American Cancer Society
National Lung Cancer Roundtable

April 17, 2025
Loews Chicago O'Hare
Chicago, IL

2025 BIOMARKER WORKSHOP

Optimizing Lung Cancer Biomarkers in Practice

EXECUTIVE SUMMARY

American Cancer Society | NATIONAL LUNG CANCER ROUNDTABLE | BIOMARKER INITIATIVE

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Introduction

The American Cancer Society National Lung Cancer Roundtable (ACS NLCRT) held the ***2025 Biomarker Workshop*** on April 17, 2025, in Chicago, Illinois. The workshop brought together 90 participants from 64 organizations to generate actionable ideas to improve comprehensive biomarker testing for individuals with non-small cell lung cancer (NSCLC). Building on insights from the 2022 Biomarker Summit, participants focused on developing projects that support reflex testing, establish best practices, improve reporting, and strengthen clinician and patient education, advancing practical solutions to close critical gaps in care.

The American Cancer Society is a national leader in the fight to end cancer, advancing equitable, evidence-based care through advocacy, research, and patient support. The ACS NLCRT reflects this mission by uniting diverse partners to drive progress across the lung cancer continuum. Its work spans risk reduction, tobacco control, early detection, staging, biomarker testing, treatment, and survivorship, while also addressing stigma, health equity, state coalitions, and policy change.

The 2025 Biomarker Workshop consisted of three level-setting sessions, along with two rounds of breakout sessions and one report-out session.

- **Opening Session:** Welcome, Overview, and Patient Advocate Story
- **Level-Setting Presentations #1**: Updates in Biomarker Testing and Treatments
- **Topic-Specific Breakout Groups Round 1:** Generate, Develop, and Communicate New Ideas
- **Level-Setting Presentations #2:** Challenges in Biomarker Testing
- **Level-Setting Presentations #3:** Are Things that Different in Community Practice?
- **Topic-Specific Breakout Groups Round 2:** Refine and Prioritize Ideas
- **Breakout Group Updates:** Present Top Proposal
- **Closing Session:** Summary and Closing Remarks

This document includes highlights from selected panels, final breakout group priorities, and the results of participant voting on proposals.

Welcome, Overview, and Patient Advocate Story

Dr. Bruce Johnson, professor emeritus at Dana-Farber Cancer Institute and co-chair of the ACS NLCRT Biomarker Initiative, opened the workshop with an overview of the Roundtable's strategic priorities: increasing the adoption and quality of lung cancer screening, ensuring guideline-concordant diagnosis and treatment, and reducing stigma and nihilism. He revisited the 2022 biomarker workshop, where participants in four breakout groups developed key messages and action items, including simplifying biomarker testing initiation, standardizing reports, harmonizing guidelines, and reducing testing turnaround times. He also emphasized the need for improved diagnostic biopsies, reflex testing, and unified Medicare coverage for biomarker testing. Dr. Johnson highlighted progress on state legislation to expand access to biomarker testing, with 16 states having passed laws, and 14 expected to follow. He also shared an update on the ACS NLCRT Lung Cancer Biomarker Testing ECHO Program, which has now reached 25 states, 96 sites, and 319 participants across four years. Dr. Johnson expressed gratitude to the ACS NLCRT sponsors and explained that the goal of this year's workshop is to generate tangible products, resources, and projects for clinicians. He outlined the workshop's structure, which includes two breakout sessions: one to brainstorm and collect ideas, and a second to refine those ideas for sharing in the main session.

Mr. Michael Hu, a patient advocate, shared his lung cancer journey via video, highlighting the life-saving role of biomarker testing. Diagnosed with stage IV ALK-positive lung cancer—a subtype with one of the best targeted treatment options—he began medication immediately after receiving his test results. Within five days, his pain subsided, and two years later, his cancer remains under control. Despite these results, his insurance refused to cover the test that enabled his treatment. He emphasized that no patient should be denied access to biomarker testing and called for broader insurance coverage. His home state of Pennsylvania has recently passed legislation but still faces gaps in implementation. Mr. Hu also provided an update on his ongoing treatment. Now on a third-line TKI, his latest scans show positive results, but he noted the limited data available for patients with double mutations or those progressing through multiple therapies. He called for improvements in biomarker-informed decision-making, especially as more patients live longer and face complex treatment choices. He outlined key patient needs: awareness of biomarker testing, knowledge of coverage options, standardized panels aligned with emerging science, and centralized resources that connect biomarker results with clinical options. Finally, he advocated for a shift from linear treatment pathways to a more dynamic, personalized approach guided by real-time biomarker data.

Level-Setting Presentations #1: Updates in Biomarker Testing and Treatments

Dr. M. Patricia Rivera, distinguished professor of pulmonary medicine and chief of pulmonary and critical care medicine at the University of Rochester Medical Center, presented ***Guidelines for Biomarker Testing: With an Increasing Number of Targets, Can the Guidelines Keep Up?*** She highlighted the challenges created by multiple professional organizations issuing biomarker testing guidelines with differing methodologies and update schedules. To address this complexity, Dr. Rivera and her team conducted a modified Delphi process with a multidisciplinary panel to compare and align recommendations from NCCN, ASCO, and CAP/IASLC/AMP. They aimed to determine where guidelines were concordant and where expert consensus existed. The panel identified 70 recommendations, which they restructured into 11 clinical scenarios. CAP/IASLC/AMP guidelines were excluded from the final analysis due to being outdated at the time of voting. Ultimately, 9 of 11 scenarios showed concordance between NCCN and ASCO guidelines, though consensus was reached for only 6 scenarios. Dr. Rivera noted that the lack of consensus was driven by both physician-related factors, such as reliance on personal experience, and guideline-related barriers, such as complexity and lack of clarity. The team is now preparing a report to highlight these issues and promote more consistent, actionable language in future biomarker testing guidelines.

Dr. Adam Fox, assistant professor and pulmonologist at the Medical University of South Carolina, presented ***Biomarker Testing and Treatment Patterns in Metastatic NSCLC*** from the ACS NLCRT Triage for Appropriate Treatment Task Group, which explored critical gaps in treatment and biomarker testing for patients with metastatic NSCLC. Using SEER-Medicare data from over 200,000 patients aged 65 and older diagnosed between 2006 and 2019, Dr. Fox highlighted that while 58% of patients had an oncology visit, only 37% received systemic therapy, and 40% died within 90 days of diagnosis. Key predictors of receiving treatment included patients surviving ≥90 days, referral to an oncologist, being married, and having fewer comorbidities. Even among a healthier subgroup—those under 80, who survived 90 days, and had three or fewer comorbidities—only 61.2% received treatment. Dr. Fox also shared early findings from VA data and Flatiron Health's national EHR dataset, which support the trend of under-treatment and indicate a gradual shift toward multiplex biomarker testing. However, he cautioned that updated SEER-Medicare results may reveal an even lower treatment rate, especially for those under 65. He emphasized that turnaround time for diagnosis, staging, biomarker testing, and referrals is critical to ensuring patients receive timely and appropriate care.

Dr. Jessica Donington, professor of surgery and chief of thoracic surgery at the University of Chicago, presented ***The Changing Treatment Paradigm for Resectable Lung Cancer: Adjuvant, Neoadjuvant, and Perioperative Strategies That All Require Biomarker Testing***, emphasizing the critical role of biomarker testing in shaping perioperative strategies. Marking the 20th anniversary of the EGFR discovery, she traced how biomarker-directed therapies have transformed care for resectable NSCLC, shifting the field away from a one-size-fits-all approach. With 11 major randomized trials reported in the past three years and eight new FDA approvals, surgeons are now routinely asking, "Does this tumor have a targetable mutation?" Landmark trials like ADUARA and ALINA demonstrated profound survival benefits, with the former showing a 50% reduction in death, prompting a re-evaluation of surgical and systemic treatment planning. Dr. Donington also reviewed a growing body of immunotherapy trials in the adjuvant, neoadjuvant, and perioperative settings, all showing improvements in disease-free and overall survival regardless of PD-L1 expression. These advances underscore the need for early biomarker testing in stage II–IIIA disease, yet she acknowledged persistent barriers, such as added steps and delays. She stressed that these therapeutic tracks are mutually exclusive and require timely, coordinated decisions, ideally through multidisciplinary tumor boards. Dr. Donington concluded by affirming that advances in agents, patient selection, and surgical approaches have laid the groundwork for significantly improved outcomes in early-stage lung cancer, so long as the right tests are done at the right time.

Dr. Christine Lovly, associate professor of medicine at Vanderbilt University Medical Center, presented ***Biomarker Testing Applications in Unresectable Lung Cancer: Multiple Targets, Multiple Treatments***. She began by highlighting the transformative shift from empiric to precision medicine, driven by the emergence of two treatment paradigms: targeted therapies and immunotherapies. In 2025, there are now over a dozen FDA-approved biomarker-driven therapies for NSCLC, and clinical decision-making increasingly depends on identifying the specific mutation, not just the presence of one. She noted that biomarker testing must occur both at the time of diagnosis and disease progression and should eventually extend to surveillance and monitoring. Dr. Lovly discussed the practical and technical considerations of biomarker testing, including sample type, testing platform (e.g., DNA vs. RNA sequencing), turnaround time, and result interpretation. She illustrated the profound clinical impact of biomarker-driven care by sharing data on lorlatinib, a third-generation ALK inhibitor, which has achieved over five years of progression-free survival in some patients. She also emphasized the role of PD-L1 expression in guiding immunotherapy, noting that precision approaches have significantly improved survival outcomes. Looking ahead, she highlighted the need for continued innovation not only in drug development—through novel targets and therapies like antibody-drug conjugates and bispecific and trispecific antibodies—but also in the infrastructure needed to ensure equitable implementation, including timely and accurate biomarker testing.

Level-Setting Presentations #2: Challenges in Biomarker Testing

Dr. Sinchita Roy-Chowdhuri, a professor and molecular pathologist at The University of Texas MD Anderson Cancer Center, presented ***Is Tissue Really the Issue? The Increased Reliance on Liquid Biopsies***, exploring the expanding role of plasma-based testing in lung cancer care. As someone deeply involved in diagnosis and molecular testing, she highlighted two persistent challenges: making the right diagnosis and ensuring adequate tissue for biomarker analysis. With more than a dozen biomarkers now recommended in national guidelines, she emphasized that even as testing needs increase, tissue availability has not kept pace, driving a growing reliance on liquid biopsy. Dr. Roy-Chowdhuri explained that while liquid biopsies offer rapid turnaround and a non-invasive alternative when tissue is limited or a re-biopsy is not feasible, they also come with limitations. Plasma-based testing cannot assess protein expression or histologic transformation, has a higher false negative rate, and may miss oncogenic drivers in patients with low circulating tumor DNA. Most institutions now use a complementary or sequential approach—starting with plasma and confirming with tissue if needed. She stressed that while not a substitute for diagnosis, liquid biopsy can provide actionable genotyping, particularly in the metastatic setting, and may be increasingly useful for monitoring treatment response in the future. Her presentation underscored that implementation strategies must account for test sensitivity, timing, and patient context to ensure optimal precision oncology.

Dr. Gerard Silvestri, professor of medicine and a lung cancer pulmonologist at the Medical University of South Carolina, presented ***Turnaround Time: The Bottlenecks May Not Be Where You Think***, highlighting how delays in biomarker testing can lead to suboptimal treatment for patients with advanced lung cancer. He shared survey findings showing that while many oncologists believe that patients don't mind waiting for results, nearly half reported starting non-targeted chemotherapy if biomarker results weren't available within two weeks, despite knowing that targeted therapies lead to significantly better outcomes for patients with actionable mutations. Dr. Silvestri pointed out that the greatest delays aren't in the molecular testing process itself, but in the time it takes to order the test after diagnosis. Drawing from unpublished data on 40,000 patients, he demonstrated that institutions with higher testing volumes had faster turnaround times, largely because they placed orders more quickly. He noted that reflex testing—automatically initiating biomarker testing at diagnosis—dramatically reduced turnaround time in one hospital from over 50 days to just 15. Dr. Silvestri emphasized that biomarker testing is standard of care, and the most modifiable barrier is not the lab, but institutional workflow. He urged attendees to examine their own institutions' processes and implement reflex testing to ensure timely, targeted treatment.

Dr. Charu Aggarwal, professor for lung cancer excellence at the University of Pennsylvania and director of Precision Oncology Innovation at Penn Medicine, presented ***Reflex Testing—It's the Right First Step***, making a compelling case for timely and systematic biomarker testing in lung cancer. She highlighted that targeted therapies have transformed the outlook for patients with NSCLC, improving median survival from less than one year to over three. However, these gains are only possible if molecular testing is completed early, and results are available before treatment begins. Dr. Aggarwal stressed that the survival benefit of targeted therapies is lost if the appropriate treatment is delayed. She described reflex testing as a critical tool for improving timeliness and consistency. At Penn, implementation of reflex testing dramatically shortened the time to test initiation, expanded the use of cytology samples, and increased the proportion of patients receiving complete sequencing. She called for reflex testing to become standard for all patients with stage I–III non-squamous NSCLC, emphasizing that precision medicine depends on education, communication, and collaboration among multidisciplinary teams. In her words, reflex testing is like "having a recipe before you start to cook"—a necessary foundation for delivering the right treatment at the right time.

Ms. Cori Chandler, senior state and local campaigns manager at the American Cancer Society Cancer Action Network (ACS CAN), presented ***What's Covered? Improving Access to Insurance Coverage for Biomarker Testing***, outlining the policy and advocacy work underway to expand access to this critical component of precision medicine. She began by defining biomarkers as measurable indicators that help match patients to the right treatment at the right time, avoiding unnecessary therapies and improving outcomes. While biomarker testing is rapidly expanding across disease areas, disparities in access remain, particularly for patients who are Black, older, low-income, or insured through Medicaid. Ms. Chandler emphasized that insurance coverage is a major barrier, with most plans covering some testing but often in ways that are more restrictive than national clinical guidelines. To address this, ACS CAN developed model legislation requiring comprehensive coverage of biomarker testing when supported by medical and scientific evidence, regardless of disease type or stage. Twenty-one states have passed such laws, but implementation remains a challenge. ACS CAN is working with stakeholders—including providers, payers, and regulators—to ensure effective rollout. Ms. Chandler closed by underscoring that increasing access to biomarker testing is essential to reducing health disparities and ensuring that all patients can benefit from advances in personalized cancer care.

Level-Setting Presentations #3: Are Things That Different in Community Practice?

The community practice panel offered multidisciplinary insights into the real-world challenges and opportunities of biomarker testing for lung cancer. **Dr. Hasnain Bawaadam** described a community hospital's successful implementation of a liquid biopsy-first approach to reduce time from diagnosis to treatment. He emphasized how early molecular testing before invasive procedures can optimize therapy decisions and improve outcomes, with his institution achieving an average turnaround time under seven days and no billing issues for Medicare patients. **Dr. Peter Baik** shared a thoracic surgeon's view on the critical role of biomarker testing in surgical planning, highlighting the need for clear processes to track test orders and results, especially for patients diagnosed at outside institutions. His case examples showed how biomarker data influenced neoadjuvant therapy and ultimately surgical outcomes.

Dr. Samuel Caughron discussed the unique dynamics of community pathology practices, where variability in workflows, lab preferences, and unclear test ownership often impede standardization. He stressed the need for reflex testing protocols, centralized reporting, and collaborative education to bridge practice gaps and improve test utilization. **Dr. Frank Weinberg** highlighted efforts at the University of Illinois Chicago to overcome persistent barriers in an urban safety-net setting. Drawing on local demographic and clinicopathologic data, he described the institution's progress toward equitable testing, including streamlined ordering, staff training, and centralized communication through a secure chat platform. He emphasized that despite historical disparities, UIC now achieves equitable biomarker testing turnaround times across racial groups, supporting precision oncology in a diverse population.

Breakout Group Discussions

Workshop participants were organized into five groups that each focused on one topic area for their two breakout sessions. The five focus areas are listed below:

1. How do we advance implementation of reflex testing?
2. What are the best practices for comprehensive biomarker testing?
3. How do we optimize reporting of biomarker test results?
4. How do we educate clinicians?
5. How do we educate patients?

Breakout groups were tasked with generating, refining, and prioritizing ideas for their assigned topic. In the first session, participants focused on generating new ideas related to their focus area. In the second session, they refined and prioritized one key activity to advance that focus area.

Priority Activities

Group 1: How do we advance implementation of reflex testing?

Subject Matter Experts

Adam H. Fox, MD, MS
Assistant Professor, Dept. of Medicine
Medical University of South Carolina

Shetal Patel, MD, PhD
Assistant Professor, Dept. of Medicine
University of North Carolina School of Medicine

Proposed Activity

Define minimal consensus biomarker testing guidelines and promote reflex pathologist-driven biomarker testing to be incorporated into CAP/ASCO/NCCN guidelines.

Group 2: What are the best practices for comprehensive biomarker testing?

Subject Matter Experts

Lynette M. Sholl, MD, FCAP
Chief, Thoracic Pathology
Brigham and Women's Hospital
Associate Professor of Pathology
Harvard Medical School

M. Patricia Rivera, MD, ATSF, FCCP
Chief, Dept. of Pulmonary and Critical Care Medicine
Distinguished Professor in Pulmonary Medicine
University of Rochester

Proposed Activity

Comprehensive biomarker testing for all styles of NSCLC with implementation of quality measures.

Group 3: How do we optimize reporting of biomarker test results?

Subject Matter Experts

Charu Aggarwal, MD, MPH
Director, Precision Oncology Innovation
Section Chief, Head & Neck and Thoracic Cancers
Penn Medicine

Ignacio I. Wistuba, MD
Professor and Chair, Dept. of Translational Molecular Pathology
The University of Texas MD Anderson Cancer Center

Proposed Activity

- Convene working group to create a consensus statement guideline for biomarker test reporting with minimal elements needed and standardized language.
- Multidisciplinary team – pathology, medical oncology, surgery, pulmonary, EMR, testing companies, pharmaceutical, FDA, patient advocates.

Group 4: How do we educate clinicians?

Subject Matter Experts

Raymond U. Osarogiagbon, MBBS, FACP
Chief Scientist
Director, Multidisciplinary Thoracic Oncology Program
Baptist Memorial Health Care

Gerard A. Silvestri, MD, MS, Master FCCP
Hillenbrand Distinguished Professor
Professor, Dept. of Medicine
Medical University of South Carolina

Proposed Activity

Create tailored approaches to teach the various stakeholders how to develop best practices to optimize workflows for biomarker testing.

Group 5: How do we educate patients?

Subject Matter Experts

Nancy V. Torrison
Executive Director
A Breath of Hope Lung Cancer Foundation

Douglas E. Wood, MD, FACS, FRCSEd
Vice Chair, ACS NLCRT
Professor, Dept. of Surgery
University of Washington

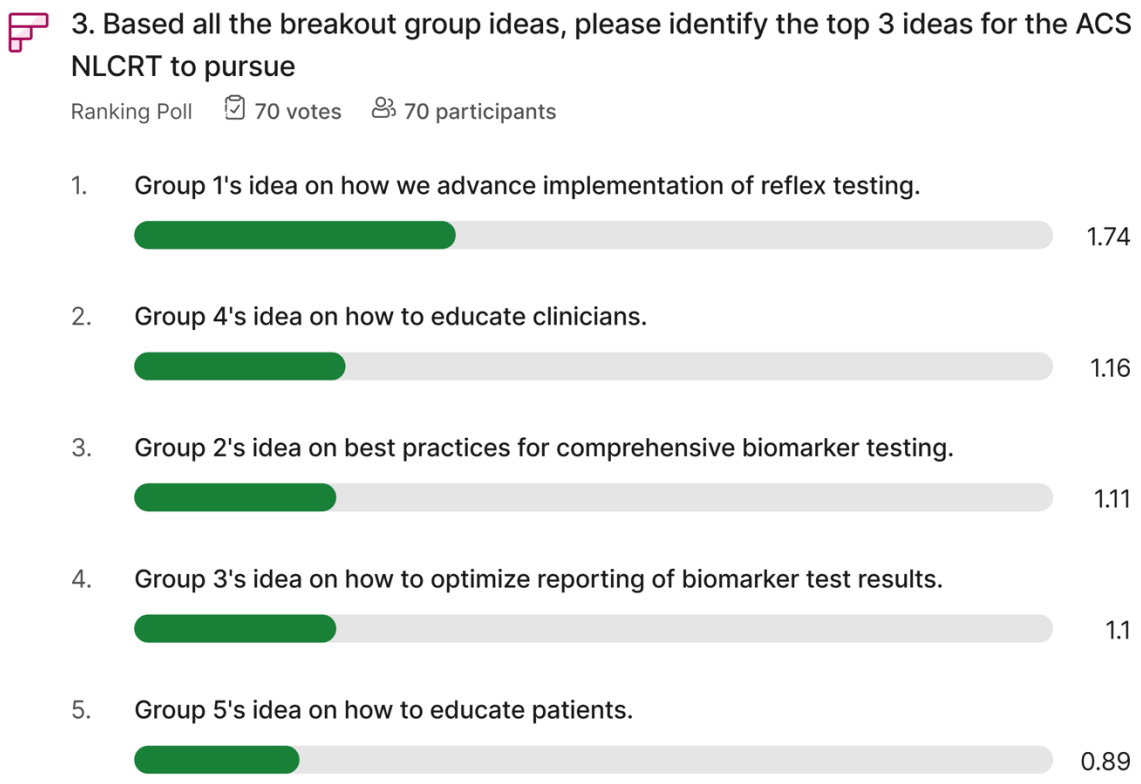
Proposed Activity

Multimodality educational materials (video series, patient information sheet, patient journey checklist; all accessible and evidence-based)

- Repository that is available to all patient-facing groups.

Slido Results

Following the breakout group report-outs, participants voted on their top three proposals. The results of this vote are shown below.



List of Presentations

Welcome, Overview, and Patient Advocate Story
Bruce E. Johnson, MD, FASCO, Dana-Farber Cancer Institute and Harvard Medical School Michael Hu, Patient Advocate
Level-Setting Presentations #1: Updates in Biomarker Testing and Treatments
Moderator: Raymond U. Osarogiagbon, MBBS, FACP, Baptist Memorial Health Care **Moderator:** Lynette M. Sholl, MD, FCAP, Brigham and Women's Hospital and Harvard Medical School M. Patricia Rivera, MD, ATSF, FCCP, University of Rochester *Guidelines for Biomarker Testing: With an Increasing Number of Targets, Can the Guidelines Keep Up?* Adam H. Fox, MD, MS, Medical University of South Carolina *Biomarker Testing and Treatment Patterns in Metastatic NSCLC* Jessica S. Donington, MD, MSCR, FACS, University of Chicago *The Changing Treatment Paradigm for Resectable Lung Cancer: Adjuvant, Neoadjuvant, and Perioperative Strategies That All Require Biomarker Testing* Christine Lovly, MD, PhD, FASCO, Vanderbilt-Ingram Cancer Center *Biomarker Testing Applications in Unresectable Lung Cancer: Multiple Targets, Multiple Treatments*
Level-Setting Presentations #2: Challenges in Biomarker Testing
Moderator: Bruce E. Johnson, MD, FASCO, Dana-Farber Cancer Institute and Harvard Medical School **Moderator:** Ignacio I. Wistuba, MD, The University of Texas MD Anderson Cancer Center Sinchita Roy-Chowdhuri, MD, PhD, The University of Texas MD Anderson Cancer Center *Is Tissue Really the Issue? The Increased Reliance on Liquid Biopsies* Gerard A. Silvestri, MD, MS, Master FCCP, Medical University of South Carolina *Turnaround Time: The Bottlenecks May Not Be Where You Think* Charu Aggarwal, MD, MPH, Penn Medicine *Reflex Testing—It's the Right First Step* Cori Chandler, MPA, American Cancer Society Cancer Action Network *What's Covered? Improving Access to Insurance Coverage for Biomarker Testing*

***Level-Setting Presentations #3*: Are Things that Different in Community Practice?**
Moderator: Jennifer Aversano, MSN, RN, OCN, ONN-CG, Northwest Community Hospital **Moderator:** Shetal Patel, MD, PhD, University of North Carolina School of Medicine
Hasnain Bawaadam, MD, MPH, FCCP, FRCP, D-AABIP, Aurora Medical Center Kenosha *Pulmonology*
Peter Baik, DO, FACOS, FACS, City of Hope Cancer Center Phoenix *Surgery*
Samuel K. Caughron, MD, FCAP, MAWD Pathology Group *Pathology*
Frank Weinberg, MD, PhD, University of Illinois College of Medicine Chicago *Oncology*
***Breakout Group Updates*: Present Top Proposals**
Moderator: Ella A. Kazerooni, MD, MS, FACR, FACC, FSABI, Chair, ACS NLCRT, University of Michigan
Group 1: How do we advance implementation of reflex testing?
Group 2: What are the best practices for comprehensive biomarker testing?
Group 3: How do we optimize reporting of biomarker test results?
Group 4: How do we educate clinicians?
Group 5: How do we educate patients?
Summary and Closing Remarks
Gerard A. Silvestri, MD, MS, Master FCCP, Medical University of South Carolina

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Additional thanks to Boehringer Ingelheim, Foundation Medicine, and Gilead

American Cancer Society National Lung Cancer Roundtable

The ACS NLCRT, established by the American Cancer Society in 2017, is a coalition of multidisciplinary organizations and individuals dedicated to reducing the burden of lung cancer. The roundtable fosters sustained partnerships across diverse sectors and communities to tackle both long-standing and emerging issues in lung cancer.

Mission
Our mission is to create lung cancer survivors.

Values
Patient-Centered, Evidence-Based, Inclusive & Diverse, Proactive & Visionary

Strategic Priorities
- Accelerate implementation and uptake of, and adherence to, early detection of lung cancer.
- Improve guideline-concordant lung cancer staging and optimize the use of lung cancer biomarkers in practice.
- Promote initiatives to eliminate lung cancer-related stigma and nihilism.

ACS NLCRT Health Equity Statement
The ACS NLCRT believes that every person should have a fair and just opportunity to find, treat, and survive lung cancer, regardless of income, ethnicity, skin color, sexual orientation, gender identity, disability status, language, or zip code.