



NATIONAL
LUNG CANCER
ROUNDTABLE



**Addressing Lung Cancer
Biomarker Testing
Through Project ECHO:
2022-2023 Expansion**

Session Six: Tennessee

Welcome to Session Five: Tennessee State Session

ACS/NLCRT Lung Cancer Biomarker Testing Project ECHO



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Questions about Zoom? Type them in the chat box @Korey Hofmann



Agenda Preview & Introductions



**Dr. Philip Lammers,
*Facilitator,
Baptist Cancer
Center***



Today's Agenda

01 **Agenda Preview & Introductions** (10 min)

02 **Didactic Presentation: Dr. Sean Jordan** (15min)

03 **Didactic Q/A** (5-10 min)

04 **Case Presentation:** *Tennessee Biomarker & Precision Medicine*
Legislative Update: **Maddie Bushnell** (10 min)

05 **Case Presentation Q/A** (5 min)

06 **Post-Session Poll & Wrap Up** (5 min)

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Introductions: Meet our Tennessee ECHO Hub Core Faculty



Philip Edward Lammers, MD, MSCI
Baptist Cancer Center
Facilitator & Faculty Member



J. Rob Headrick, MD, MBA
CHI Memorial Chest & Lung Cancer Center
Faculty Member



Melissa Johnson, MD
Sarah Cannon/Tennessee Oncology
Faculty Member



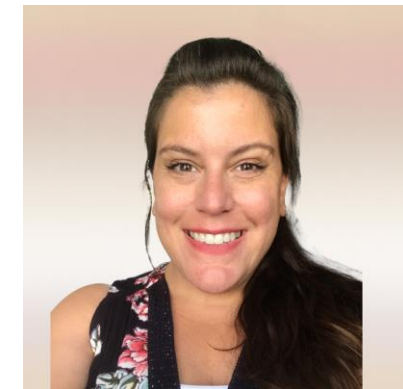
Raymond U. Osarogiagbon, MD
Baptist Cancer Center
Faculty Member



Sean A. Jordan, MD, MHS
UTK Medical Center
Faculty Member



Korey Hofmann, MPH
American Cancer Society
ECHO Coordinator



Jocelyn Phillips
American Cancer Society
ECHO Coordinator

Introductions: Meet our Tennessee Spoke Sites

Tennessee



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Didactic Presentation: *Navigating Insurance Complexities*



*Sean A. Jordan, MD,
MHS
UT Knoxville*

Navigating Insurance Complexities with Biomarker Testing

Sean Jordan, MD, MHS

May 19, 2023

Our Mission

To serve through healing,
education and discovery

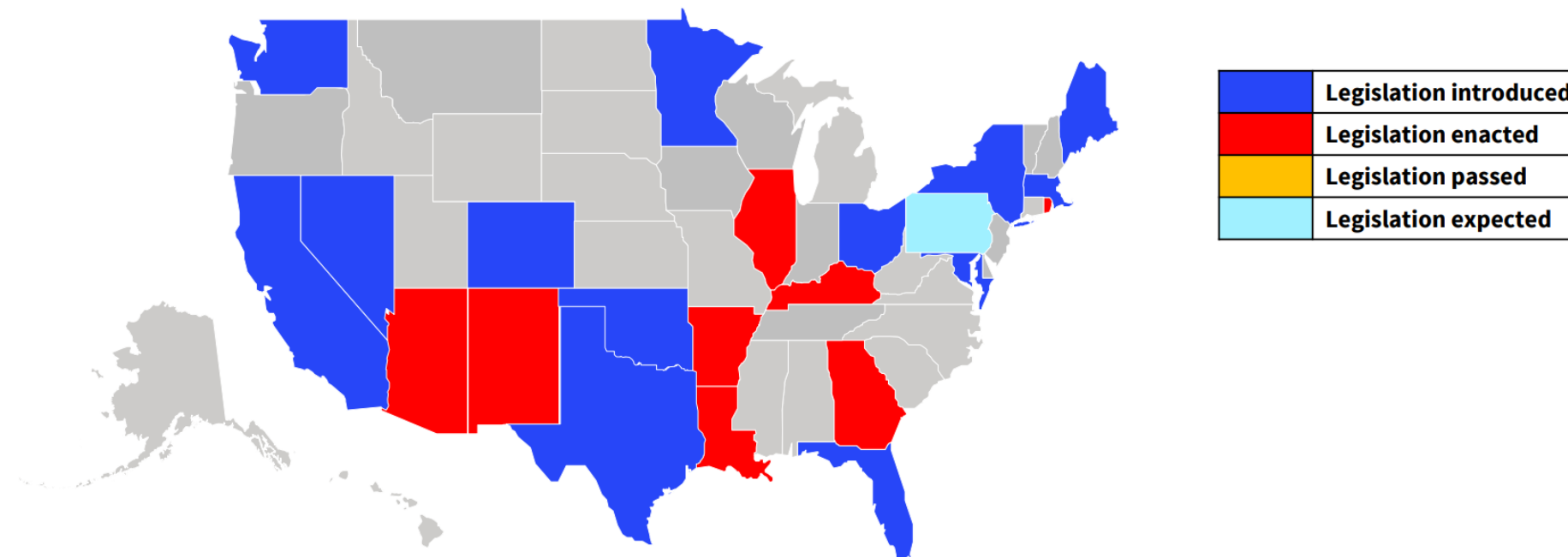


- None

- Molecular biomarker testing is vital for the treatment of NSCLC
- Multiple actionable biomarkers have been identified
- Blood-based tests (liquid biopsies) have emerged as a useful adjunct for improving identification of actionable biomarkers

- Multiple states currently have legislation regarding requiring state-regulated insurance companies to cover molecular based biomarker testing for lung cancer
- Legislation has been proposed and is pending in even more states
- Tennessee currently has no legislation regarding molecular testing, leaving it up to individual insurance companies to decide

Legislation to Expand Access to Biomarker Testing



Legislation enacted: AZ, IL, LA, RI, KY, NM, AR*, GA

Legislation passed (2023 session): MD

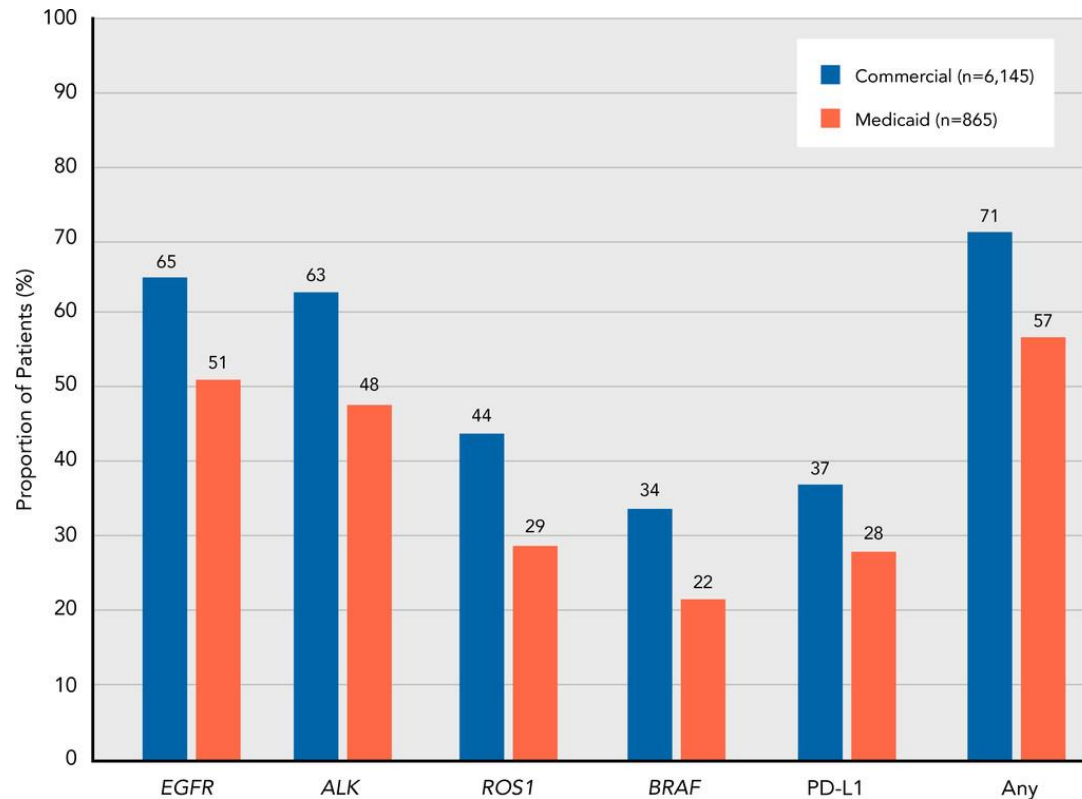
Legislation expected in 2023: CA, CO, FL, MA, ME, MN, NV, NY, OH, OK, PA, TX, WA

*commercial coverage only



- Follow medical necessity based on NCCN guidelines
- If ordering individual tests, each individually ordered tumor marker is evaluated separately for medical necessity
- If ordering five or more (or just ordering a panel), the lab is directed to use a panel CPT code for billing

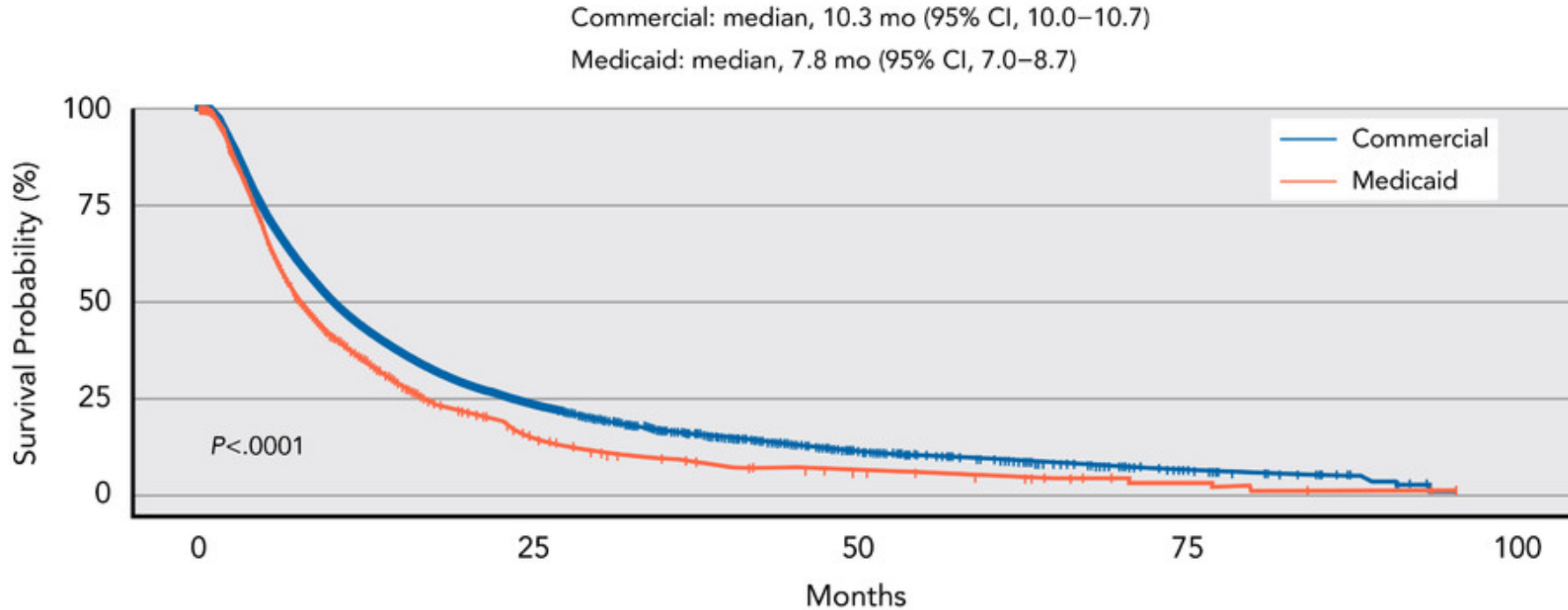
- Medicaid recipients are less likely to undergo appropriate biomarker testing



Source: Gross, C.P., Meyer, C.S., Ogale, S., Kent, M., Wong, W.B., 2022. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. *Journal of the National Comprehensive Cancer Network* 20, 479–487.e2.. <https://doi.org/10.6004/jnccn.2021.7083>

Medicaid vs. Commercial Insurance

A



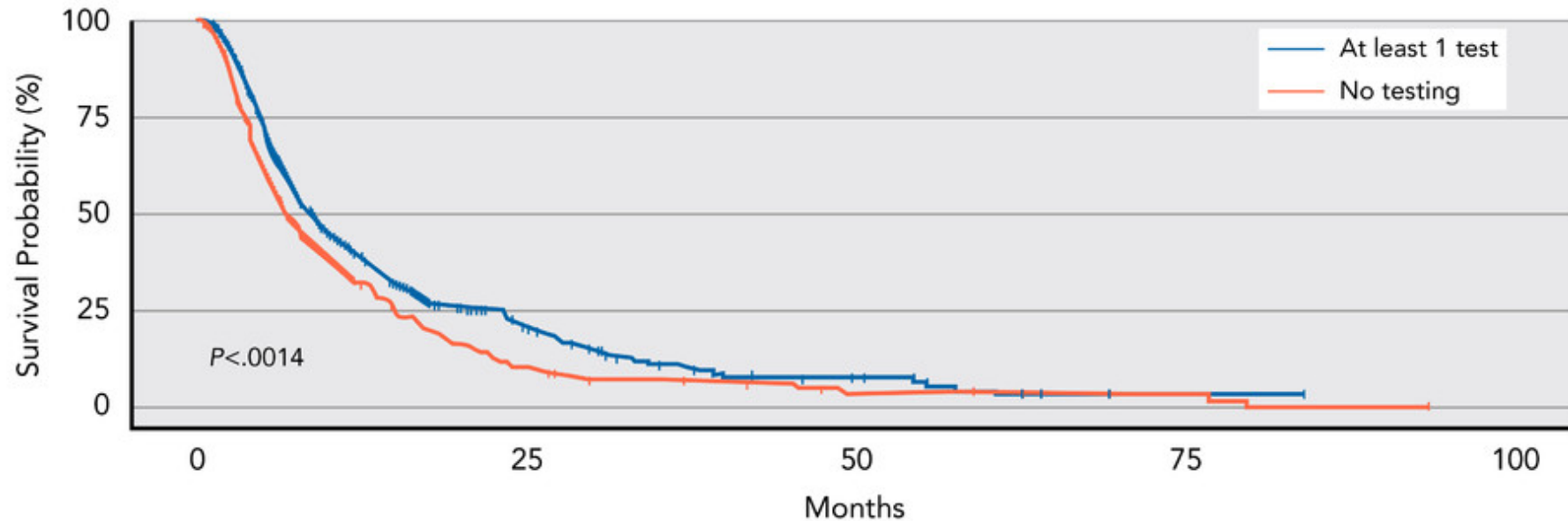
Number at risk

Commercial	6,145	819	195	37	0
Medicaid	865	81	19	4	0

Source: Gross, C.P., Meyer, C.S., Ogale, S., Kent, M., Wong, W.B., 2022. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. Journal of the National Comprehensive Cancer Network 20, 479–487.e2.. <https://doi.org/10.6004/jnccn.2021.7083>

B

At least 1 test: median, 8.7 mo (95% CI, 7.6–10.3)
 No testing: median, 6.9 mo (95% CI, 6.2–7.9)

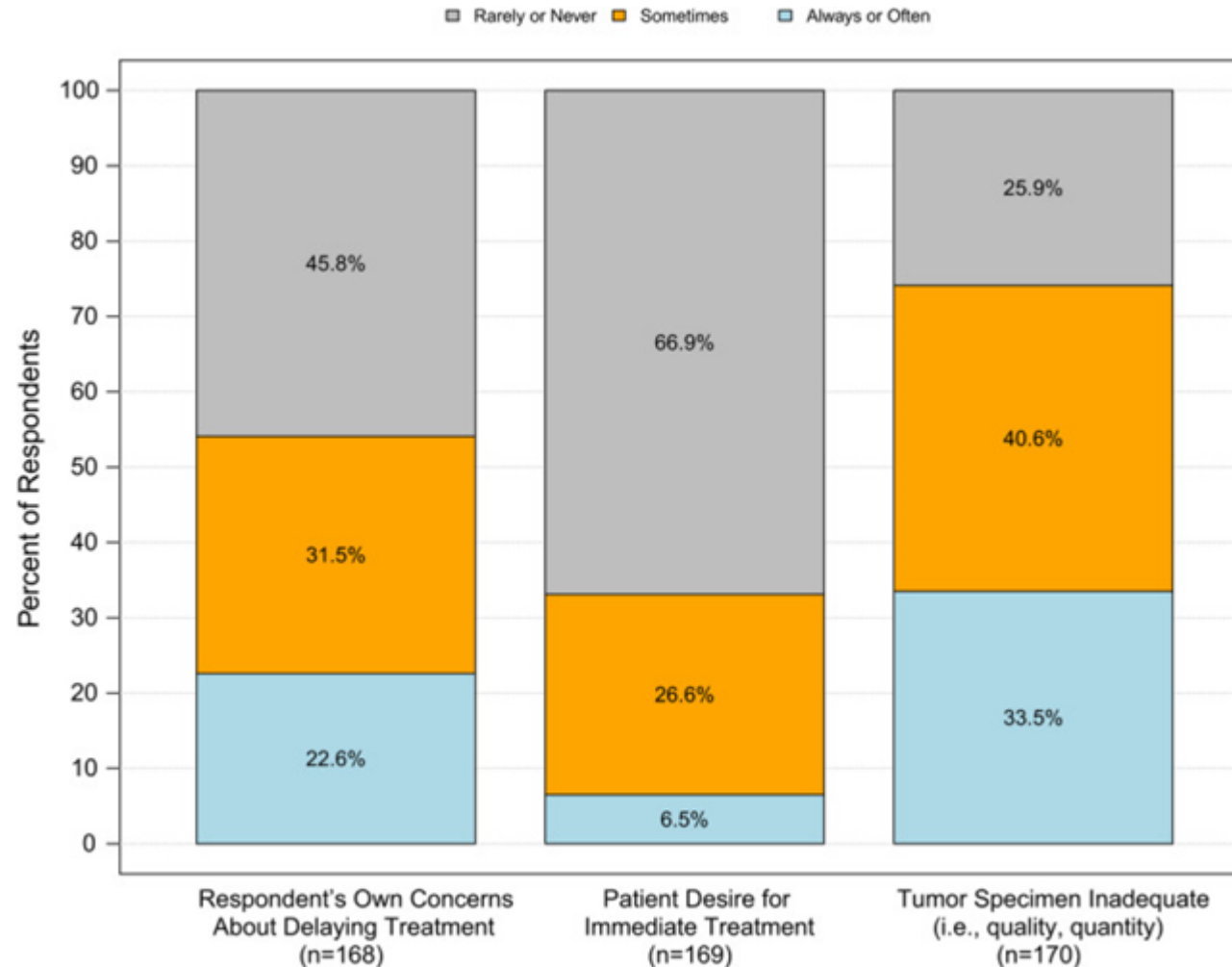


Number at risk

At least 1 test	489	52	10	1	0
No testing	376	29	9	3	0

Source: Gross, C.P., Meyer, C.S., Ogale, S., Kent, M., Wong, W.B., 2022. Associations Between Medicaid Insurance, Biomarker Testing, and Outcomes in Patients With Advanced NSCLC. *Journal of the National Comprehensive Cancer Network* 20, 479–487.e2.. <https://doi.org/10.6004/jnccn.2021.7083>

- Most frequent reasons for not ordering biomarker testing



Source: Mileham, K.F., Schenkel, C., Bruinooge, S.S., Freeman-Daily, J., Basu Roy, U., Moore, A., Smith, R.A., Garrett-Mayer, E., Rosenthal, L., Garon, E.B., Johnson, B.E., Osarogiagbon, R.U., Jalal, S., Virani, S., Weber Redman, M., Silvestri, G.A., 2022. Defining comprehensive biomarker-related testing and treatment practices for advanced non-small-cell lung cancer: Results of a survey of U.S. oncologists. *Cancer Medicine* 11, 530–538. doi:10.1002/cam4.4459

- Generally, CMS bundles lab tests in with the hospital admission
- In 2018, they added a date-of-service policy that allows the lab to bill separately for a stored specimen provided certain criteria are met, i.e., it is ordered 14 days after the patient is discharged from the hospital on specimens collected as an inpatient
- As of 2018, labs can bill Medicare separately for outpatient encounters on tests run after the outpatient has been discharged (e.g., CT-guided biopsies, bronchoscopic-guided biopsies, etc.)

- This adds considerable complexity
- In a surgically collected specimen (nearly all will require inpatient admission), the test must be ordered for 14 days after discharge, not day of surgery
- In a planned outpatient procedure in which the patient has an unexpected complication and requires admission (pneumothorax after CT-guided biopsy), the 14 day rule kicks into effect and Medicare can deny coverage for molecular testing if ordered as part of original outpatient orders
- This also applies to blood-based biomarker testing

- No in-house PD-L1 testing
- Partnered with private companies who are able to provide comprehensive molecular biomarker testing
- Challenging to get investment from multiple departments and specialties
- “Tissue is the issue” – with multiple possible companies and small specimens, challenging for pathologists to allocate already small specimens for tissue-based molecular testing

- Legislative
 - Tennessee needs legislation to enforce coverage of biomarker testing like other states
 - Federal changes to CMS rules like the 14 day rule
- Education
 - Understanding regulations regarding molecular testing
 - Advocacy for increased biomarker testing in all patient populations

Thank you

Didactic Questions & Discussion



Case Presentation:
*Tennessee Biomarker &
Precision Medicine
Legislative Update*



***Maddie Bushnell,
Government
Relations Director,
Tennessee
ACS CAN***



Biomarker Testing and Precision Medicine

Maddie Bushnell

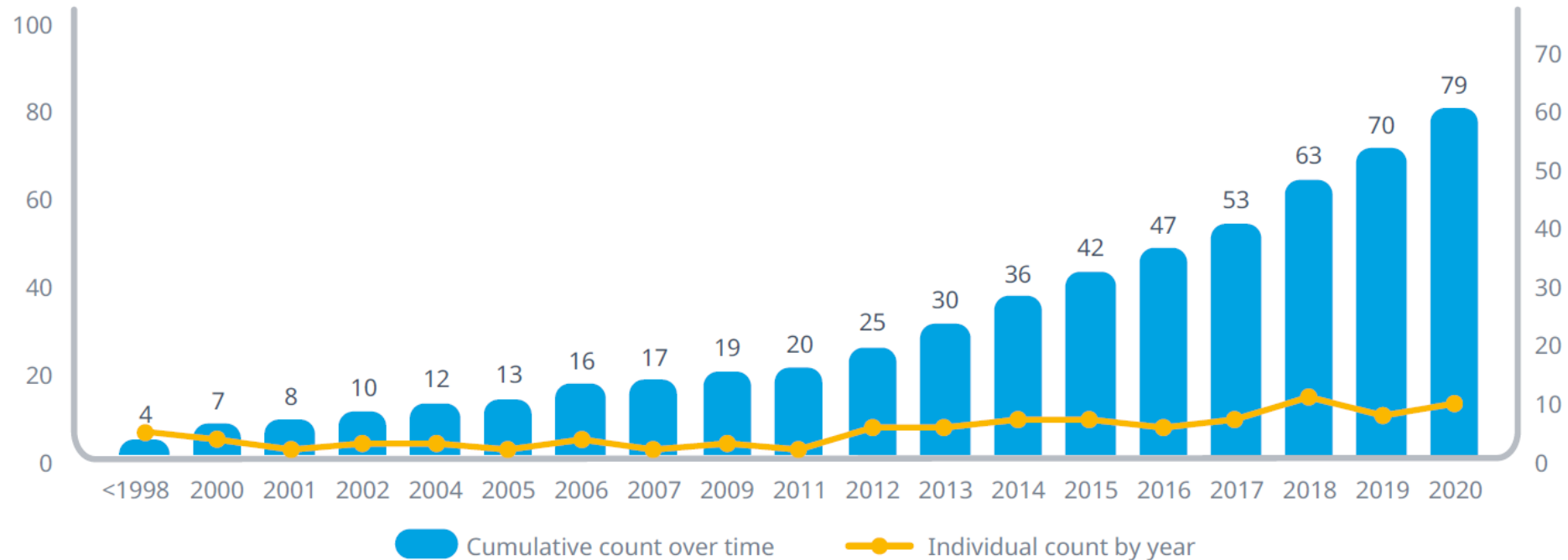
Government Relations Director, Tennessee

American Cancer Society Cancer Action Network

Trends in biomarker testing

Nearly 80 oncology medicines are used after a predictive biomarker test up from 20 in 2011

Exhibit 38: Number of U.S. Oncology Medicines with Required or Recommended Predictive Biomarker Testing

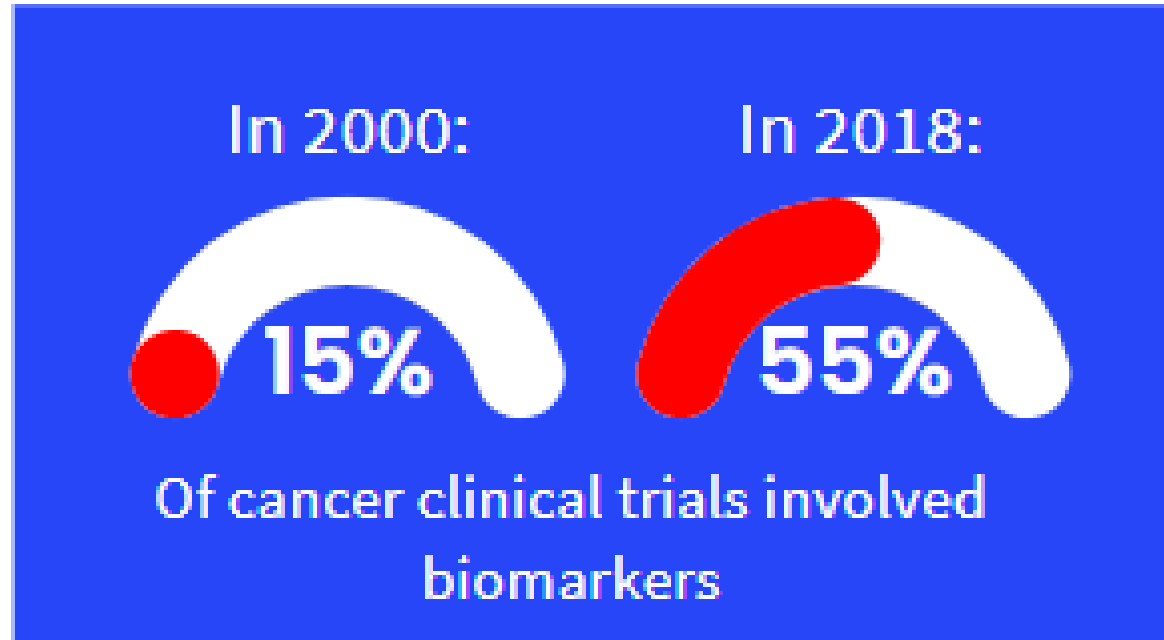


Source: IQVIA Institute, May 2021



Biomarker testing and clinical trials

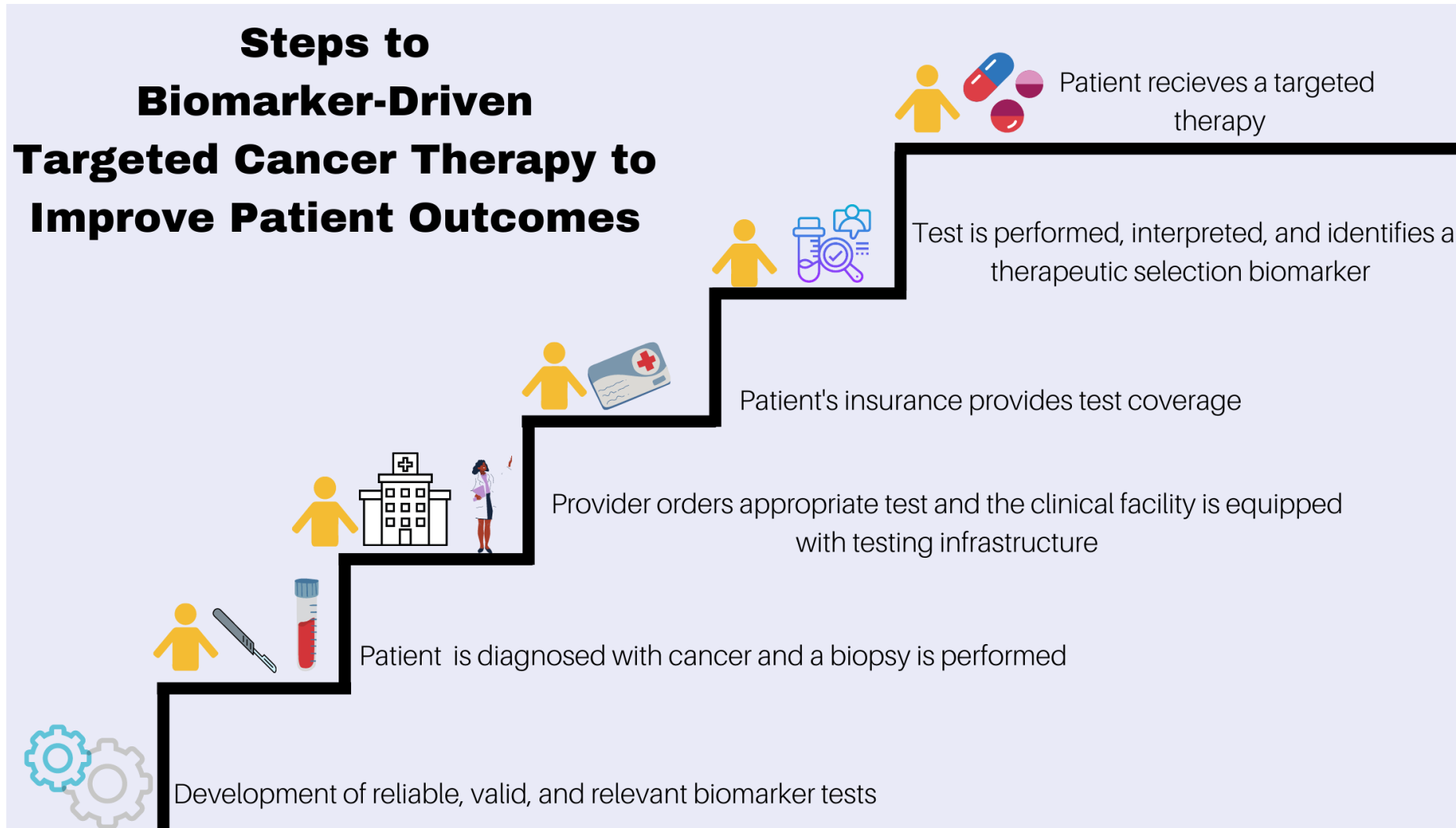
Cancer clinical trials are increasingly driven by biomarkers and the development of targeted therapies



Increasing access to biomarker testing key to supporting access to clinical trials

[1] The Evolution of Biomarker Use in Clinical Trials for Cancer Treatment Key Findings and Implications. Personalized Medicine Coalition 2019.

Barriers to Biomarker Testing



Barriers to Cancer Biomarker Testing

Coverage of tests differs greatly across payers

- Coverage policies generally more common for single-gene tests vs. multi-gene panel tests

Plans aren't necessarily following the evidence

- A recent paper in *Personalized Medicine* highlights gaps between insurance coverage and clinical practice guidelines.
 - Although 91% of plans evaluated reference NCCN treatment guidelines in their biomarker testing policies, **30% of plans under the largest insurer are “more restrictive” than these guidelines for biomarker testing in breast, non-small cell lung cancer, melanoma and/or prostate cancer patients.**

Wong, W., et al. (2022) *Alignment of health plan coverage policies for somatic multigene panel testing with clinical guidelines in select solid tumors.*



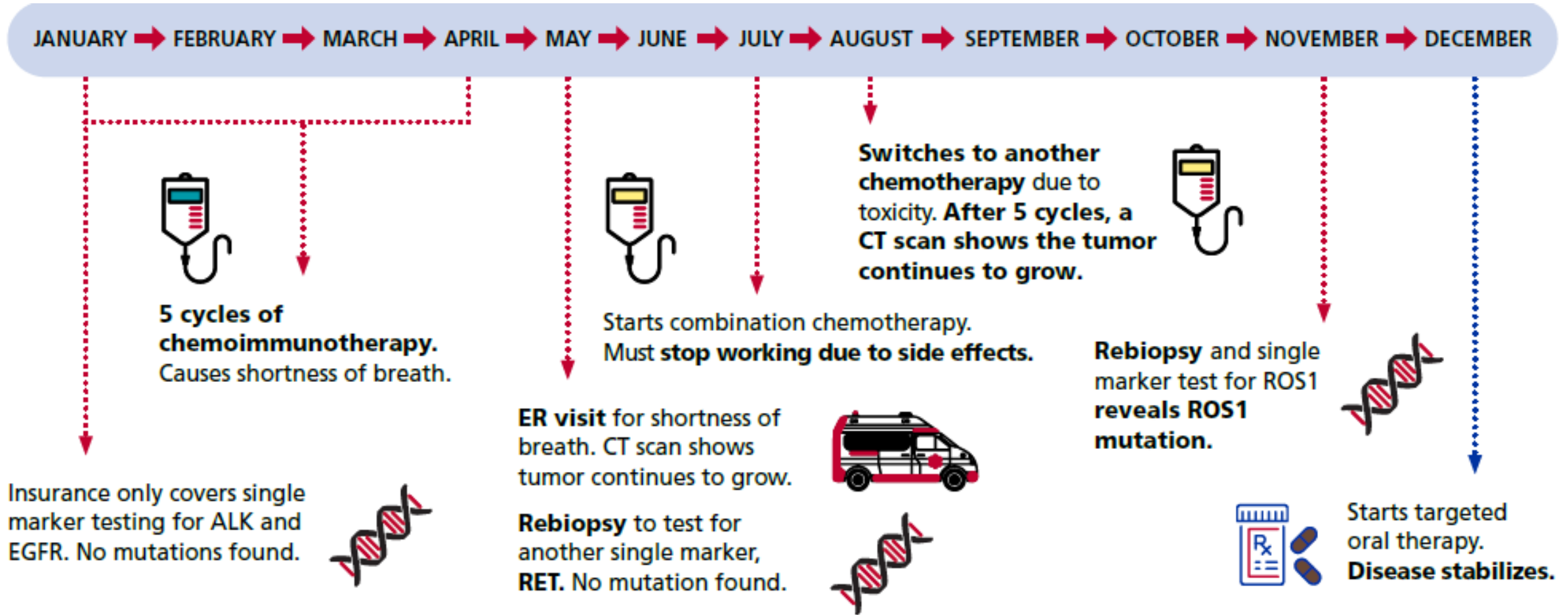
What does this look like for a patient?

Kathy is a 54-year-old white woman with no history of tobacco use. After visiting her primary care physician for persistent cough and shortness of breath, she was ultimately referred to an oncologist. Her oncologist ordered a diagnostic CT scan which revealed a large mass in the left lung with lymph node involvement. A biopsy confirmed stage IV non-small cell lung cancer, and her PET/CT scan was consistent with extensive bone metastases.



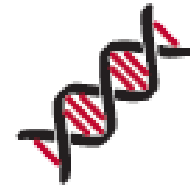
**Kathy, 54
Lung Cancer Patient**

Without Comprehensive Biomarker Testing



With Comprehensive Biomarker Testing

Comprehensive biomarker testing reveals a **ROS1** mutation
Starts targeted oral therapy. **Disease stabilizes.**



JANUARY → FEBRUARY → MARCH → APRIL → MAY → JUNE → JULY → AUGUST → SEPTEMBER → OCTOBER → NOVEMBER → DECEMBER



Legislation to Address Coverage Gaps

Requires state-regulated insurance plans including Medicaid to cover comprehensive biomarker testing when supported by medical and scientific evidence

Biomarker testing must be covered for the purposes of diagnosis, treatment, appropriate management, or ongoing monitoring of an enrollee's disease or condition when the test is supported by medical and scientific evidence, including, but not limited to:

1. Labeled indications for an FDA-approved or -cleared test
2. Indicated tests for an FDA-approved drug;
3. Warnings and precautions on FDA-approved drug labels
4. Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations and Medicare Administrative Contractor (MAC) Local Coverage Determinations; or
5. Nationally recognized clinical practice guidelines and consensus statements.

Disease and stage agnostic



Why Disease Agnostic?

Biomarker testing applications extend beyond oncology

- Biomarker testing is increasingly important for the treatment of diseases including:
 - Arthritis and other autoimmune conditions
 - Rare diseases

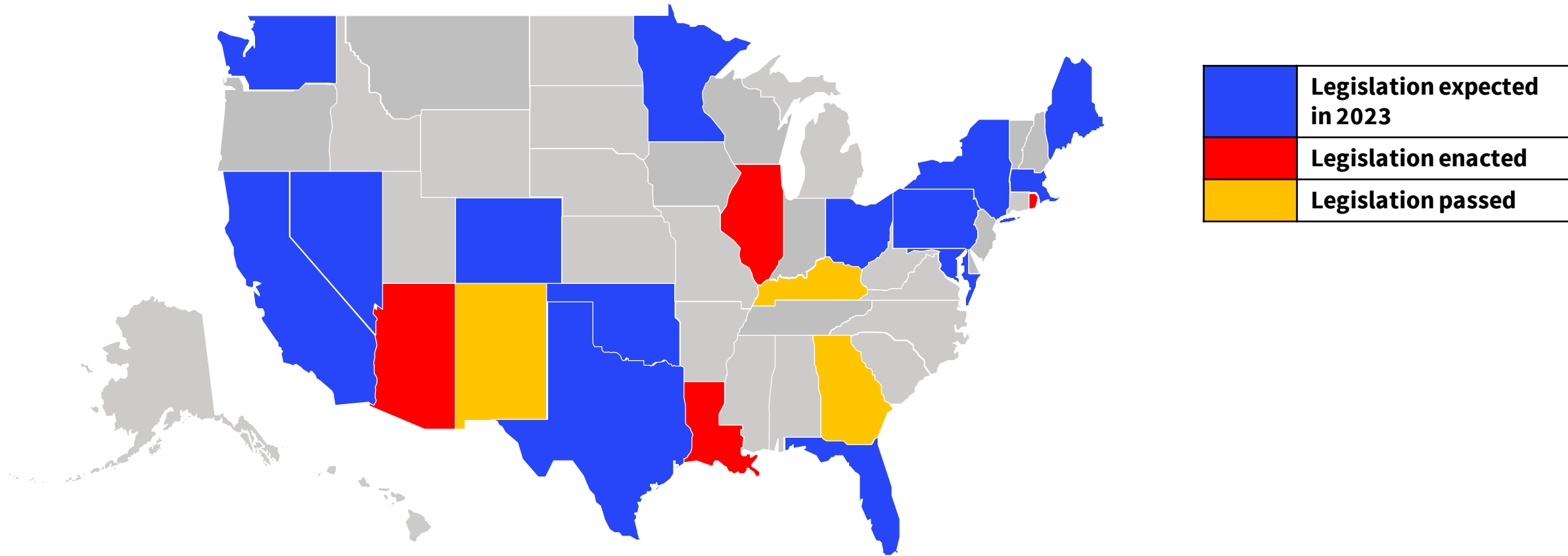
Research is happening in many other areas including Alzheimer's, other neurological conditions, and cardiology.

Cancer patients and survivors have high rates of comorbidities

- Substantial progress has been made in the fight against cancer in recent decades, resulting in a 33% reduction in the cancer death rate since its peak in 1991.
- As patients are living longer, and some cancers become more of a chronic condition, cancer patients are often living with one or more comorbidities.
 - Most common comorbidities include diabetes, cardiac conditions (COPD, congestive heart failure, cerebrovascular disease, peripheral vascular disease), renal failure, and rheumatological conditions.
 - A recent study found that nearly two-thirds of patients diagnosed with colorectal cancer, lung cancer, or Hodgkin's lymphoma had at least one comorbidity at the time of their diagnosis, and about half of patients had multiple comorbidities.



Legislation to Expand Access to Biomarker Testing



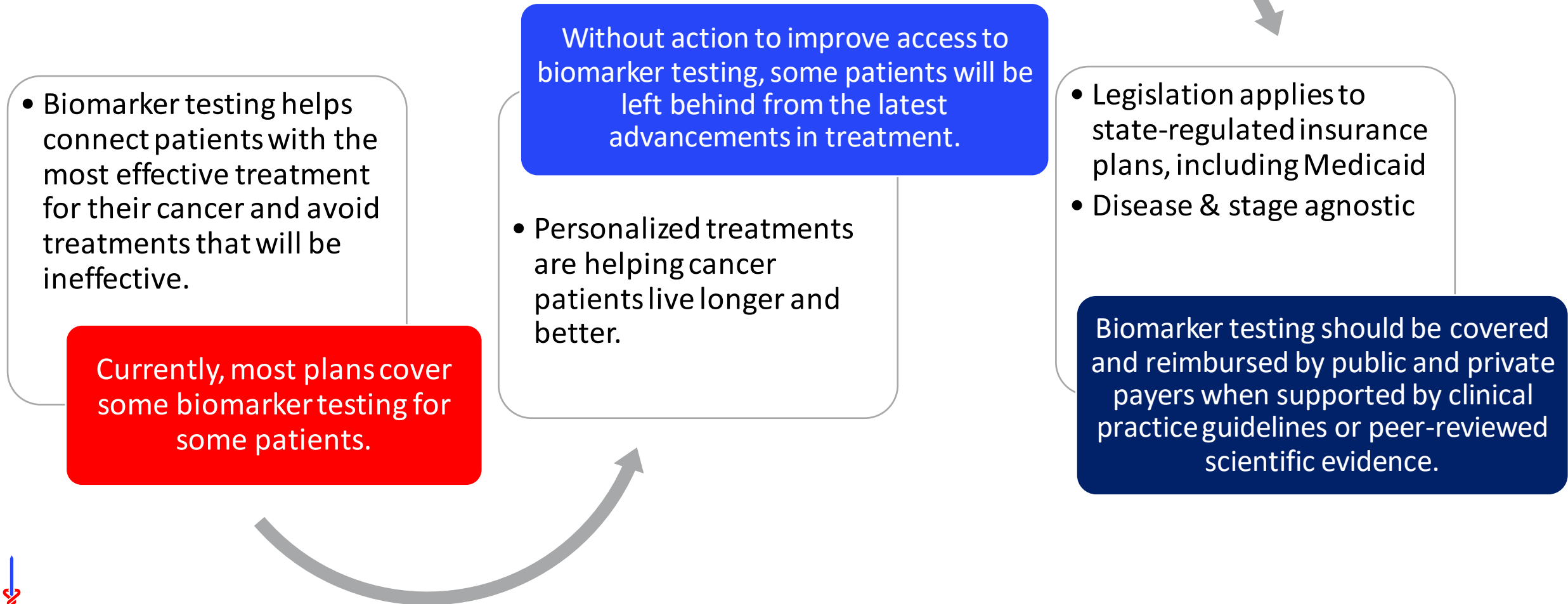
Legislation enacted: AZ, IL, LA, RI

Legislation passed (2023 session): GA, KY, NM

Legislation expected in 2023: AR, CA*, CO, FL, MA, MD, ME, MN, NV, NY, OH, OK, PA, TX, WA



Why will increasing coverage of appropriate biomarker testing help?



Broad Patient & Provider Support for Biomarker Testing





Questions?

For more information contact Maddie Bushnell
at Maddie.Bushnell@cancer.org or visit

www.fightcancer.org/biomarkers



Wrap-Up & Post-Session Poll Questions



Reminder: Post-ECHO Series Assessment Survey



We need your help to continue improving this ECHO Series and appreciate your feedback.



Please check your email inbox and junk folders for an email from “redcap@vumc.org” with a Post-ECHO Survey link.

You will also receive a Six-Month Follow-Up Survey in late November/early December.



Materials and Resources will be available soon on the [ACS ECHO Website](#)



Questions: Contact korey.hofmann@cancer.org and Jocelyn.Phillips@cancer.org

Thank you!



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