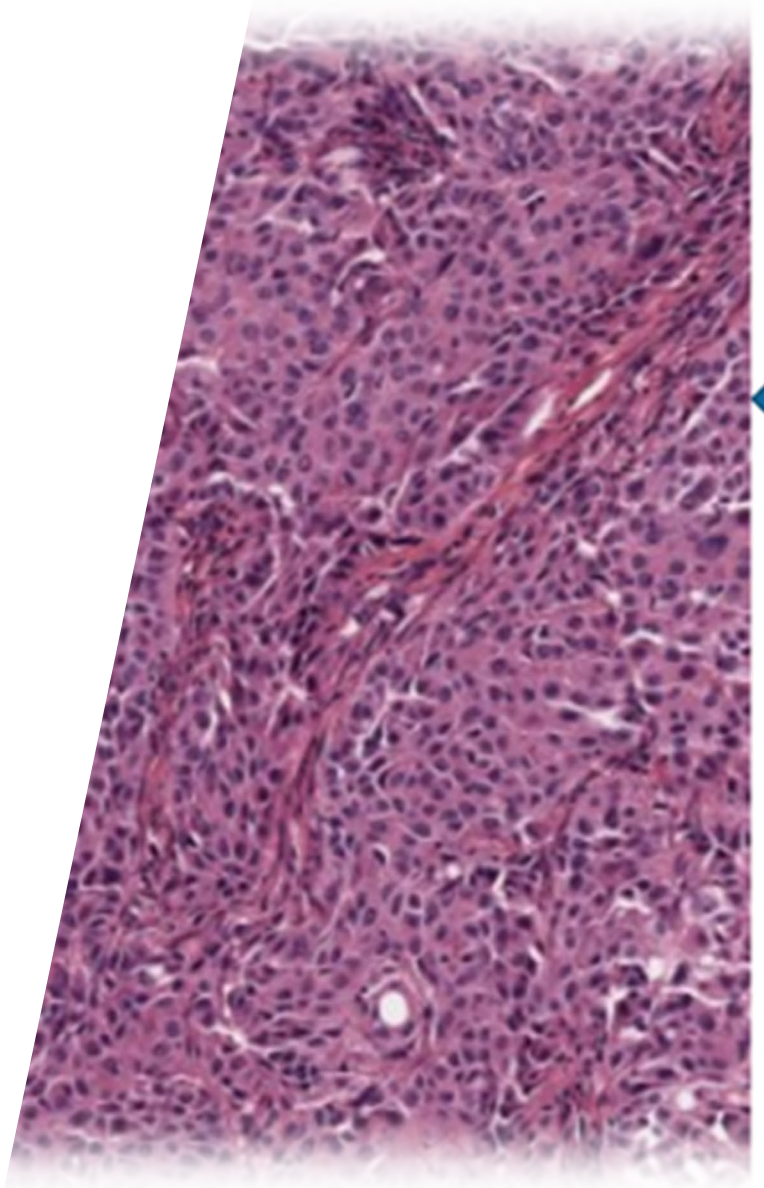
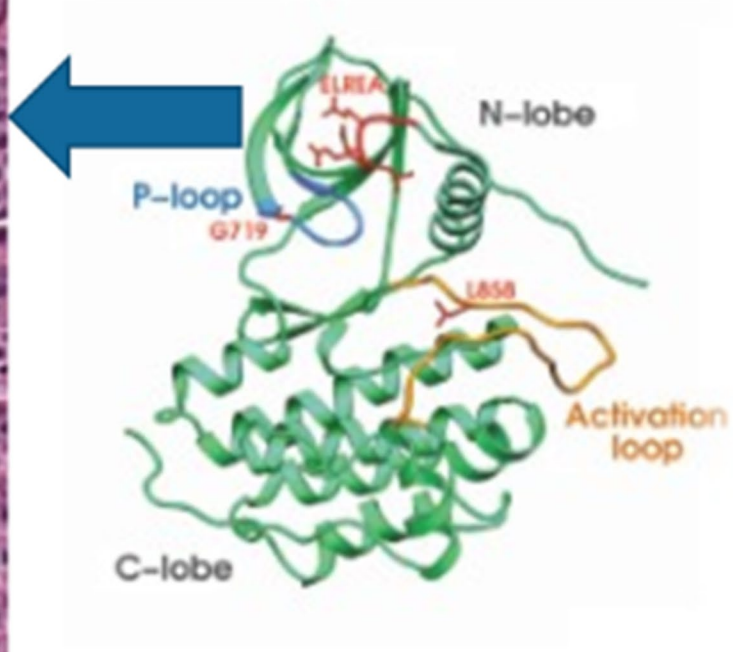
Welcome!

Before we begin…

Today's session will be recorded

Please add your name and organization in the chat





EGFR Mutation

Wednesday, December 13, 2023 • 4:00 - 5:00 pm EST

Lung Cancer Biomarker Testing ECHO Year 3

Session 0: Orientation

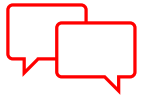
Welcome to the Orientation Session of the

Lung Cancer Biomarker Testing ECHO Year 3

Each ECHO session will be recorded and will be posted to a publicly-facing website

You will be muted with your video turned off when you join the call. Use the buttons in the *black* menu bar to unmute your line and to turn on your video. **If you do not wish to have your image recorded, please turn OFF the video option**.

Today's materials will be made available on our ACS ECHO website, https://echo.cancer.org.



Please type your full name, the full name of your organization, and e-mail in the chat box

This ECHO session takes place on the Zoom platform. To review Zoom's privacy policy, please visit zoom.us/privacy

Questions about Zoom? Type in the chat box @Mindi Odom

The Biomarker ECHO series is made possible with funding provided by:

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SCIENCE TO MEDICINE®

SANOFI GENZYME

Genentech
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Bristol Myers Squibb™

Takeda | ONCOLOGY

MERCK

Roche

Additional thanks to Foundation Medicine and founding sponsor, Amgen

Thank You!

ACS Community Impact Team project leads in seven participating states:

Patrick Casebolt
Kate Caufield
Jason Coleman
Nikole Johnston
Kaitlyn Keen
Jennifer Myrick
Robbie Tilley
Cathleen Zoller

Have a question? Don't wait to ask! Feel free to enter in the Chat at any time.

Today's Agenda

1. **Welcome & Housekeeping**
   2 minutes
2. **ECHO Subject Matter Expert (SME) & Facilitator Introductions**
   8 minutes
3. **Project Goals, ECHO Model, Case Presentation & Expectations**
   15 minutes
4. **The Burden of Lung Cancer**
   5 minutes
5. **Introduction to Lung Cancer Biomarker Testing**
   10 minutes
6. **Introduction to Biomarker Legislation Campaigns**
   5 minutes
7. **Wrap Up**
   5 minutes

Your ECHO Support Team

Korey Hofmann, MPH
ECHO Lead
Program Manager, National Lung Cancer Roundtable

Mindi Odom
Director, Project ECHO
Your ECHO Co-Lead

Beth Graham, MPH, CHES
Program Manager, Project ECHO

Jennifer McBride, PhD
Senior Data & Evaluation Manager

Donoria Evans, PhD, MPH
Director, Data and Evaluation,
National Roundtables and Coalitions

Introductions

Meet Our Lung Cancer Biomarker Testing ECHO HUB Subject Matter Experts (SMEs)

Millie Das, MD
Chief, Oncology
VA Palo Alto Health Care System
Clinical Associate Professor
Stanford University

Aaskash Desai, MBBS, MPH
Assistant Professor of Medicine
O'Neal Cancer Center
University of Alabama, Birmingham

Grace Dy, MD
Professor of Oncology
Roswell Park Comprehensive Cancer Center

DuyKhanh Pham "Mimi" Ceppa, MD, FACS
Associate Professor of Thoracic Surgery
Indiana University School of Medicine

Matthew Facktor, MD
System Chair, Thoracic Surgery
Geisinger Heart Institute

Adam Fox, MD
Assistant Professor
Medical University of South Carolina

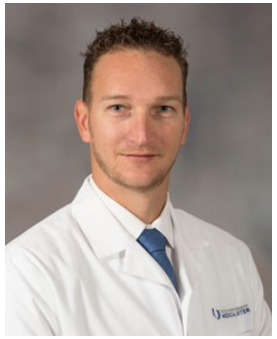
Jason Merker, MD, PhD
Associate Professor, Department of Pathology and Laboratory Medicine & Genetics
University of North Carolina Lineberger Comprehensive Cancer Center

Introductions

Meet Our Lung Cancer Biomarker Testing ECHO HUB Subject Matter Experts (SMEs)

Koosha Paydary, MD, MPH, MSc
Assistant Professor, Department of Internal Medicine
Rush University

Catherine R. Sears, MD
Associate Professor of Medicine, Division of Pulmonary, Critical Care, Sleep and Occupational Medicine
Indiana University School of Medicine
Simon Comprehensive Cancer Center



Michal Senitko, MD
Assistant Professor
The University of Mississippi Medical Center

Gerard Silvestri, MD, MS
Hillenbrand Professor of Thoracic Oncology
Medical University of South Carolina

Heather Wakelee, MD (Ad Hoc)
Professor of Medicine and Chief of the Division of Oncology,
Stanford University School of Medicine
Deputy Director, **Stanford Cancer Institute**

Ignacio Wistuba, MD
Professor and Chair, Department of Translational Pathology
The University of Texas MD Anderson Cancer Center

Bruce E. Johnson, MD, FASCO
Dana-Farber/Harvard Cancer Center
Lung Cancer Program
Senior Advisor to the President,
Dana-Farber Cancer Institute

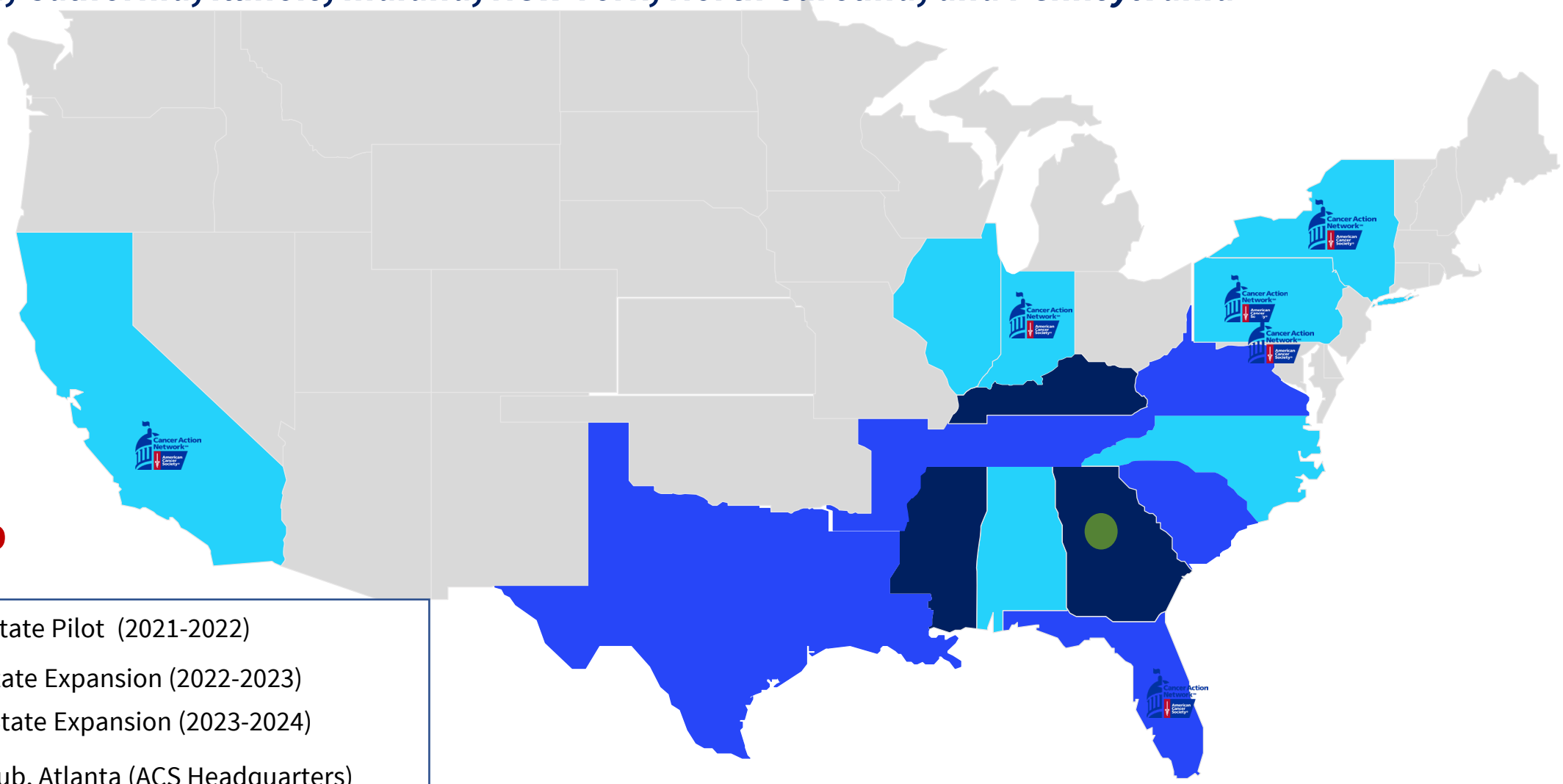
Lung Cancer Biomarker Testing ECHO
FACILITATOR

Timothy Mullett, MD, MBA, FACS
Medical Director, Markey Cancer Center Network Development

Lung Cancer Biomarker Testing ECHO
FACILITATOR

Welcome to the Participant Learning Sites in Sev[illegible]

Alabama, California, Illinois, Indiana, New York, North Carolina, and Pennsylvania



LEGEND

- Three-State Pilot (2021-2022)
- Eight-State Expansion (2022-2023)
- Seven-State Expansion (2023-2024)
- ECHO Hub, Atlanta (ACS Headquarters)
- Current ACS CAN State Advocacy Target State

Brief Overview: Project Goals & Expectations, Anatomy of ECHO, and Case Presentations

ECHO Project Goals & Objectives

Knowledge & confidence will be gained

Participant Teams will gain knowledge & confidence

- To address the common barriers to biomarker testing that may exist within their institutions; and
- To help implement or enhance NSCLC biomarker testing at their institutions

The state-based ECHO approach will foster *connection*

- To address the common barriers related to biomarker testing in a state/geographic area
- Create networking opportunities for participants & connections to ACS CAN activity

ECHO 101

What is ECHO? How does it work?

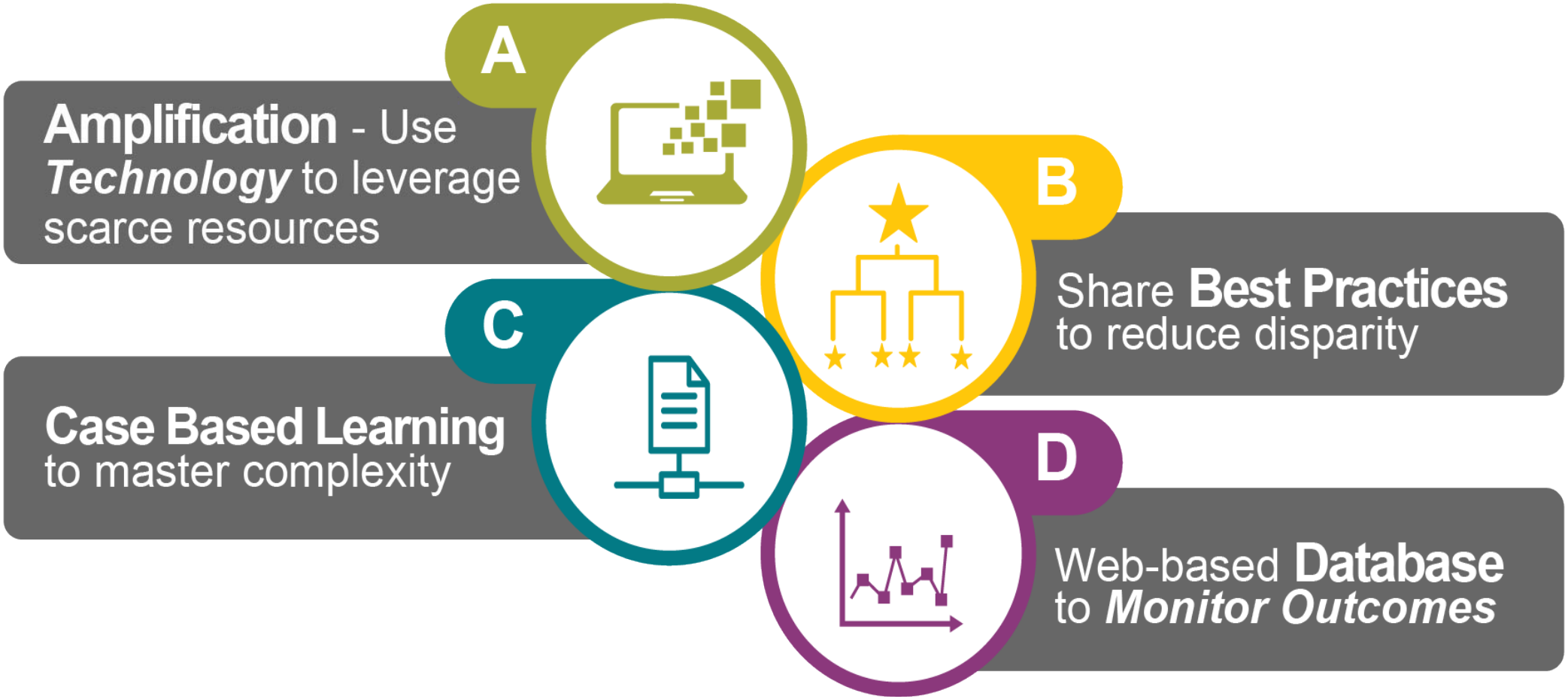
Mindi Odom
Director, Project ECHO

American Cancer Society | NATIONAL LUNG CANCER ROUNDTABLE | Project ECHO

Today's Session will **NOT** serve as a typical ECHO session but instead will function more like a traditional interactive webinar.

The ECHO Model

Extension for Community Healthcare Outcomes



About Project ECHO

- **Moving Knowledge, Not People**
- Empowering people to make a difference in their communities with the **right knowledge**, at the **right place**, at the **right time**
- Builds **communities of practice** through **virtual mentoring & learning**
- **One-to-many** intervention proven effective to reduce disparities, strengthen health systems, & drive collaborative solutions for local priorities
- **Effective/Efficient** vehicle for dissemination of evidence-based strategies to improve cancer outcomes
- Participants **attend virtual case-based sessions** with subject-matter experts
- The participants and subject-matter experts all learn from each other: knowledge is generated, refined and tested by local experience. This **"all teach, all learn"** method **democratizes expertise** and makes it relevant to local cultural contexts.

The American Cancer Society serves as a **Project ECHO** (Extension for Community Healthcare Outcomes) **Hub**

ECHO is all teach, all learn

Interactive

Co-management of cases

Peer-to-peer learning

Collaborative problem solving

What to Expect:
The Anatomy of an ECHO Session

- **Welcome & introductions** (5 minutes)
- **Announcements & session overview** (5 minutes)
- **Brief Didactic Lecture** (10-15 minutes at most)
- **Didactic Q/A** (5 minutes)
- **Case Presentation(s)** (25 minutes total)
  - **Case Presentation** (3 -5 minutes)
  - **Clarifying Questions** – (5 minutes)
  - **Recommendations** – (15 minutes)
- **Closing remarks, Wrap-Up & Post-Session Survey Poll** (5 min)

What is a Case Presentation?

Case presentations can be **patient-level** or **system-level** and should provide an opportunity for participant sites to request advice and/or recommendations from subject matter experts and other participants.
These cases are challenges or perceived barriers and are encouraged to be thematic to the didactic presentation.

This section of each ECHO session is **vital** to the success of the program and serves as an interactive learning for all attendees.

! For more about the **ECHO Model™** or **Project ECHO**, please visit https://hsc.unm.edu/echo/

Expectations of Participant Learning Sites

- ✓ Build a small multidisciplinary ECHO team from their system/center
- ✓ *If available*, each team will provide baseline data related to lung cancer caseload and biomarker testing rates
- ✓ Have at least **one** team member *actively participate* in each monthly, 60-minute ECHO session from December 2023-May 2024
  - ✓ Come prepared to participate in discussion; ask questions, share best practices, and offer recommendations
- ✓ Complete the post-session polls
- ✓ Complete the three survey/assessments (pre, post, and six-month follow-up)
- ✓ Deliver (as a team) **one case presentation** over the course of the ECHO Program

Case Presentation Overview

Lung Biomarker Testing ECHO
Case Presentation Overview

Expectations:

- ✓ Cases can be **patient-level** or **system-level**
- ✓ The presentation should range from **3-5 mins**
- ✓ Patient-related cases must be deidentified
- ✓ Complete and submit case presentation form electronically
- ✓ Submit **two weeks prior** to scheduled session

Participant learning sites are committed to presenting at least one case

Lung Biomarker Testing ECHO
Case Presentation Instructions

Example of Case Presentation Content: System-level

- ✓ Describe your current workflow and/or system
- ✓ Perceived challenges or barriers to biomarker testing
- ✓ Describe ideal state of workflow
- ✓ Question(s) for SMEs and participants

Example of Case Presentation Content: Patient-level

- ✓ Patient (deidentified) demographics
- ✓ Case summary
- ✓ Perceived challenges
- ✓ Question(s) for SMEs and peers

Participant learning sites are committed to presenting at least one case

DuyKhanh Pham Ceppa, MD, FACS
Associate Professor of Thoracic Surgery
Indiana University School of Medicine

The Burden of Lung Cancer

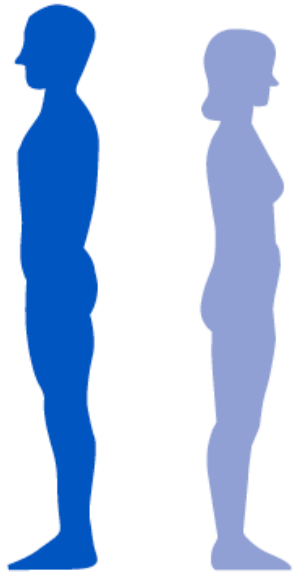
Faculty Disclosures

- Astra Zeneca (consultant; advisory board)
- Cook Medical (consultant)
- Medtronic (consultant)

Lung Cancer Burden at a Glance

Estimated New Cases

Male		
Prostate	288,300	29%
Lung & bronchus	117,550	12%
Colon & rectum	81,860	8%
Urinary bladder	62,420	6%
Melanoma of the skin	58,120	6%
Kidney & renal pelvis	52,360	5%
Non-Hodgkin lymphoma	44,880	4%
Oral cavity & pharynx	39,290	4%
Leukemia	35,670	4%
Pancreas	33,130	3%
All sites	**1,010,310**	



Female		
Breast	297,790	31%
Lung & bronchus	120,790	13%
Colon & rectum	71,160	8%
Uterine corpus	66,200	7%
Melanoma of the skin	39,490	4%
Non-Hodgkin lymphoma	35,670	4%
Thyroid	31,180	3%
Pancreas	30,920	3%
Kidney & renal pelvis	29,440	3%
Leukemia	23,940	3%
All sites	**948,000**	

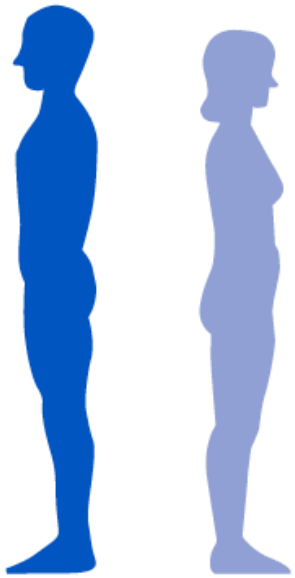
12% of all new cancer cases

Cancer Facts & Figures 2023, American Cancer Society

2023 Estimate Lung Cancer Deaths

Estimated Deaths

Male		
Lung & bronchus	67,160	21%
Prostate	34,700	11%
Colon & rectum	28,470	9%
Pancreas	26,620	8%
Liver & intrahepatic bile duct	19,000	6%
Leukemia	13,900	4%
Esophagus	12,920	4%
Urinary bladder	12,160	4%
Non-Hodgkin lymphoma	11,780	4%
Brain & other nervous system	11,020	3%
All sites	**322,080**	



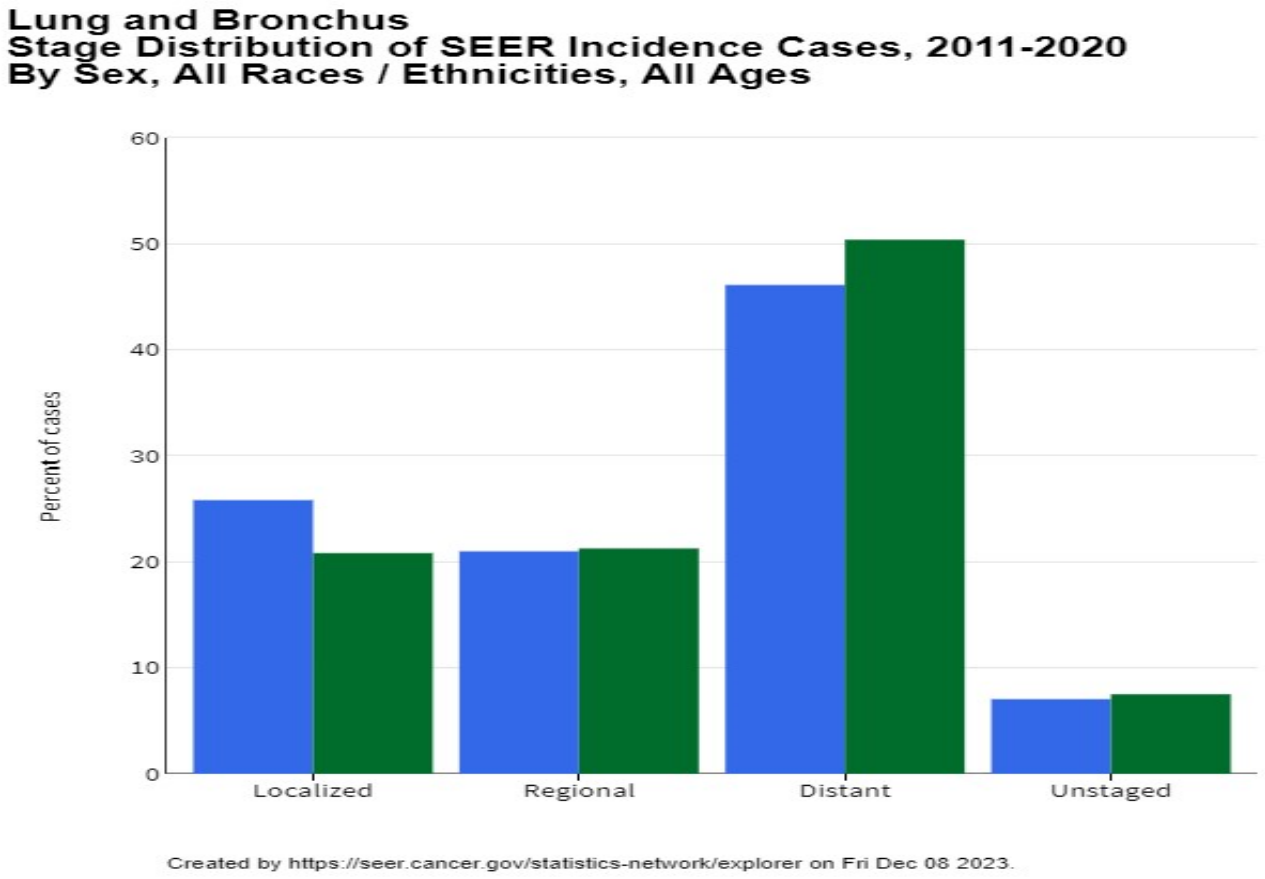
Female		
Lung & bronchus	59,910	21%
Breast	43,170	15%
Colon & rectum	24,080	8%
Pancreas	23,930	8%
Ovary	13,270	5%
Uterine corpus	13,030	5%
Liver & intrahepatic bile duct	10,380	4%
Leukemia	9,810	3%
Non-Hodgkin lymphoma	8,400	3%
Brain & other nervous system	7,970	3%
All sites	**287,740**	

21% of all new cancer cases

Cancer Facts & Figures 2023, American Cancer Society

Lung Cancer Burden At a Glance

Majority of lung cancers diagnosed at distant metastatic disease.

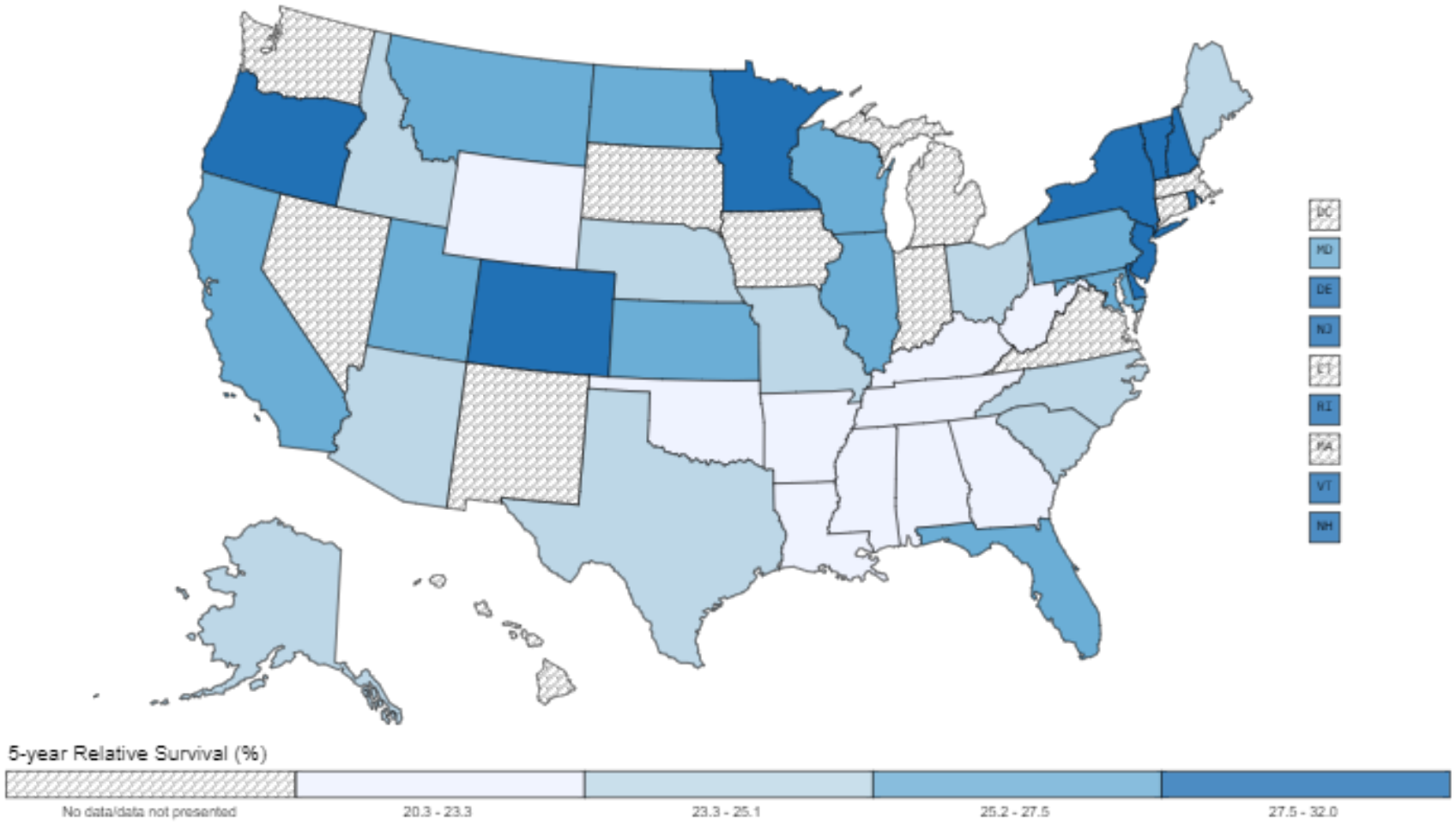


5-Year Relative Survival

22.9%

https://seer.cancer.gov/statfacts/html/lungb.html

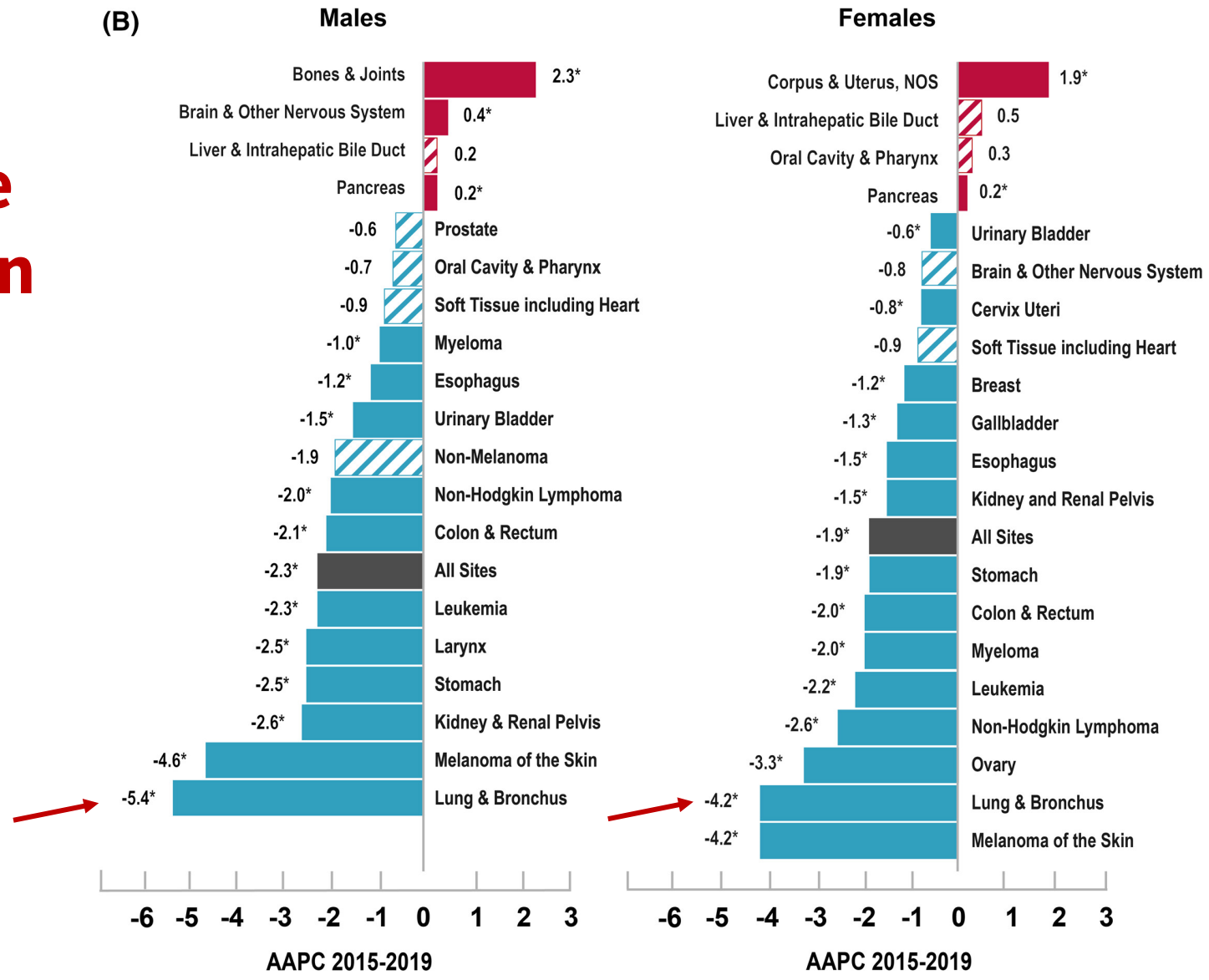
5-Year Relative Survival (%) by State, Lung and Bronchus, All Races and Ethnicities, Male and Female



U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute; https://www.cdc.gov/cancer/dataviz, released in November 2023.

Targeted therapies are accelerating declines in lung cancer mortality

Annual Report to the Nation on the Status of Cancer, Part 1: National Cancer Statistics. Average annual percent change (AAPC) in age-standardized death rates for 2015-2019 for the most common cancer deaths in men and women.

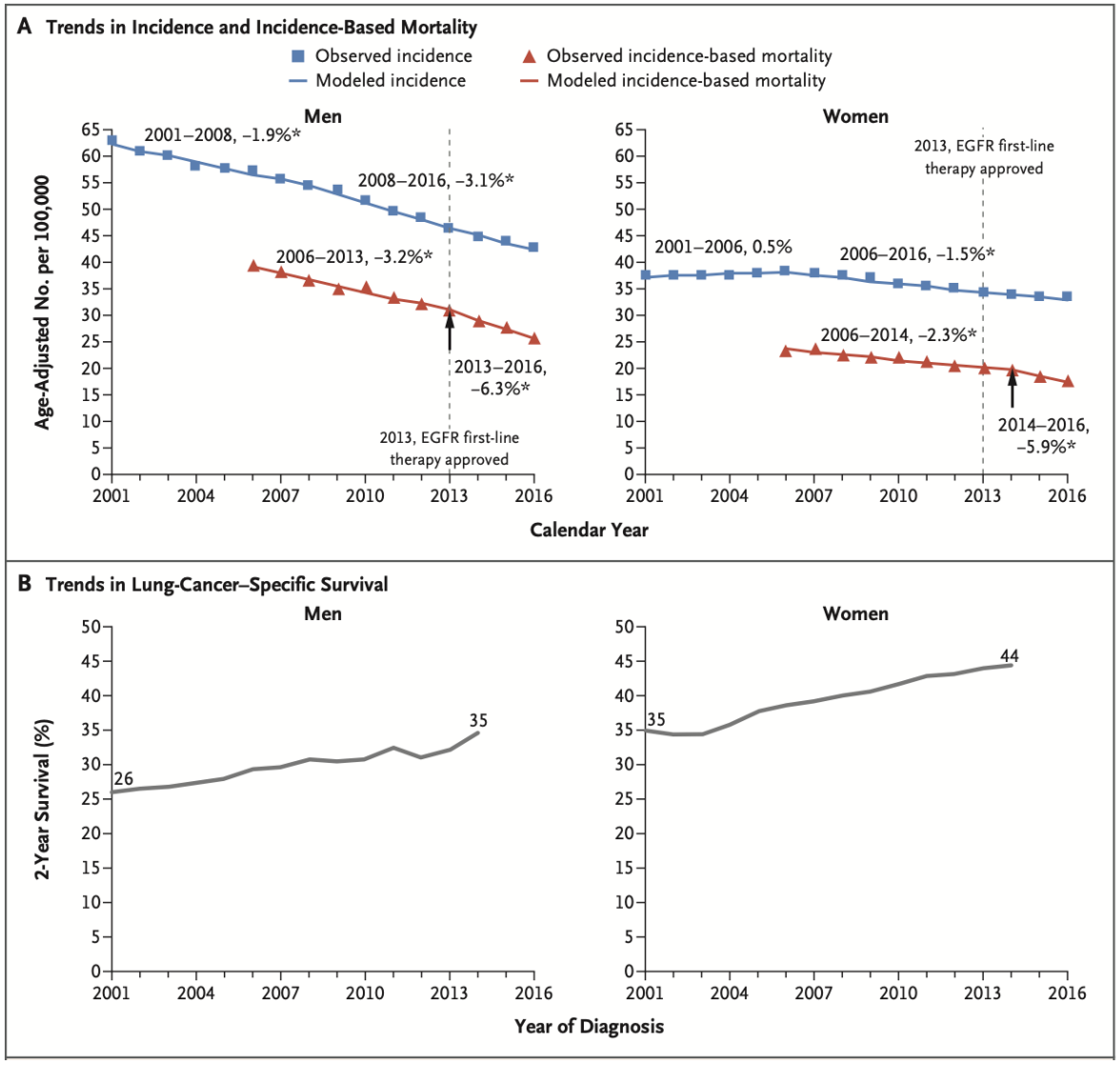


Cancer 2022; 128(24): 4251-4284

ORIGINAL ARTICLE

The Effect of Advances in Lung-Cancer Treatment on Population Mortality

Nadia Howlader, Ph.D., Gonçalo Forjaz, D.V.M., Meghan J. Mooradian, M.D., Rafael Meza, Ph.D., Chung Yin Kong, Ph.D., Kathleen A. Cronin, Ph.D., Angela B. Mariotto, Ph.D., Douglas R. Lowy, M.D., and Eric J. Feuer, Ph.D.



- Population-level mortality from NSCLC fell sharply from 2013 to 2016
- Survival after diagnosis improved substantially
- Use of targeted therapies explains mortality reduction

N Engl J Med 2020; 383:640-649

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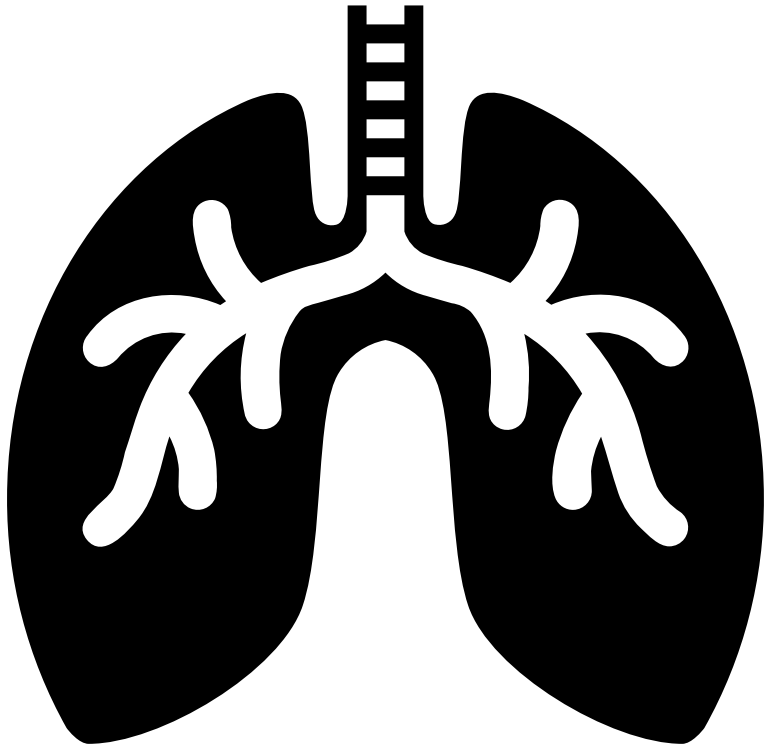
Aakash Desai, MBBS, MPH
Assistant Professor of Medicine
O'Neal Comprehensive Cancer Center
University of Alabama Birmingham

Introduction to Lung Cancer Biomarker Testing

Conflict of Interest

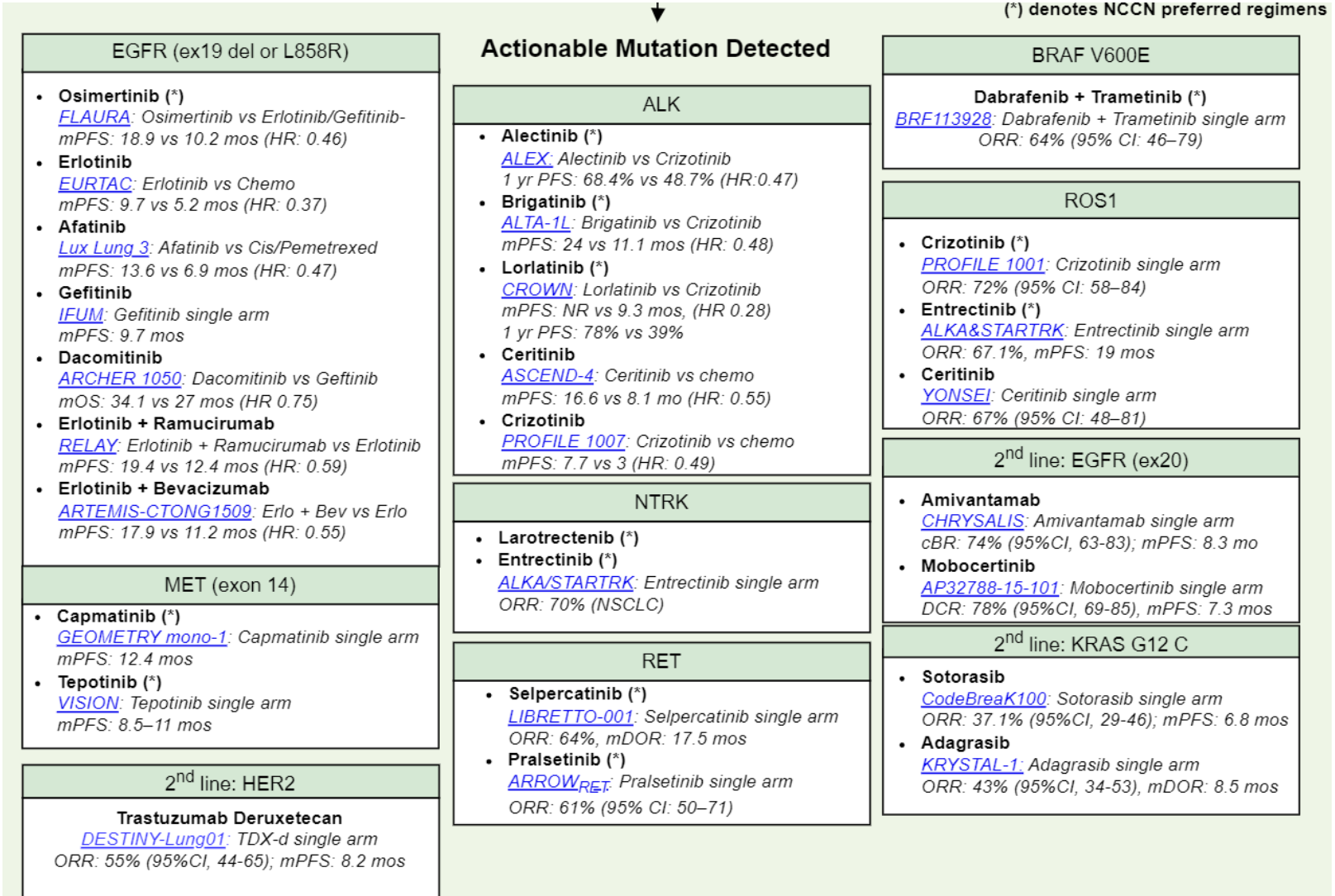
- Disclosures:
  - ❑ Consulting or Advisory Role: Sanofi, Amgen, Foundation Medicine, Janssen Oncology, AstraZeneca
  - ❑ Research Funding: Lung Cancer Research Foundation

Learning objectives



1. Review impact of biomarkers on management of NSCLC
2. Overview of the current biomarker guidelines
3. Define the ideal state of biomarker testing

There has been unprecedented progress with new treatment of non-small cell lung cancer (NSCLC) that targets specific biomarkers



Prescribing the right treatment option for a patient *requires* comprehensive biomarker testing

Personalized Treatment of advanced Non-Small Cell Lung Cancer (NSCLC) *is guided by* molecular biomarker assessment

Biomarker-Driven Treatment for Lung Cancer At-A-Glance

10

FDA-Approved Genomic Biomarkers for directing targeted therapies for Non-Squamous NSCLC

3

PD-L1 TPS >50% Directs 3 Immunotherapy-Only first line treatment options

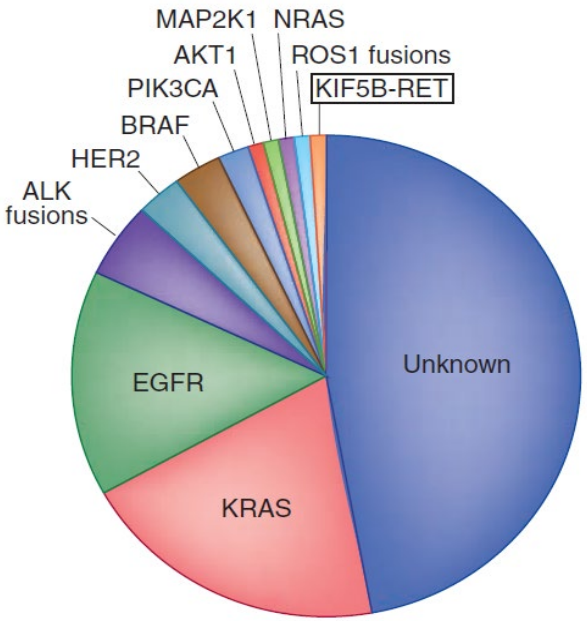
Clinical Trials

Numerous biomarker-driven drugs are presently in clinical trials for NSCLC and small cell lung cancer (SCLC)

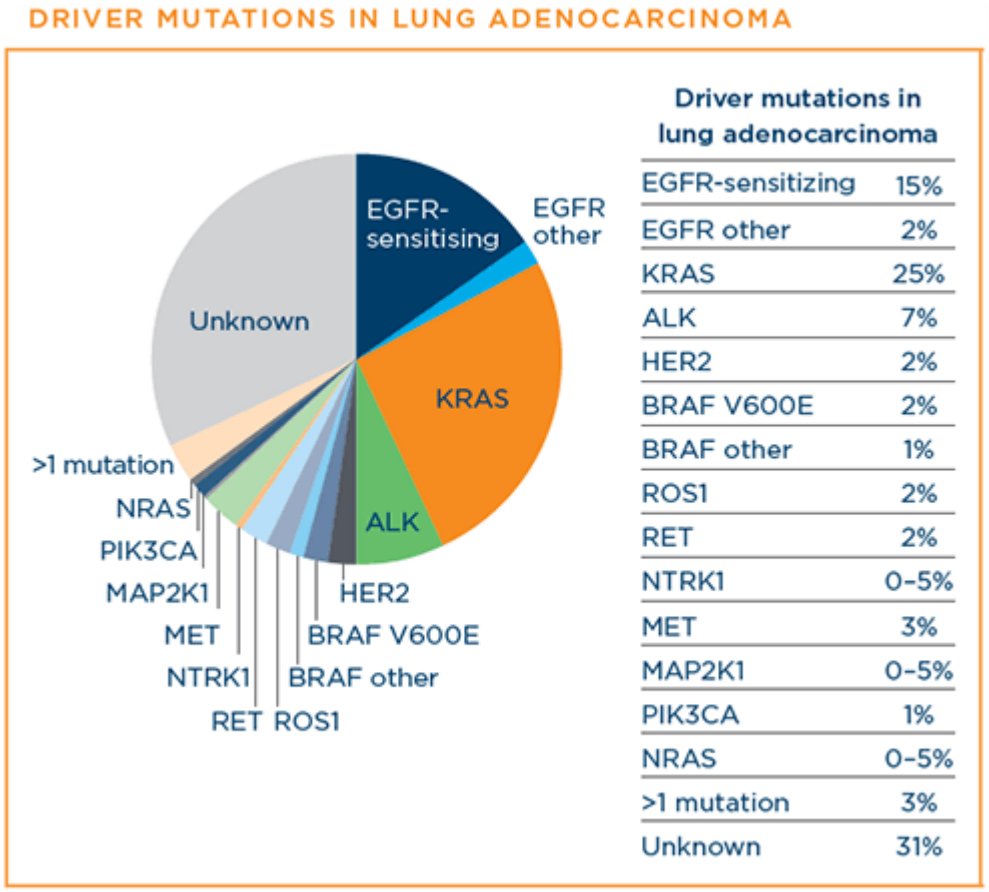
5

5 Organizations with guidelines for testing for comprehensive biomarker testing for NSCLC

Updates in Biomarkers



Pao and Hutchinson 'Chipping away at the lung cancer genome' Nature Medicine. **March 2012**



2023: biomarkers with drug targets

Current NSCLC Lung Cancer Biomarker Guidelines

NCCN

The National Comprehensive Cancer Network® NCCN has released updated evidence-based guidelines on comprehensive biomarkers in lung cancer[1]

CAP, IASLC, & AMP

Evidence-based consensus guidelines on biomarker testing in NSCLC from **the College of American Pathologists (CAP)**, **International Association for the Study of Lung Cancer (IASLC)**, and the **Association for Molecular Pathologists (AMP)** recommend that all late-stage NSCLC patients with advanced stage lung adenocarcinoma should receive biomarker testing for three mutations (EGFR, ALK, and ROS1)[2] in 2018

ASCO

The American Society of Clinical Oncology (ASCO) released an update in February 2022 to their 2017 guideline on systemic therapy for patients with stage IV NSCLC with driver alterations[3]

Synopsis of Common Recommendations for Lung Cancer Biomarker Testing

Type of Lung Cancer	Stage of Lung Cancer	Common Recommendations
NSCLC Lung **Non-Squamous**	**Stages IB and Above**	Testing for mutations in the **EGFR** gene should be conducted *Clinical trial options may exist for other mutations*
NSCLC Lung **Non-Squamous**	**Stage IV** adenocarcinoma that has **recurred or progressed** after an initial diagnosis of stage I, II, or III lung cancer in patients who were **NOT** previously tested	Comprehensive Biomarker Testing, e.g., **Next-Generation Sequencing (NGS)** is recommended **PD-L1** is recommended to determine whether a patient will benefit from immunotherapy **alone** in the first line setting
NSCLC Squamous Cell Lung Cancer	**Stages I, II, and III**	Currently, biomarker testing e.g., Next-Generation Sequencing (NGS) is performed **ONLY** for clinical trials
All NSCLC: Large-Cell, Squamous and Non-Squamous	**Stage II to IIIA**	FDA approval for adjuvant atezolizumab for tumors with PD-L1 expression on ≥ 1% of tumor cells
NSCLC Squamous Cell Lung Cancer	**Stage IV**	**PD-L1** is recommended to determine whether a patient will benefit from immunotherapy **alone** in the first line setting **Consider testing** for **ALK**, **BRAF V600E**, **EGFR**, **KRAS**, **MET exon 14 skipping**, **NTRK**, **RET**, and **ROS1** at the time of diagnosis, contingent on a patient's or pathology. *Testing for other biomarkers may be helpful in deciding eligibility for clinical trials*
Small Cell Lung Cancer (SCLC)	**All Stages**	Currently, biomarker testing is performed **ONLY** for clinical trials

Resources:

Non-Small Cell Lung Cancer (NSCLC)—NCCN Clinical Practices Guidelines in Oncology. Version 5.2023. **Accessed Dec. 2023**

Updated Molecular Testing Guideline for the Selection of Lung Cancer Patients for Treatment with Targeted Tyrosine Kinase Inhibitors. **Accessed Dec. 2023**

Small Cell Lung Cancer (SCLC)—NCCN Clinical Practice Guidelines to Oncology. Version 2.2024. **Accessed Dec. 2023**

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Anatomy-based Prognostication is *insufficient*

- Stage IV EGFR+ adenocarcinoma with 5-year survival rate >20% vs 5% for stage IV adenocarcinoma without identifiable predictive biomarker….

  Lin JJ, et al. J Thorac Oncol. 2016 PMCID: PMC4979601.
  Hirsch FR, et al. Cancer. 2018 PMID: 29579334.

- ALEX: 5-year survival Alectinib v Crizotinib- 62.5 (95% CI 54.3- 70.8) v 45.5% (95% CI 33.6-57.4)

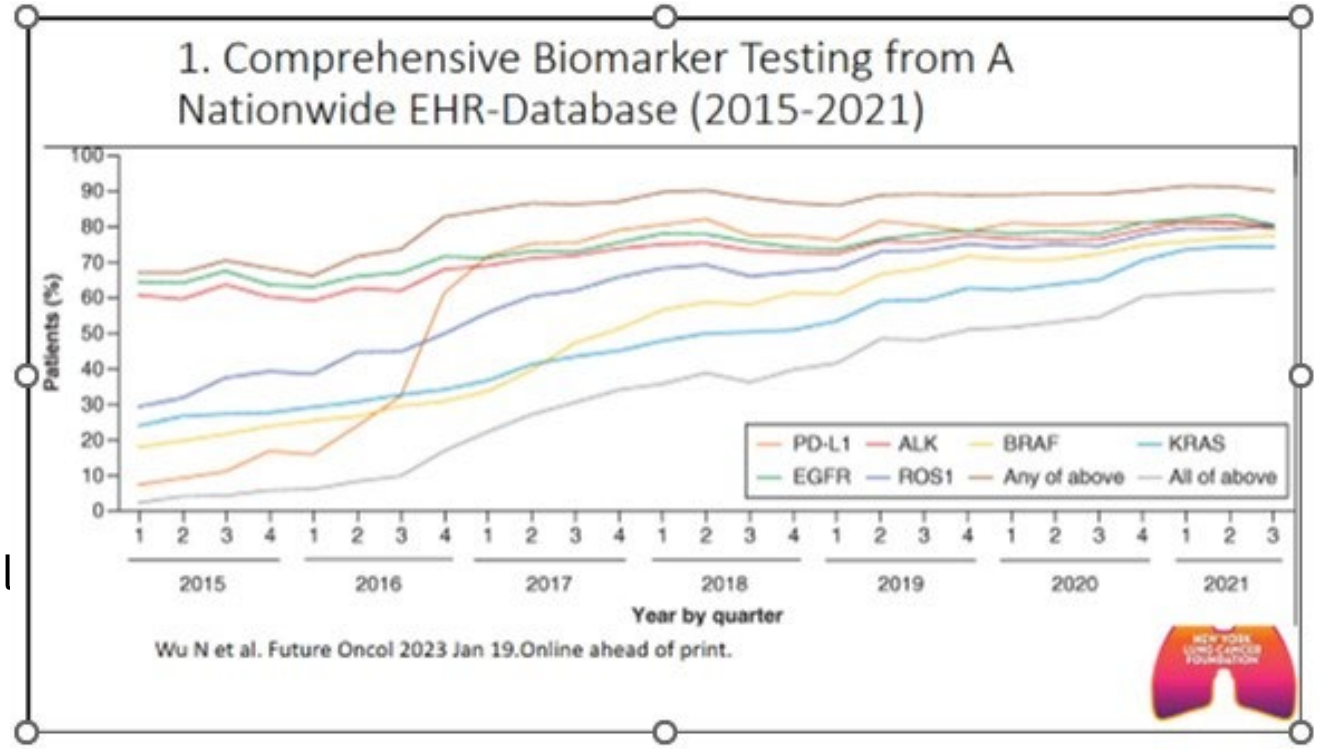
  Mok T, et al. Ann Oncol. 2020 PMID: 32418886.

  …are they even the same disease?

Despite this unprecedented progress, current data shows suboptimal rates in biomarker testing

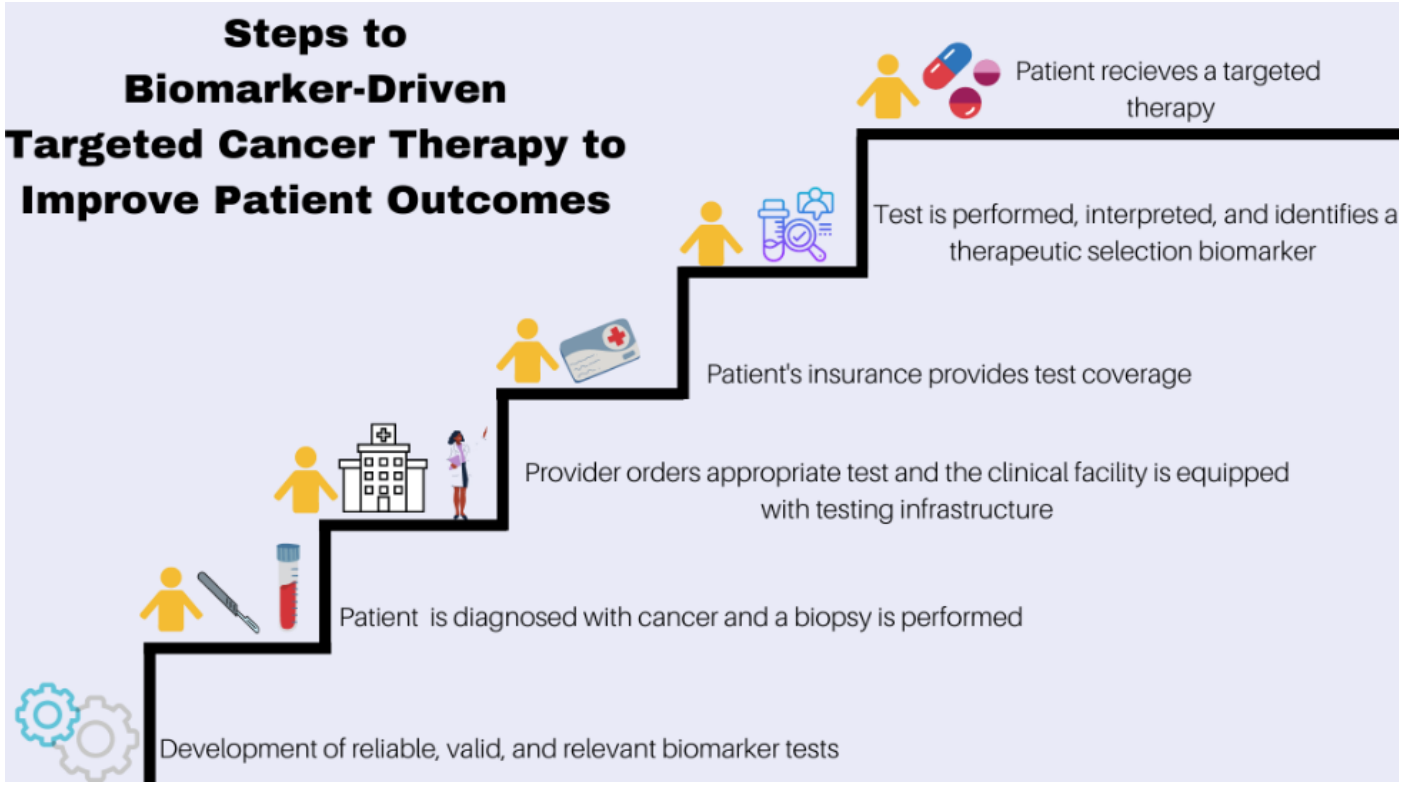
Biomarker Testing Rate

- Current data have inherent limitations due to selection bias, response bias, limited assessment by insurance type, etc. ***However…***
- Testing rates **vary across regions** and academic and community practices
- Use of **single assay tests are more common** than use of multi-gene panels using NGS or multiplex PCR *(White paper, Friends of Cancer Research, 2018)*
- *EGFR and ALK* testing represent the most common testing. However, patients who are older, male, have a history of smoking, and are not covered by commercial insurance have lower testing rates
- Among 4,335 NSCLC patients in a 2018 commercial database from 280 clinics, **only 71% received *ROS1* testing**. *Clinical Lung Cancer* 2020



Wong W, Wu N, Gupta R, Mansfield AS. Utilization Trends and Factors Associated With ROS1 Testing Among Patients With Advanced Non-small-cell Lung Cancer in US Community Practices. Clin Lung Cancer, 06/29/2020
Fox, A. et al. Knowledge and Practice Patterns Among Pulmonologists for Molecular Biomarker Testing in Advanced NSCLC. CHEST, 06/25/ 2021
Wu, N et al. Future Oncol 2023 Jan 19

Many patients face challenges receiving comprehensive biomarker testing



THE IDEAL STATE

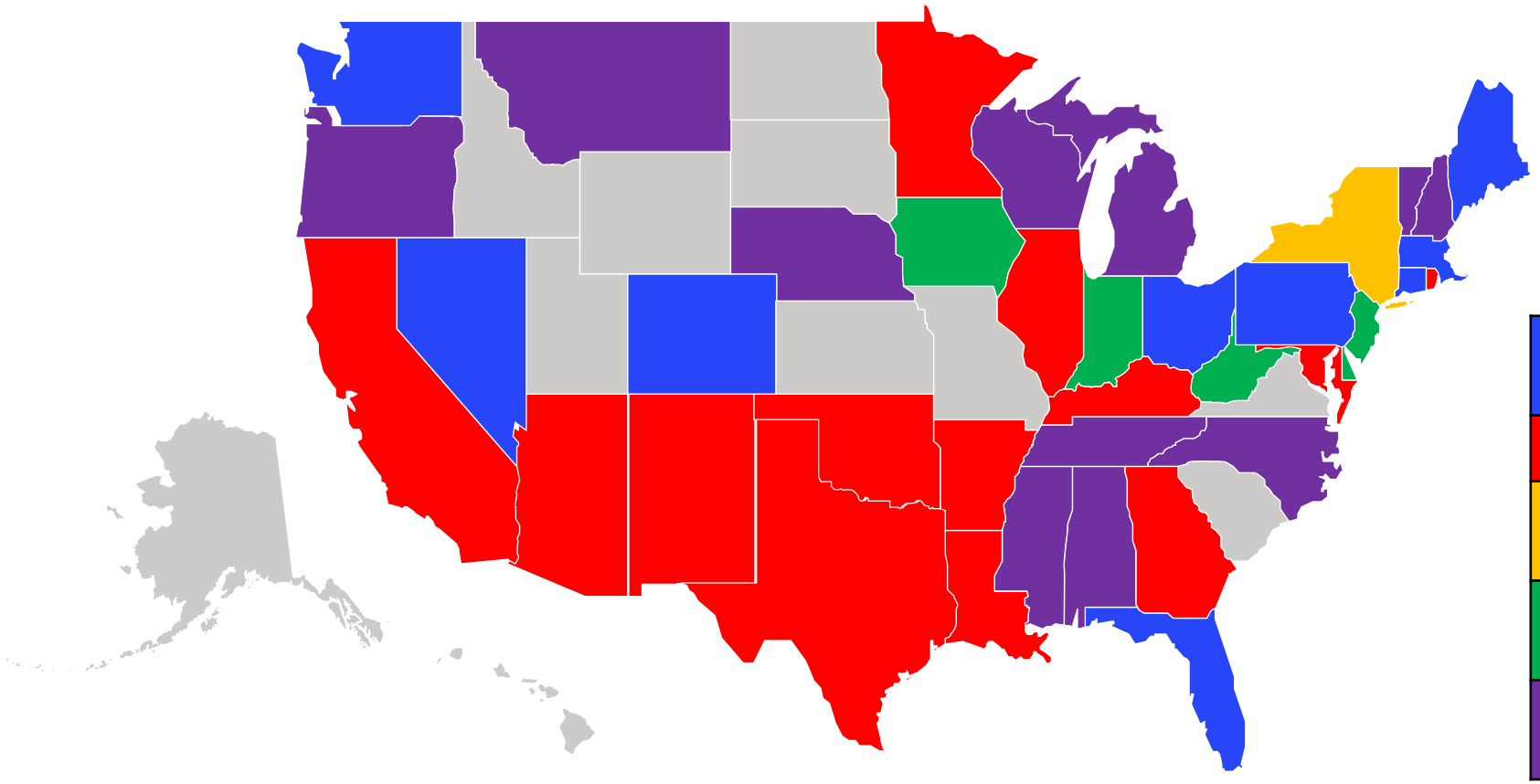
"Access to High Quality Biomarker Testing for All Eligible Patients with Non-Small Cell Lung Cancer: No Patient Will Be Left Behind"

American Cancer Society | NATIONAL LUNG CANCER ROUNDTABLE | Project ECHO

Hilary Gee Goeckner
Director, State & Local Campaigns – Access to Care
ACS Cancer Action Network

Introduction to Biomarker Legislative Campaigns

Legislation to Expand Access to Biomarker Testing



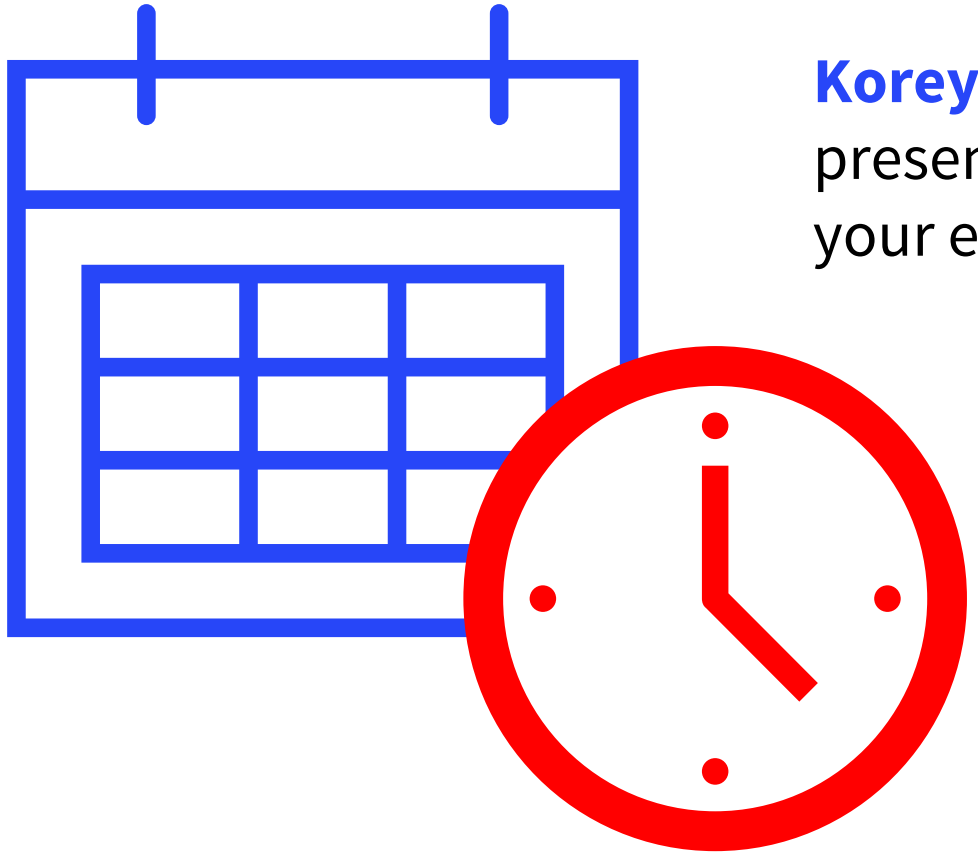
	Legislation introduced 2023
	Legislation enacted
	Legislation passed/ awaiting signature
	New legislation expected in 2024
	Education/ground softening for future leg

Legislation enacted: AR*, AZ, CA, GA, IL, KY, LA, MD, MN, NM, OK, RI, TX
Legislation passed in 2023 awaiting signature: NY
Legislation introduced, continuing in 2024: CO, CT, FL, MA, ME, OH, PA, WA
New legislation expected in 2024: IA, IN, NJ, WV Revisit in 2024: NV
*commercial coverage only

What’s Next?

Ready to Schedule Your Case Presentation?

Please volunteer in the **chat** now



Korey Hofmann will confirm your case presentation date and work with you to ensure your experience is **easy** and **valuable**.

The electronic case presentation form will be shared with all **site champions via email**

Session #	Month	Date	Time (ET)	Didactic Topic	Didactic Presenter	Facilitator
0	December	Weds. 12/13	4:00 - 5:00pm	Series Kick-Off: Introduction to ECHO and Biomarker Testing Guideline Overview:	Mimi Ceppa, MD, Aakash Desai, MBBS, MPH, Hilary Goeckner	Bruce E. Johnson, MD, FASCO
1	January	Weds. 1/17	4:00 -5:00pm	Understanding the Barriers and Pathways to Lung Cancer Biomarker Testing	Millie Das, MD	Timothy Mullett, MD, MBA, FACS
2	February	Fri. 2/9	4:00 -5:00pm	Adequate Tissue for Sampling	Gerard Silvestri, MD, MS	Bruce E. Johnson, MD, FASCO
3	March	Weds. 3/6	4:00 -5:00pm	Choice of Panel, Interpretation of Results and Next Steps	Ignacio Wistuba, MD	Timothy Mullett, MD, MBA, FACS
4	March	Weds. 3/27	4:00 -5:00pm	Improving Turnaround Time	Jason Merker, MD, PhD	Bruce E. Johnson, MD, FASCO
5	April	Weds. 4/24	2:00 - 3:00pm	Navigating Insurance Complexities	Hilary Goeckner & Cori Chandler	Bruce E. Johnson, MD, FASCO
6	May	Fri. 5/24	12:00 - 1:00pm	Series Wrap Up and Next Steps	Patient speaker	Timothy Mullett, MD, MBA, FACS

A Few Reminders

Next ECHO Session: January 17, 2024, 4:00-5:00 PM ET Topic: Understanding the Barriers and Pathways to Lung Cancer Biomarker Testing

Please *register now* for **Session 1** by using the QR code or the link in the chat.

Slides, Recordings, & Resources will be made available within one week. All resources will be available on the **ACS ECHO Website.**

Case Presentations: Ready to schedule your presentation?
Contact Korey.Hofmann@cancer.org

Please send us a high-definition logo for your system.

Look for a calendar invitation from Korey for **Sessions 1 -6**.

Questions? Korey Hofmann - korey.hofmann@cancer.org or Mindi Odom – mindi.odom@cancer.org

Questions?

American Cancer Society | NATIONAL LUNG CANCER ROUNDTABLE | Project ECHO

ECHO Resources

- A Beginner's Guide to an ECHO Session
- Project ECHO: Changing the World Fast – Video
- Dr. Arora Ted Talk
- www.echo.cancer.org
- UNM Official ECHO Website
- Documenting ECHOs in Salesforce QRG
- ACS ECHO Collaborative
- ACS Resource Library

Thank You