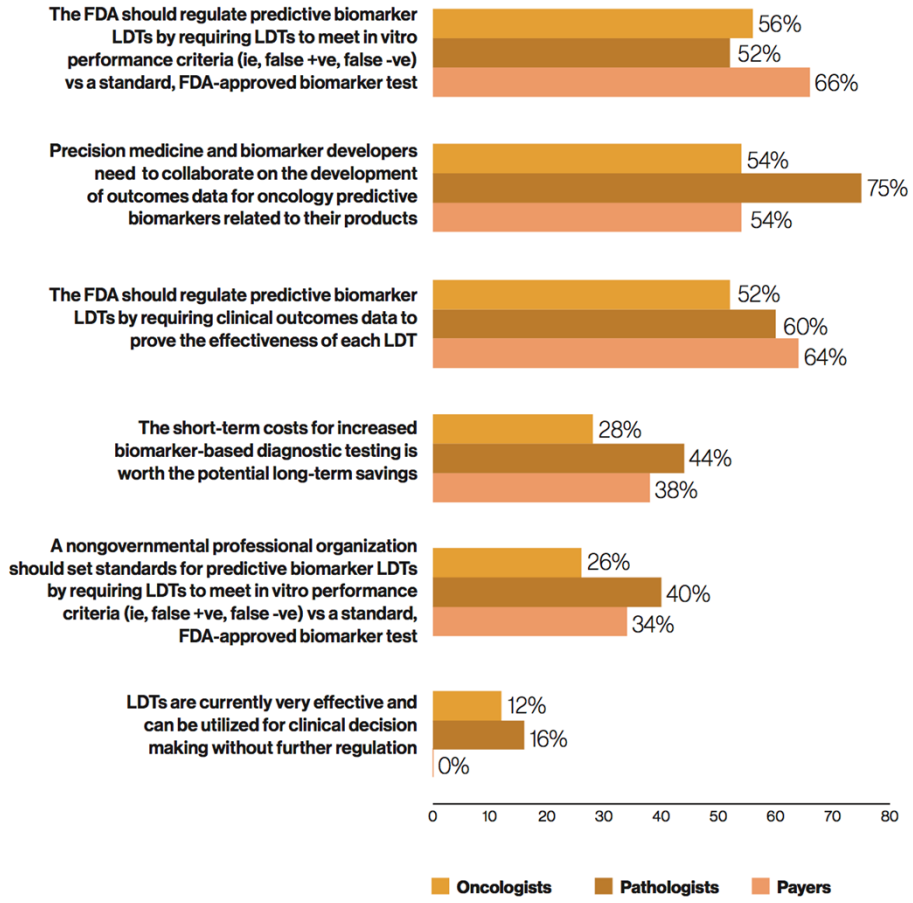
- One third of patients received some reimbursement for NGS testing.
- Reimbursement was more frequent and higher in managed care programs, both Private and Medicare. No reimbursement was received from non-HMO Medicare.
- Reimbursement was more likely for younger age patients.
- Actionable NGS results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

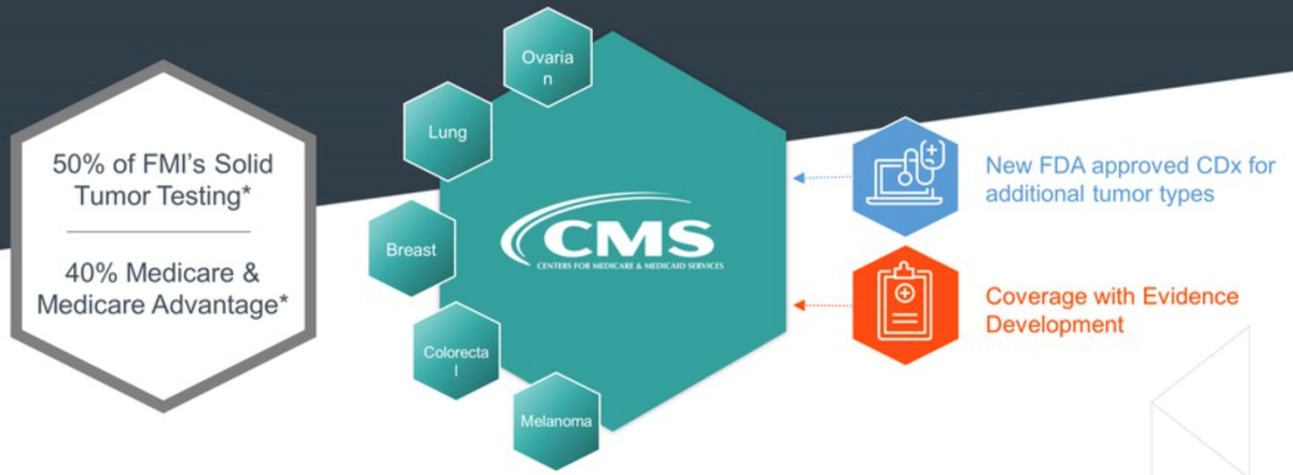
Providers and payers strongly agree that LDTs require regulation and oversight of their effectiveness.

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



Be careful what you ask for…

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.

The Academy
The Health Management Academy

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

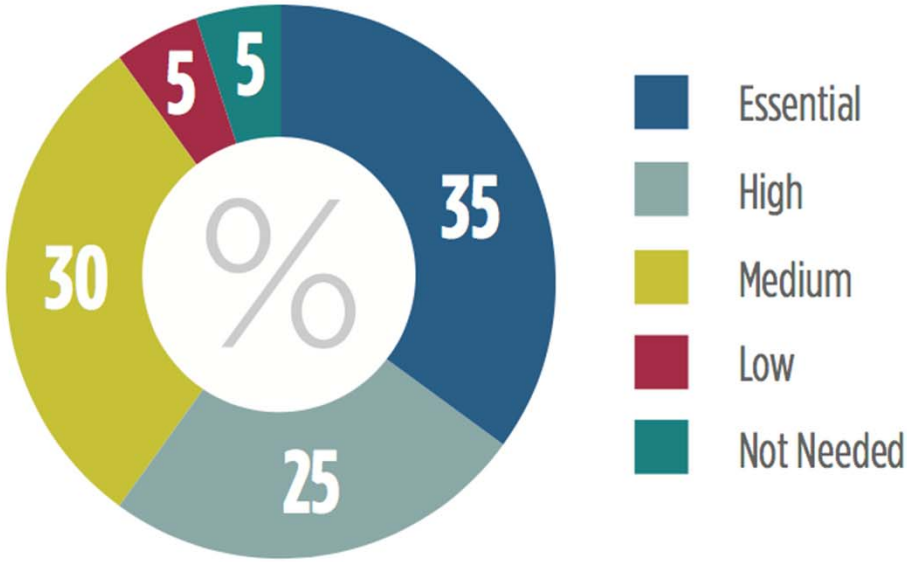


FIGURE 2. WHAT STAGE IS YOUR ORGANIZATION IN DEVELOPING A PRECISION MEDICINE PROGRAM?

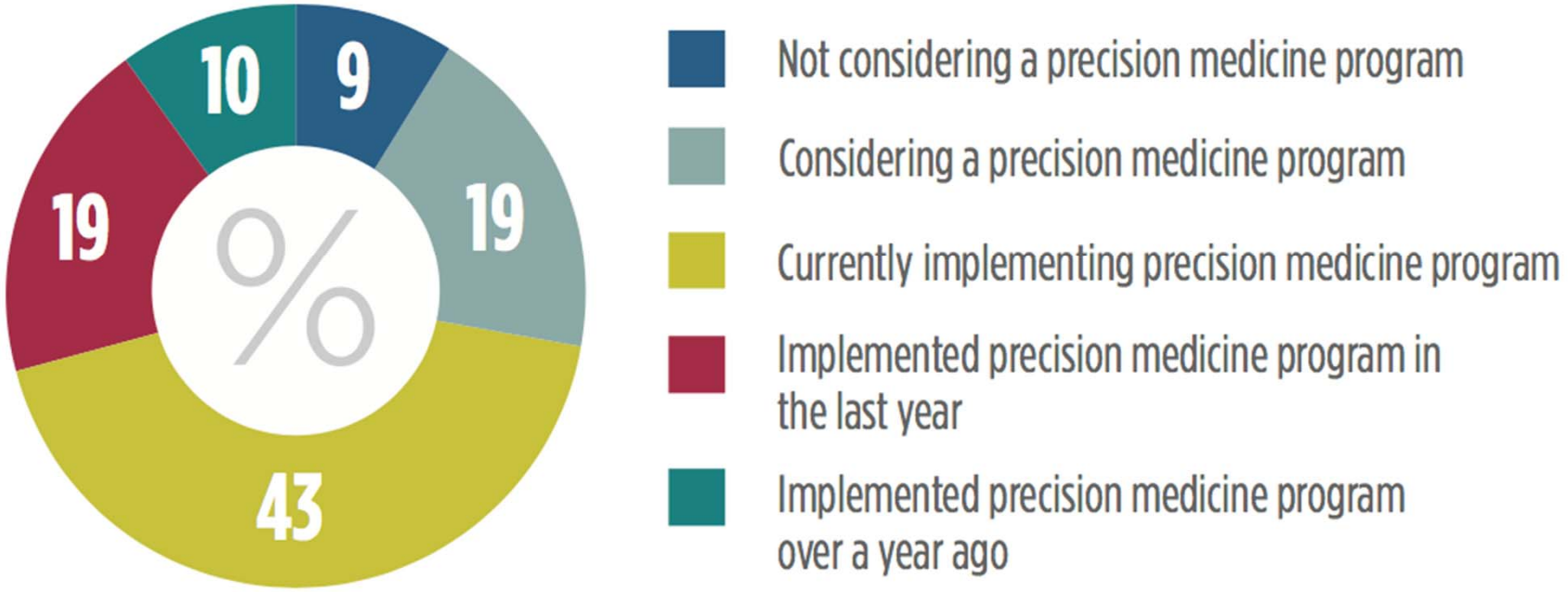


FIGURE 6. HOW MUCH HAS/ WOULD YOU EXPECT A PRECISION MEDICINE PROGRAM TO IMPACT THE FOLLOWING?

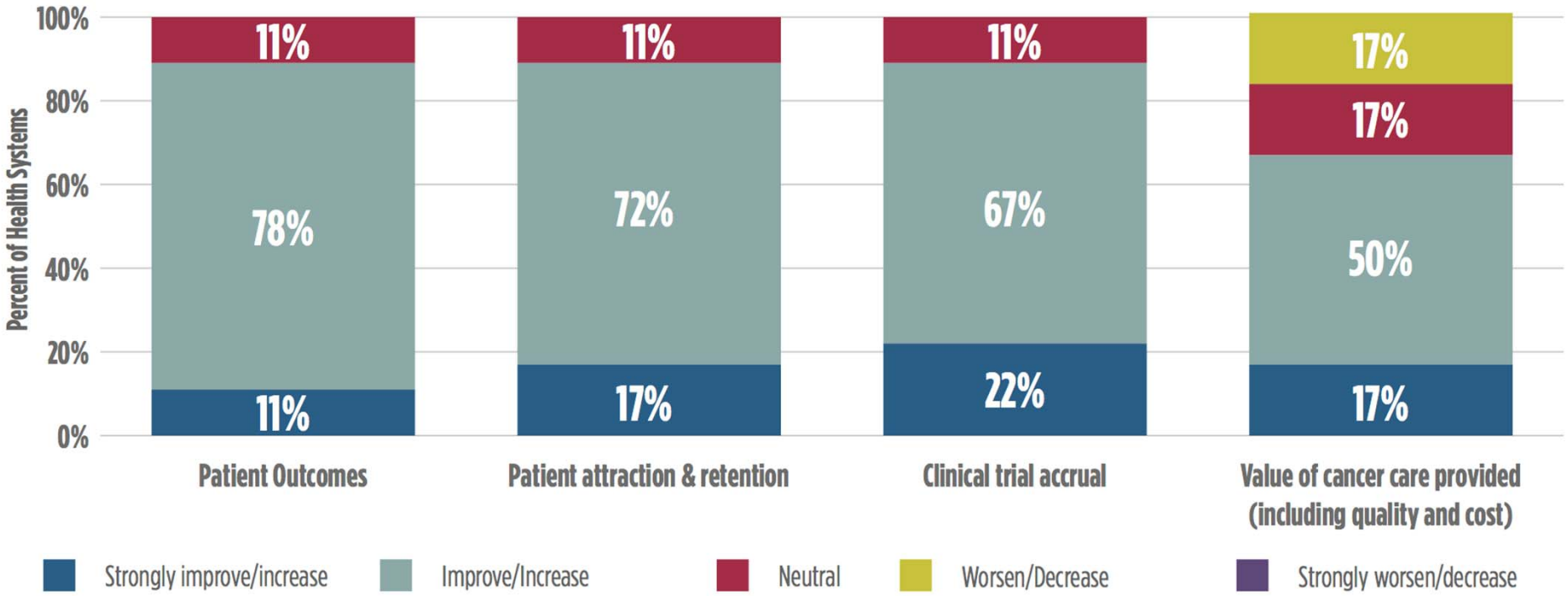


FIGURE 9. HOW CONCERNED ARE YOU REGARDING THE FOLLOWING:

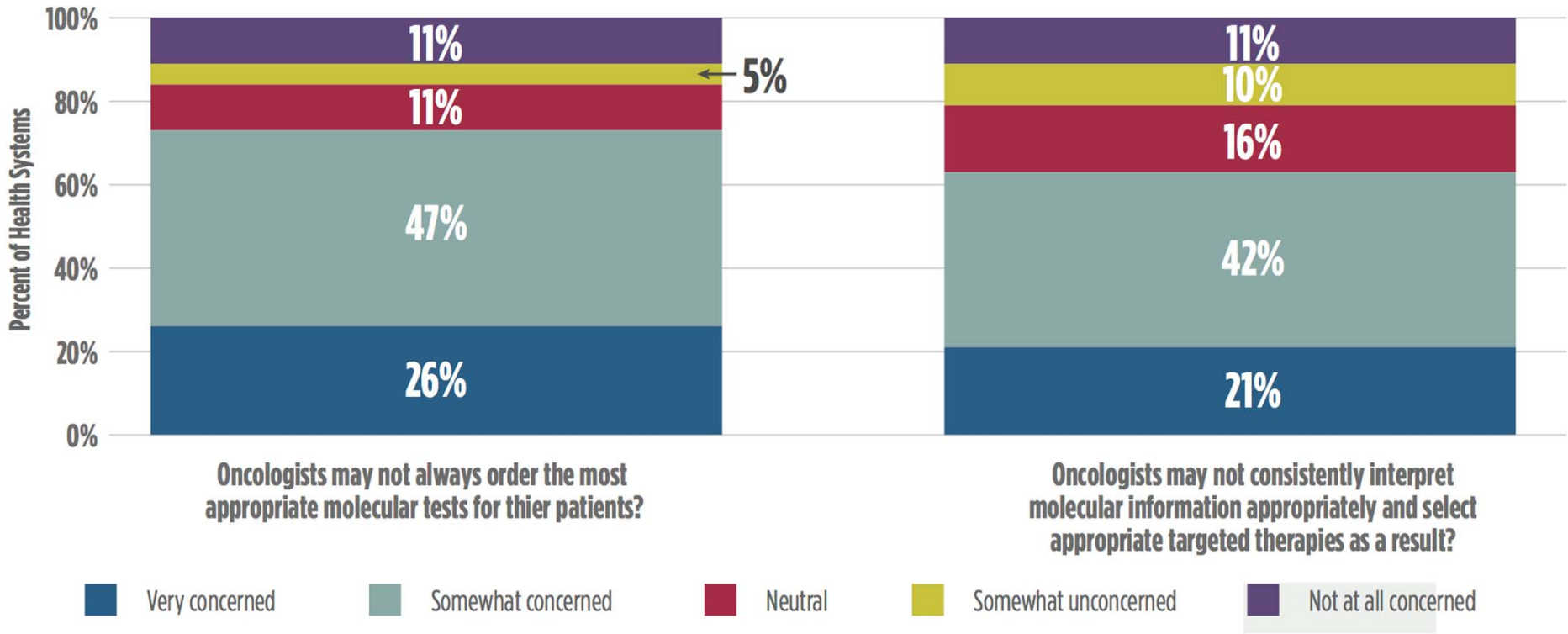


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FIGURE 10. WHAT IS INCLUDED IN YOUR ORGANIZATION'S PLAN FOR TUMOR SITE AGNOSTIC DRUGS? (PLEASE CHECK ALL THAT APPLY.)

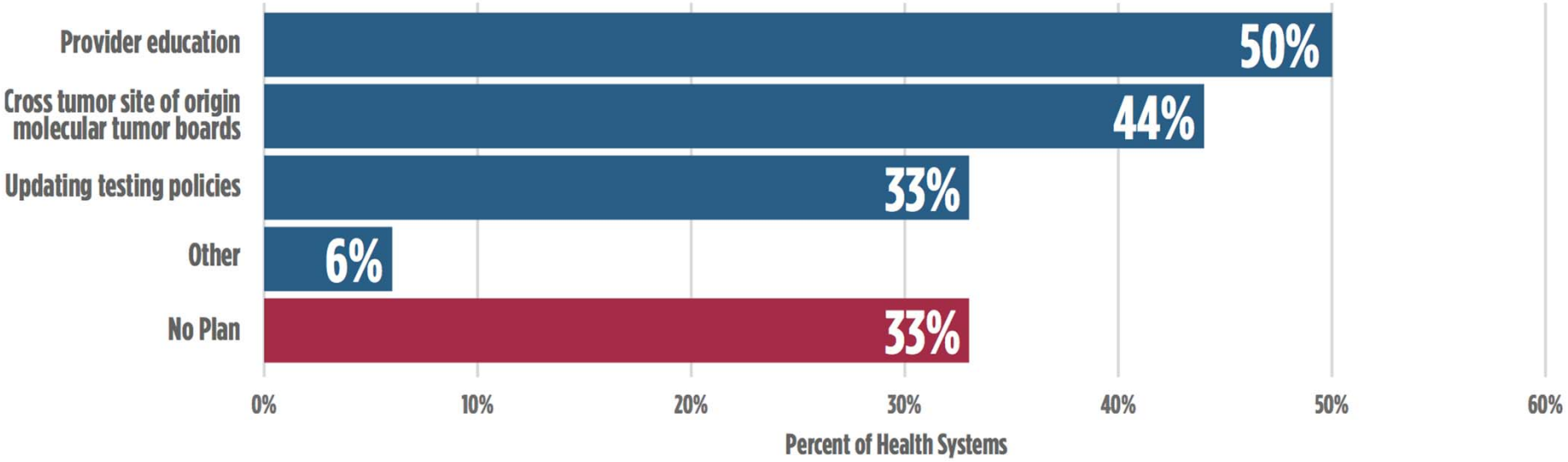


FIGURE 11. HOW IMPORTANT DO YOU THINK IT IS TO PROVIDE GUIDANCE TO ONCOLOGISTS TO HELP THEM NAVIGATE MOLECULAR DIAGNOSTIC AND TARGETED THERAPIES

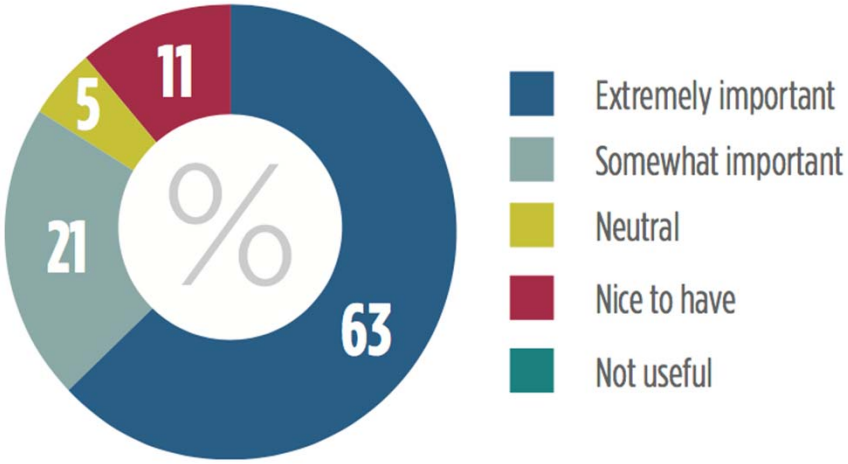


FIGURE 13. IN THE FUTURE, HOW IMPORTANT WILL REAL WORLD OUTCOMES FROM AGGREGATED DE-IDENTIFIED DATA BECOME IN GUIDING PHYSICIAN DECISION MAKING IN COMPLEX CASES?

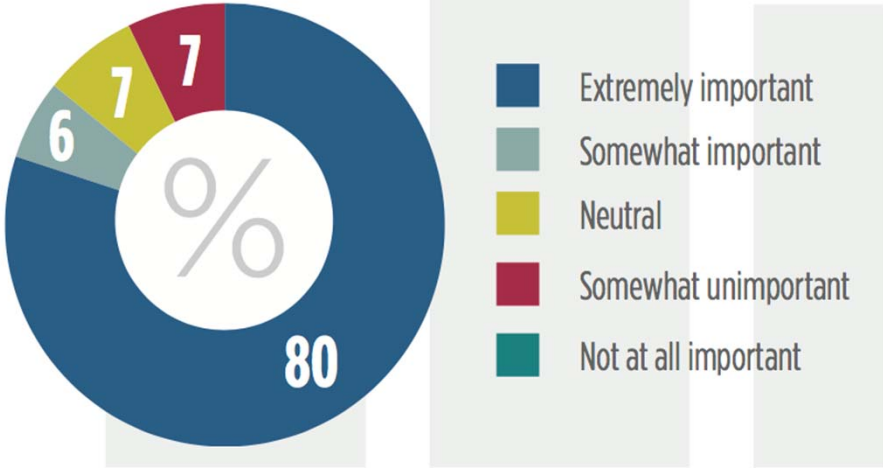
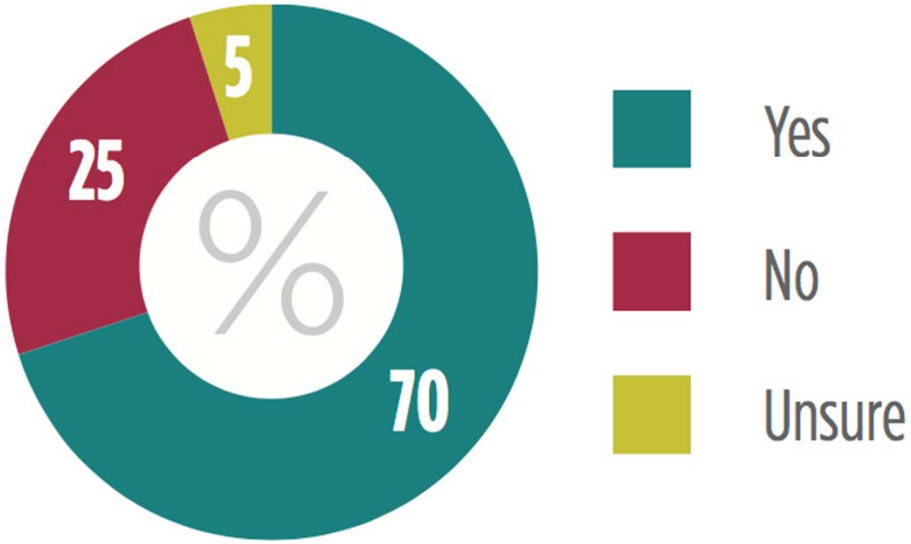


FIGURE 7. DO YOU BELIEVE THAT YOU MUST INVEST IN SOFTWARE TO POWER A PRECISION MEDICINE PROGRAM? (NOTE: PLEASE EXCLUDE ANY SOFTWARE NEEDED TO SUPPORT IN HOUSE SEQUENCING ANALYTICS.)



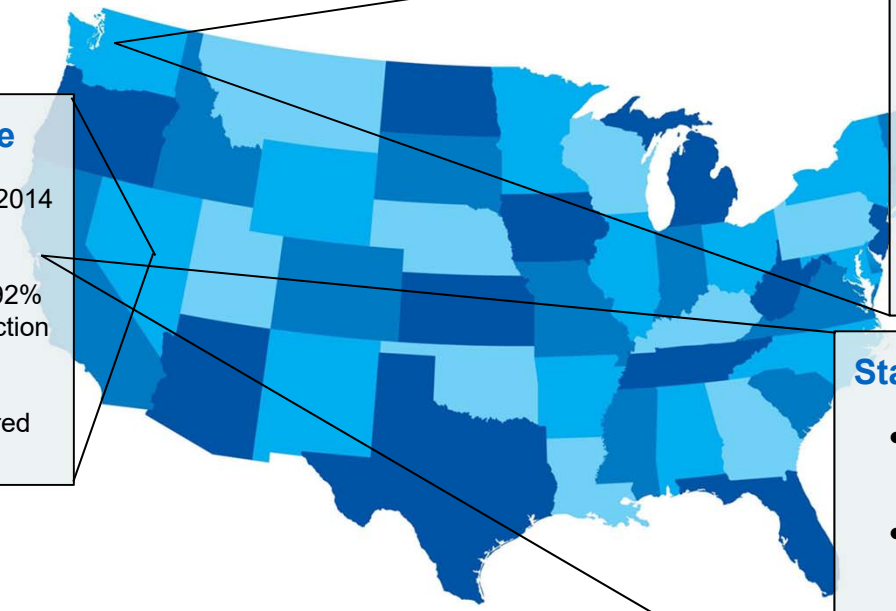
Syapse Mission

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
- **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

Early Adopters Demonstrate Leadership



Intermountain Healthcare

- Partnered with Syapse in 2014 to power the Precision Genomics program
- Intermountain reported a 92% increase in PFS, 9% reduction in costs per PFS week
- 82% of targeted therapy orders successfully procured

Providence St. Joseph Health

- In 2013, PSJH established precision medicine as a system-wide priority
- Goal: to scale the delivery of precision medicine across 50 hospitals and 43,000 new cancer cases per year
- 3000+ patients sequenced
- 22% of physicians reported clinical impact of molecular results

Stanford Cancer Institute

- Partnered with Syapse to leverage molecular data for its NCI-designated cancer center
- Utilizing Syapse to pioneer new approaches to disease treatment and management
- SCI harnesses shared data and insights to improve patient care

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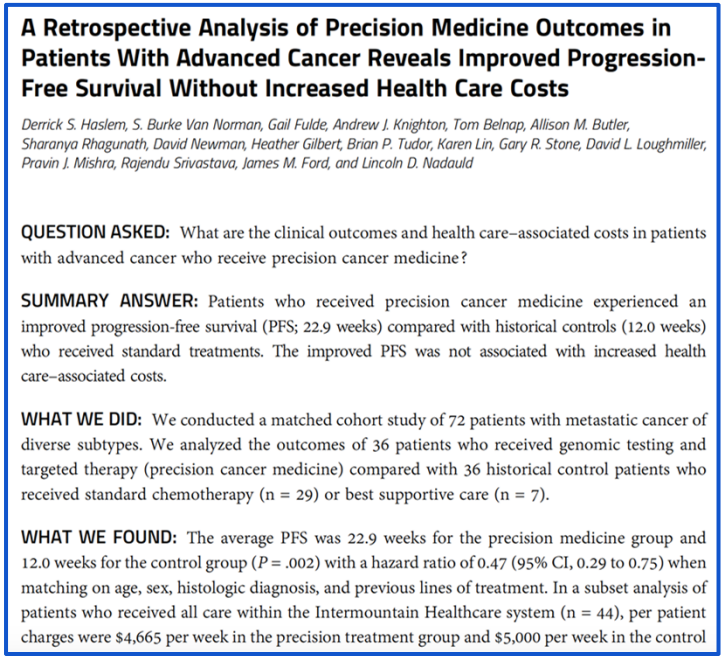
Delivering Better Outcomes for Patients

Intermountain℠ Healthcare

In 2016, Intermountain Healthcare published one of the first real-world clinical utility studies on precision medicine.

- 92% increase in progression-free survival[1]
- 9% reduction in cost of care per progression-free survival week[1]



A Retrospective Analysis of Precision Medicine Outcomes in Patients With Advanced Cancer Reveals Improved Progression-Free Survival Without Increased Health Care Costs

Derrick S. Haslem, S. Burke Van Norman, Gail Fulde, Andrew J. Knighton, Tom Belnap, Allison M. Butler, Sharanya Rhagunath, David Newman, Heather Gilbert, Brian P. Tudor, Karen Lin, Gary R. Stone, David L. Loughmiller, Pravin J. Mishra, Rajendu Srivastava, James M. Ford, and Lincoln D. Nadauld

QUESTION ASKED: What are the clinical outcomes and health care–associated costs in patients with advanced cancer who receive precision cancer medicine?

SUMMARY ANSWER: Patients who received precision cancer medicine experienced an improved progression-free survival (PFS; 22.9 weeks) compared with historical controls (12.0 weeks) who received standard treatments. The improved PFS was not associated with increased health care–associated costs.

WHAT WE DID: We conducted a matched cohort study of 72 patients with metastatic cancer of diverse subtypes. We analyzed the outcomes of 36 patients who received genomic testing and targeted therapy (precision cancer medicine) compared with 36 historical control patients who received standard chemotherapy (n = 29) or best supportive care (n = 7).

WHAT WE FOUND: The average PFS was 22.9 weeks for the precision medicine group and 12.0 weeks for the control group ($P = .002$) with a hazard ratio of 0.47 (95% CI, 0.29 to 0.75) when matching on age, sex, histologic diagnosis, and previous lines of treatment. In a subset analysis of patients who received all care within the Intermountain Healthcare system (n = 44), per patient charges were $4,665 per week in the precision treatment group and $5,000 per week in the control

[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.

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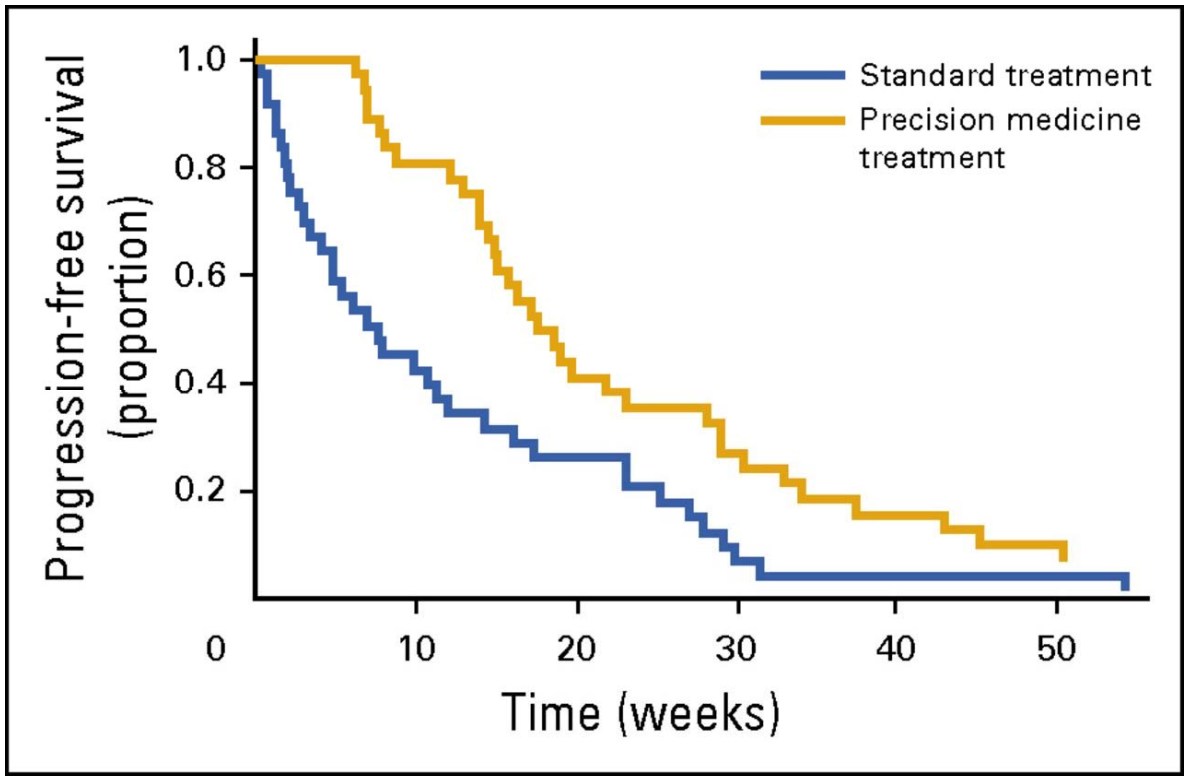
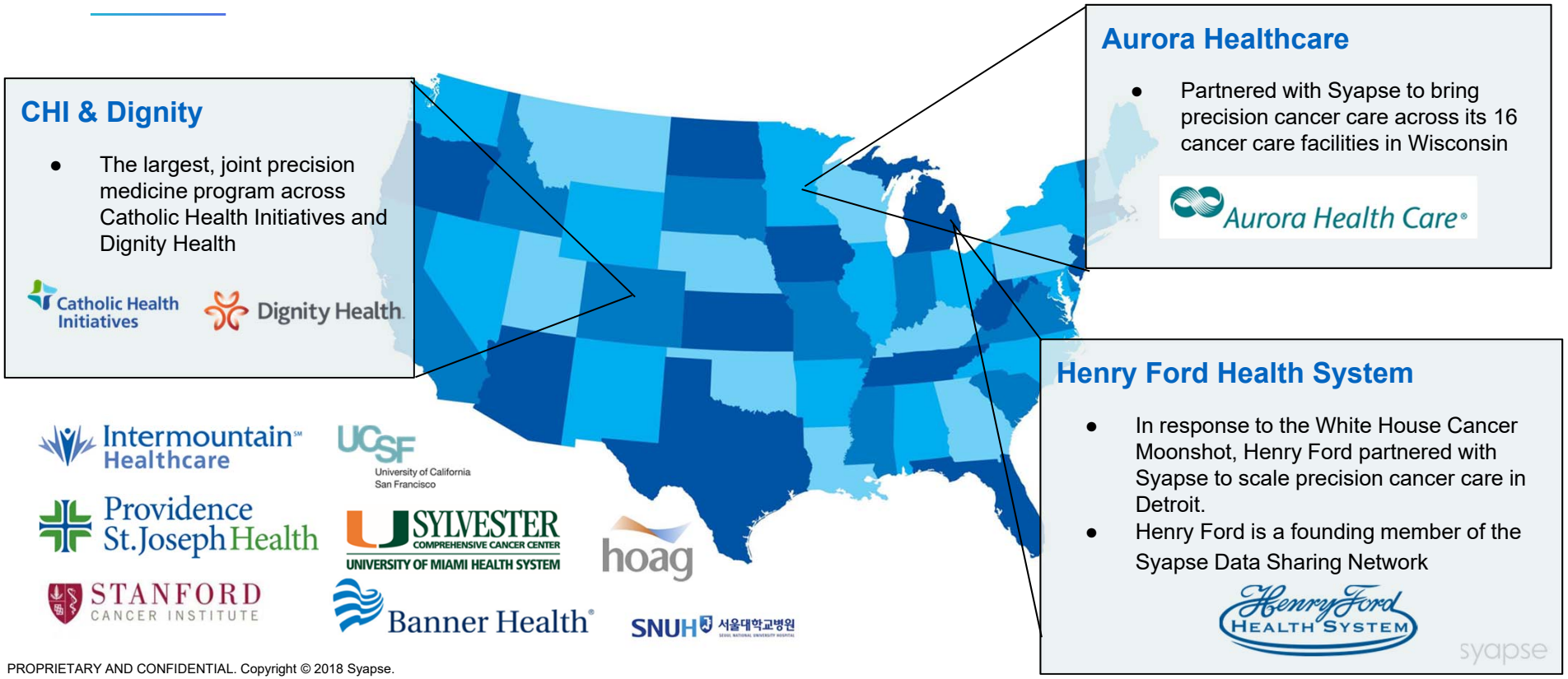
The progression-free survival of patients in the standard and precision medicine treatment cohorts were measured and compared over weeks.



Derrick S. Haslem et al. JOP doi:10.1200/JOP.2016.011486

More Health Systems are Prioritizing Precision Medicine



CHI & Dignity

- The largest, joint precision medicine program across Catholic Health Initiatives and Dignity Health

Catholic Health Initiatives

Dignity Health

Aurora Healthcare

- Partnered with Syapse to bring precision cancer care across its 16 cancer care facilities in Wisconsin

Aurora Health Care

Henry Ford Health System

- In response to the White House Cancer Moonshot, Henry Ford partnered with Syapse to scale precision cancer care in Detroit.
- Henry Ford is a founding member of the Syapse Data Sharing Network

Henry Ford Health System

Intermountain Healthcare

UCSF University of California San Francisco

Providence St. Joseph Health

Sylvester Comprehensive Cancer Center University of Miami Health System

hoag

Stanford Cancer Institute

Banner Health

SNUH 서울대학교병원

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Precision Medicine is Here

Vice President Biden announced the launch of the Syapse Data Sharing Network in his address at the Cancer Moonshot Summit in 2016.

- Today, 90% of the late phase pipeline are targeted treatments
- In the past few years, 68 new cancer therapies have been approved for over 22 indications
- The FDA approved the first tumor site agnostic therapy
- Foundation NGS panel gets nod from FDA and CMS

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Scaling Nationally in the Community Setting

Providence St. Joseph Health

In 2013, Providence St. Joseph Health established precision medicine as a system-wide priority for its 50 hospitals and 20,000 physicians.

- To date, 3000+ patients have been sequenced
- Initial programs at Swedish Cancer Institute & Providence Oregon Cancer Center, is expanding system-wide

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National Reach Through Health System Consolidation

Catholic Health Initiatives

Dignity Health

The Precision Medicine Alliance, a joint venture between Catholic Health Initiatives and Dignity Health, is the most expansive community-based precision medicine program in the nation

- Partnered with Syapse to operationalize the precision medicine program and synchronize clinical operations for precision medicine
- Establishing common data standards, streamlined workflows, and data sharing at a national scale

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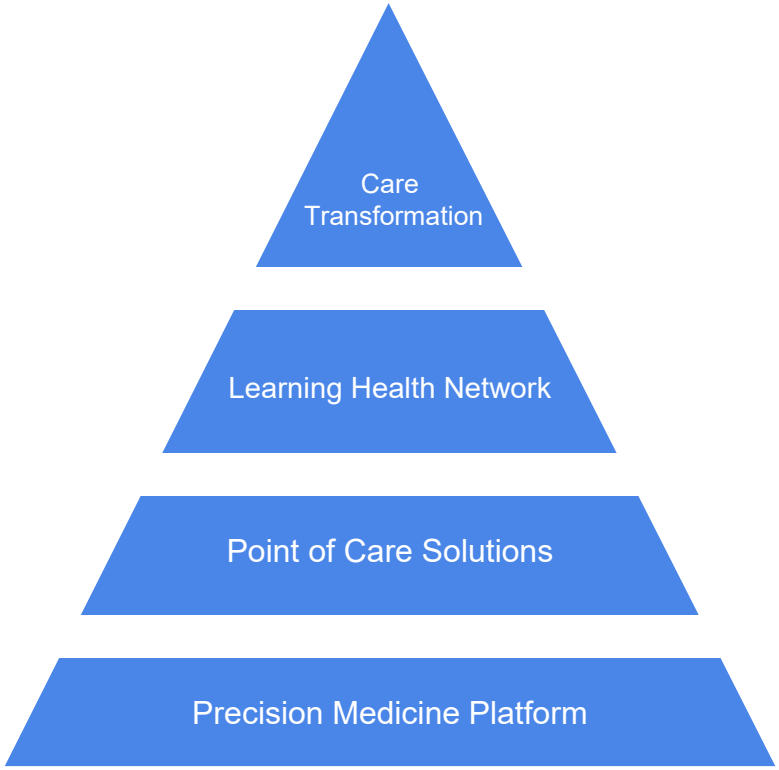
Our Solutions

We are on a mission to deliver the best care for every cancer patient through precision medicine.

- Our technology enables health systems to operationalize precision medicine programs
- We bring together leading innovators in the precision medicine ecosystem to support providers at the point of care



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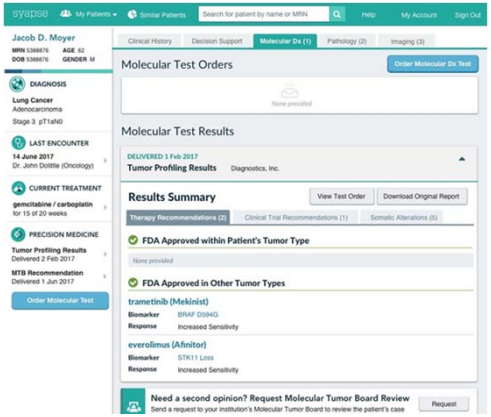
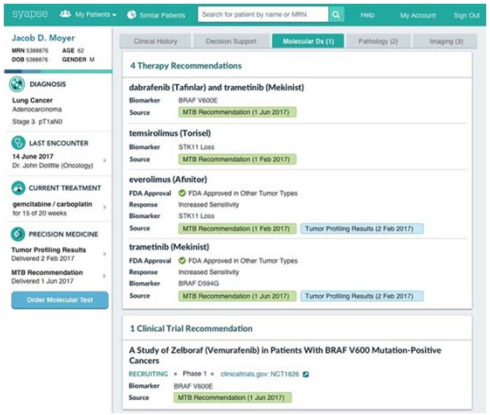
Supporting Clinicians at the Point of Care



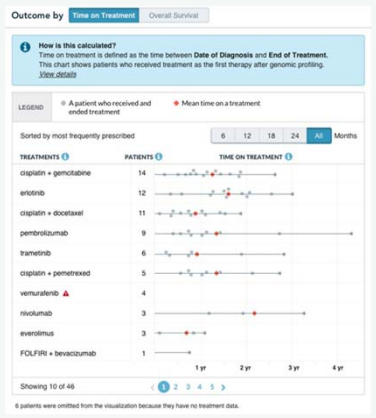
Receive Structured Molecular Results

Access molecular test results in a consistent format, regardless of lab



Support Treatment Decisions

View treatment recommendations from MTBs and other sources



Learn from Real-World Evidence

View which treatments produced the best outcomes for patients like yours

Powered by Integrated Clinical and Genomic Data

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Partnering with Health Systems to Scale Precision Medicine

Syapse Oncology is the leading software solution for enterprise precision medicine programs.

1. Aggregate clinical data sources and integrate molecular data
2. Streamline precision medicine workflows
3. Provide patient-level decision support from multiple sources

"Syapse enables us to share robust, real-world evidence with other community health systems and research practices, linking us with our peers while keeping patient data secure."

Thomas Brown, MD, MBA
Executive Director of Swedish Cancer Institute at Providence St. Joseph

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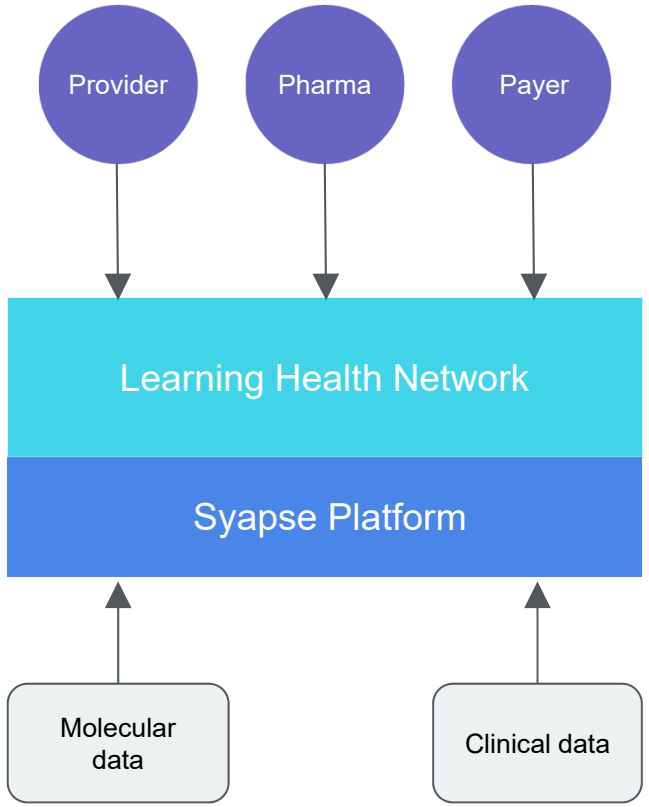
Learning Health Network

A provider-driven network built to inform treatment decisions at the point of care

- The Syapse platform integrates and standardizes clinical, molecular, treatment and outcomes data
- Health systems share real-world evidence, enabling clinicians to learn from the experience of their peers
- Leverage the ecosystem to support providers in clinical practice



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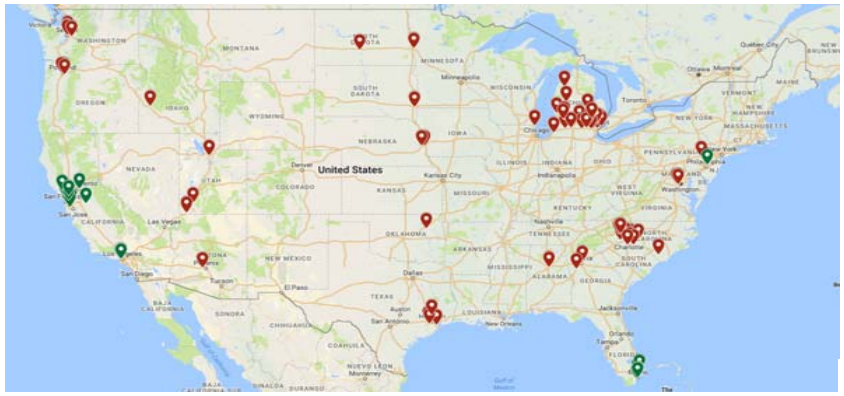
Real-World Study: ASCO TAPUR

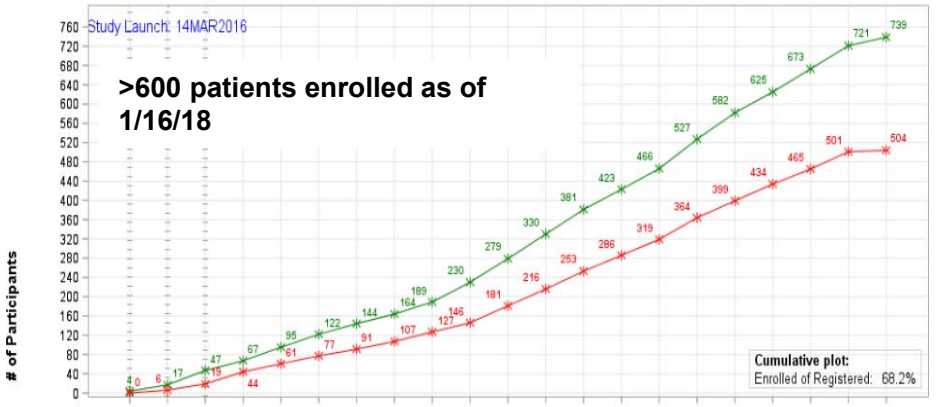
113 sites in 20 states



Study Drug	Tumor Type	Variant	Cohort Status*
Cetuximab	Ovarian Cancer	KRAS, NRAS, and BRAF wildtype	Expanded
Pembrolizumab	Breast Cancer	High tumor mutational burden	Expanded
Vemurafenib + Cobimetinib	Colorectal Cancer	BRAF_V600E mutation	Expanded
Palbociclib	Malignant neoplasm of bronchus and lung	CDKN2A mutation or loss	Expanded
Palbociclib	Pancreatic Cancer	CDKN2A loss or mutation	Closed

19 study drugs, 16 therapies

Cohorts are maturing.
1 cohort has closed after Stage I.
4 cohorts have expanded to Stage II.



RWE to Inform Payment Policy

Health Alliance Plan and Henry Ford Precision Medicine Program

"We agreed in principle to explore the concept of HAP covering up-front testing for an initial diagnosis of all solid tumors coming in to Henry Ford, if the request for testing was vetted through one of our disease specific tumor boards, to prevent an unlimited number of requests and also to ensure that medical, radiation, and surgical oncology providers for each tumor type agreed that molecular precision medicine sequencing data had a realistic chance of changing the treatment outcome."

Payers engaging in rigorous and robust joint learning that answers questions such as:

1. Did testing lead to different treatment
2. Did testing lead to better outcomes for patients
3. How did effect cost to the system
4. If there are savings how did we deploy these savings to the benefit of "population health"

Bringing RWE & Data Sharing to the Point of Care

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

1,000,000+
analytic cancer cases

250+
hospitals

Providence St. Joseph Health

Henry Ford Health System

Aurora Health Care

Dignity Health

Catholic Health Initiatives

hoag

syapse