American Cancer Society®

NATIONAL LUNG CANCER ROUNDTABLE

Optimizing Lung Cancer Biomarkers in Practice

EXECUTIVE SUMMARY

October 28, 2022

Fairmont Millennium Park

Chicago, IL

Introduction

The American Cancer Society National Lung Cancer Roundtable (NLCRT) held its second summit on Optimizing Lung Cancer Biomarkers in Practice on Friday, October 28, 2022, in Chicago, Illinois. Ninety-five attendees representing 55 organizations from across the country participated in this catalyzing summit, including people who have experienced lung cancer and their families, lung cancer advocates, clinicians, researchers, public health professionals, policy experts, and health plan and industry partners. The goals of the 2022 summit were to update attendees on the progress of activities that were initiated in response to the recommendations of the inaugural 2020 summit and to develop a new set of collaborative initiatives to equitably reduce the non-small cell lung cancer (NSCLC) burden.

The summit's objectives were to ensure a common understanding of the current state of biomarker testing, identify the most common barriers, develop strategies to overcome these barriers and increase biomarker testing, and engage key partners to participate in the developed strategies.

Speakers at the summit presented on biomarker-related topics such as lack of awareness among the multidisciplinary specialties regarding the importance of biomarker testing for treatment selection, suboptimal tissue sampling, slow turnaround time in receiving results, challenges in the interpretation of results, belief among both patients and providers that biomarker testing is an optional procedure, and persistent disparities in access to and receipt of biomarker testing that increase disparities in cancer care.

The one-day summit was divided into six sessions, including:

- Welcome, Patient Advocate Story, and State of Biomarker Testing
- NLCRT Biomarker Initiative Accomplishments
- Biomarker Testing Workflow Perspectives
- Partnerships to Optimize Biomarker Testing
- Industry Initiatives and Challenges
- What We Learned and Plans for the Future

This document summarizes the high-level points made throughout the day and provides a complete list of speakers and presentations in the appendices.

Overview of the Summit (Presentation Details begin on Page 10)

Session 1 - Welcome, Patient Advocate Story, and State of Biomarker Testing

Session 1 of the summit was opened by NLCRT Chair Dr. Ella Kazerooni. She welcomed the attendees and emphasized the value of the ACS NLCRT in its role as a convener of subject matter experts, including clinicians, researchers, public health officials, patient advocates, and industry partners across all disciplines to make optimizing lung cancer biomarker testing in practice a high priority. She thanked the NLCRT sponsors for their support, financial backing, and scientific contributions.

Dr. M. Patricia Rivera, Co-chair of the NLCRT Biomarker Initiative, described the *NLCRT Strategic Plan to Optimize Biomarker Testing for Non-Small Cell Lung Cancer* and the main activities of the NLCRT for the past two years based on the strategic plan developed as an outcome of the inaugural biomarker summit in 2020.

Next, Mr. John Hallick, President of the MET Crusaders and co-president of the Biomarker Collaborative, presented on *Patient-Centered Collaboration: The Biomarker Collaborative*. The Biomarker Collaborative is a global coalition of patient advocacy organizations and partners dedicated to patient support so patients can live longer and better.

Dr. Bruce Johnson, Co-chair of the NLCRT Biomarker Initiative, gave the last presentation of the opening session and described the *State of Biomarker Testing and Outcomes.*

Session 2 – NLCRT Biomarker Initiative Accomplishments

Session 2 provided updates on five key projects that were prioritized from the 2020 NLCRT Biomarker Summit strategic plan. One presentation discussed the development of a consensus statement that identifies common and dissimilar elements of the leading biomarker testing clinical practice guidelines and explores the value and potential to harmonize them to create a multi-society, professionally engaged and endorsed best practice statement on biomarker testing in lung cancer. Other presentations highlighted the necessity for the timely acquisition of lung tissue to enable the appropriate and timely staging of lung cancers, the identification of key factors that could prevent or delay the use of biomarker testing for patients with NSCLC, the use of Project ECHO in Mississippi beginning in 2021 to increase the knowledge of clinicians about biomarker testing, and how state legislative trends are helping to expand access to biomarker testing to improve health equity.

Session 3 – Biomarker Testing Workflow Perspectives

Session 3 contained seven presentations that described the work that needs to be done to overcome important barriers and improve the rates of biomarker testing and turnaround times.

The first presentation described the determinants of access to biomarker testing and therapy and strategies to deliver care in underserved areas. The second presentation described predictors (race, age, comorbid conditions, socioeconomic status, etc.) of those who are not receiving biomarker testing and treatment in community settings. The presenters also stressed that reflex testing must be established as a standard of care. The third presentation highlighted endobronchial ultrasound (EBUS), a procedure used by pulmonologists and surgeons, as a valuable tool for diagnosing and staging lung cancer.

The fourth presentation described challenges with specimens, tissue acquisition, and platform selection in community healthcare settings. The fifth presentation focused on metrics for success in the timing of ordering biomarker testing, quantity of tissue acquired, and turnaround time of biomarker tests.

Presentation six described some disparities in molecular testing and delivery of targeted therapies in NSCLC, that could widen the gap between specialized care centers and smaller treatment centers. Finally, the seventh presentation described the financial burden of precision oncology and how policies beyond insurance coverage are needed to ensure equitable access to care.

Session 4 – Partnerships to Optimize Biomarker Testing

Session 4 contained six presentations that addressed how national initiatives, state initiatives, and key partnerships could improve the rate of biomarker testing and create better outcomes for lung cancer patients.

The first presentation described how geospatial analysis can identify counties with the required expertise and providers to assess high lung cancer burdens. The second presentation described the experiences of a thoracic oncology nurse navigator in helping to overcome barriers to equitable and timely care, deliver appropriate patient education, and manage patient expectations and anxieties.

The third and fourth presentations described initiatives supported by two advocacy organizations, LUNGevity Foundation and GO2 For Lung Cancer. Their collective approach and collaborative efforts highlighted the ways to address barriers to biomarker testing for clinicians, including turnaround time, financial burdens, reimbursement, and insufficient tissue samples.

The fifth presentation highlighted the NCCN Guidelines V5.2022 and the need for molecular profiling in NSCLC. The final presentation of the panel described the Veterans Administration's *National Precision Oncology Program (NPOP)*, and specifically, the Lung Precision Oncology Program (LPOP),

which aims to give VA clinicians a range of tools to proactively address and treat lung cancer in Veterans.

Session 5 – Panel Discussion on Industry Initiatives and Challenges

Session 5 contained six presentations that described the challenges that industry partners encountered when they launched biomarker initiatives to ensure that all eligible individuals with NSCLC had access to biomarker testing.

The first presentation described AstraZeneca's commitment to overcoming barriers to testing, such as improving tissue insufficiency rates, slow turnaround times, and healthcare disparities. Their initiatives included creating resources, facilitating expert forums to learn from tissue proceduralists, and partnering with lung cancer coalitions. The second presentation described Genentech's focus on partnerships, education, and generating evidence-based data. The company reorganized its field teams to move both patient and provider education from the national level down to the local level.

The third presentation described Amgen's focus on education, operational barriers, and evidence generation to ensure that communities are up to date with the use of biomarkers to guide appropriate and timely testing. The company provides access to free biomarker testing for the biomarkers that are directly tied to their products. The fourth presentation described Bristol-Myers Squibb's commitment to accelerating disease awareness and education programs while improving access to care in medically underserved communities. The company is also working to increase clinical trial diversity as measured by the location of clinical trial enrollment, the people involved in the enrollment, the investigators, and internal company representatives.

The fifth presentation described Foundation Medicine's focus on diversity, inclusion, and overcoming cancer disparities that have emerged in biomarker testing. They are working to overcome the financial barriers to biomarker testing affecting physicians and patients. The final presentation described Guardant Health's program to provide financial assistance to patients for biomarker testing by implementing a bidirectional interface with electronic medical record (EMR) systems used at the point of care and is partnering to bring access to clinical trials to underserved populations.

Session 6 – What we Learned Today and Plans for the Future

Session 6, the closing session, was introduced by Dr. Ella Kazerooni. She thanked the organizers and the audience for their participation and emphasized that the ACS NLCRT strives to be an effective convener of experts from many professional communities and organizations to address important challenges in the care and control of lung cancer, with the principle goal of benefiting patients by improving the quality of their care and outcomes.

Dr. Gerard Silvestri, Chair of the NLCRT Triage for Appropriate Treatment Task Group, highlighted the main messages of all summit talks. He emphasized the importance of always thinking from the patient's perspective and celebrated that the time between drug discovery and patient treatment with new therapies has significantly decreased since 2000. Next, he highlighted the necessity of unifying guidelines and overcoming barriers to biomarker testing. Finally, he highlighted the importance of having good-quality metrics for evaluation.

The final speakers of the summit were the Co-chairs of the NLCRT Biomarker Initiatives. They proposed actions to prioritize and work on during the coming year.

Dr. M. Patricia Rivera proposed simplifying the initiation of biomarker testing, standardizing testing reports, and promoting the content of established biomarker testing guidelines in ways that are harmonized, modernized, and accessible to everyone.

Dr. Bruce Johnson proposed establishing standards for diagnostic biopsies and reflex testing, developing tools to reduce the biomarker testing turnaround time, and unifying Medicare testing coverage nationwide.

Dr. Ignacio Wistuba proposed improving patient navigation resources at a local level beyond the boundaries of academic and community healthcare institutions. He also highlighted the need to coordinate partnerships between foundations and healthcare providers and identified the ACS NLCRT's Project ECHO for biomarker testing as a model that should be emphasized and scaled up across the country.

Dr. Ella Kazerooni closed the 2022 Biomarker Summit by again highlighting the importance of American Cancer Society national and state-based roundtables as effective and efficient platforms to create more cancer survivors.

Overview of Panel Presentations with Video Links

Opening Session – Welcome, Patient Advocate Story, and State of Biomarker Testing

- **Moderator**
  Douglas Wood, MD, FACS, FRCSEd, NLCRT Vice Chair, University of Washington
- **Welcome from the NLCRT**
  Ella Kazerooni, MD, MS, FACR, FACC, FSABI, NLCRT Chair, University of Michigan
- **NLCRT Strategic Plan to Optimize Biomarker Testing for Non-Small Cell Lung Cancer**
  M. Patricia Rivera, MD, ATSF, FCCP, NLCRT Biomarker Initiative Co-Chair, University of Rochester
- **Patient-Centered Collaboration: The Biomarker Collaborative**
  John Hallick, MET Crusaders President, Biomarker Collaborative Co-President
- **State of Biomarker Testing and Outcomes**
  Bruce Johnson, MD, FASCO, NLCRT Biomarker Initiative Co-Chair, Dana-Farber Cancer Institute

NLCRT Biomarker Initiative Accomplishments

- **Moderator**
  Bruce Johnson, MD, FASCO, NLCRT Biomarker Initiative Co-Chair, Dana-Farber Cancer Institute
- **Comprehensive Biomarker Testing Consensus Statement**
  M. Patricia Rivera, MD, ATSF, FCCP, NLCRT Biomarker Initiative Co-Chair, University of Rochester
- **Acquiring Tissue for Lung Cancer Diagnosis and Comprehensive Biomarker Testing**
  Farhood Farjah, MD, MPH, FACS, NLCRT Triage for Appropriate Treatment Task Group Vice Chair, University of Washington
- **Process Map and Assessment Tools to Reduce Biomarker Testing Turnaround Time**
  Ignacio Wistuba, MD, NLCRT Biomarker Initiative Co-Chair, MD Anderson Cancer Center
- **Addressing Lung Cancer Biomarker Testing Through Project ECHO and the Mississippi Lung Cancer Roundtable**
  Pierre de Delva, MD, FACS, University of Mississippi Medical Center
- **State Legislative Trends Related to Biomarker Testing**
  Hilary Gee Goeckner, MSW, American Cancer Society Cancer Action Network

Biomarker Testing Workflow Perspectives

- **Moderator**
  Gerard Silvestri, MD, MS, Master FCCP, NLCRT Triage for Appropriate Treatment Task Group Chair, Medical University of South Carolina
- **Determinants of Access to Biomarker Testing and Therapy and Strategies to Deliver Care in Underserved Areas**
  Raymond Osarogiagbon, MBBS, FACP, Baptist Memorial Healthcare Corporation
- **Predictors of Who Does Not Receive Biomarker Testing: Can Incorporating Reflex Testing Help?**
  Adam Fox, MD, Medical University of South Carolina
- **EBUS and the Proceduralist's Role in Acquiring Tissue for Biomarker Testing**
  Nicholas Pastis, Jr., MD, FCCP, The Ohio State University Wexner Medical Center
- **Challenges within Specimens, Tissue Acquisition, and Platform Selection in the Community Setting**
  Haresh Mani, MD, Inova Health System
- **Metrics for Success on Timing of Ordering, Quantity, and Turnaround Time**
  Sinchita Roy-Chowdhuri, MD, PhD, MD Anderson Cancer Center
- **Disparities in Molecular Testing and Delivery of Targeted Therapies in NSCLC**
  H. Jack West, MD, City of Hope Comprehensive Cancer Center
- **Financial Burden of Precision Oncology**
  Aakash Desai, MBBS, MPH, Mayo Clinic, Rochester

Partnerships to Optimize Biomarker Testing

- **Moderator**
  Ignacio Wistuba, MD, NLCRT Biomarker Initiative Co-Chair, MD Anderson Cancer Center
- **Geospatial Analysis of Biomarker Testing and Treatment to Develop Strategies to Improve Access**
  Liora Sahar, PhD, GISP, American Cancer Society
- **Thoracic Oncology Nurse Navigator Experience in South Carolina**
  Claudia Miller, BSN, RN, OCN, ONN-CG, Medical University of South Carolina
- **It Takes a Community: Collaborative Efforts to Advance Precision Medicine**
  Andrea Ferris, MBA, LUNGevity Foundation
- **Barriers to Biomarker Testing Among GO2 Foundation's Centers of Excellence**
  Daniel Saez, MS, GO2 for Lung Cancer
- **Operational Pathways for Molecular Testing in the Community Setting**
  Pablo Gutman, MD, Holy Cross Health
- **VA Lung Precision Oncology Program**
  Michael Kelley, MD, Duke University School of Medicine

Panel Discussion: Industry Initiatives and Challenges

- **Moderator**
- M. Patricia Rivera, MD, ATSF, FCCP, NLCRT Biomarker Initiative Co-Chair, University of Rochester
- **Optimizing Lung Cancer Biomarker Testing in Practice**
- Melissa Lowder, PhD, AstraZeneca
- **Tackling Disparities in Access to Biomarker Testing**
  Kathryn Chandra, MA, Genentech
- **Amgen Initiatives to Support Comprehensive Biomarker Testing**
  Byeong Yoon, PhD, Amgen
- **Bristol Myers Squibb**
  Lee James, MD, PhD, Bristol Myers Squibb
- **Industry Initiatives and Challenges**
  Mia Levy, MD, PhD, Foundation Medicine
- **Biomarker Testing in Lung Cancer – Barriers and Solutions**
  Rebecca Nagy, MS, LGC, Guardant Health

What we Learned Today, Ways to Plan for the Future, and Potential Projects Moving Forward: Biomarker Summit Impressions and Priorities

- **Panel Presentation**
- Gerard Silvestri, MD, MS, Master FCCP, Medical University of South Carolina
- Bruce Johnson, MD, FASCO, NLCRT Biomarker Initiative Co-Chair, Dana-Farber Cancer Institute
- Ignacio Wistuba, MD, NLCRT Biomarker Initiative Co-Chair, MD Anderson Cancer Center
- M. Patricia Rivera, MD, ATSF, FCCP, NLCRT Biomarker Initiative Co-Chair, University of Rochester

Presentation Highlights

Opening Session – Welcome, Patient Advocate Story, and State of Biomarker Testing

The Opening Session began with NLCRT Chair **Dr. Ella Kazerooni**, University of Michigan. She welcomed the attendees and emphasized the value of the American Cancer Society National Lung Cancer Roundtable in its role as a convener of subject matter experts, including clinicians, researchers, public health officials, patient advocates, and industry partners across all disciplines to make optimizing lung cancer biomarker testing in practice a high priority. She thanked the NLCRT sponsors for both their financial and scientific contributions and support.

The next speaker was **Dr. M. Patricia Rivera**, Co-chair of the NLCRT Biomarker Initiative, University of Rochester, who presented on the **NLCRT Strategic Plan to Optimize Biomarker Testing for Non-Small Cell Lung Cancer.** In 2020, the NLCRT held the first *Optimizing Lung Cancer Biomarkers in Practice* summit (virtual, see the executive summary and key takeaways) with 85 participants and 75 organizations. The goal of the summit was to identify barriers and close knowledge gaps in biomarker testing by sharing clinician experiences. The summit participants devised a strategic plan to optimize biomarker testing for every eligible patient with NSCLC. Recommended strategic interventions included education through the Project ECHO model, publications of recommendations to overcome existing barriers such as turnaround time of tissue acquisition and biomarker testing, and creating a consensus statement from existing ASCO, NCCN, and CAP/IASLC/AMP NSCLC biomarker testing clinical practice guidelines.

Mr. John Hallick, President of the MET Crusaders and Co-President of the Biomarker Collaborative, presented on **Patient-Centered Collaboration: The Biomarker Collaborative**. The Biomarker Collaborative is an international coalition of biomarker groups dedicated to patient support and to the goal of helping patients to live longer and better lives. The collaborative initiative is crucial because it provides the education and support that are key components of comprehensive care. Hallick emphasized the importance of helping patients find targeted support at the point of diagnosis by connecting them to the right support group. A quiz posted on the Biomarker Collaborative website facilitates the connection process. He highlighted the necessity of doing a comprehensive biomarker test and optimizing the tissue collection process to maximize the information obtained from a single biopsy. Mr. Hallick concluded that targeted therapy is driven by data and that DNA sequencing banks are accelerating the growth of clinical trials around biomarkers.

The third and final presenter for the opening session was **Dr. Bruce Johnson**, Co-chair of the NLCRT Biomarker Initiative, Dana-Farber Cancer Institute, who presented on the **State of Biomarker Testing and Outcomes**. He began by emphasizing the need to expand the reach of precision

medicine beyond the academic centers. He highlighted the importance of identifying tumor resistance mechanisms for the development of new therapies by using stochastic modeling and changing patient treatments based on tumor biomarkers. Next, Dr. Johnson presented clinical evidence showing the benefits of progression-free survival in patients treated with Osimertinib for NSCLC positive for EGFR mutations and Alectinib for those showing ALK rearrangements. He described three other chromosomal rearrangements for which there are approved targeted therapies (ROS1, NTRK, and RET) and described the underlying improvements achieved with Entrectinib for ROS1 rearrangement. Finally, he showed that those patients with adenocarcinomas with PD-L1 positivity above 50% who are treated with checkpoint inhibitors have longer progression-free survival and longer survival than patients who were treated with chemotherapy.

Session 2 - NLCRT Biomarker Initiative Accomplishments

The session began with **Dr. M. Patricia Rivera**, Co-chair of the NLCRT Biomarker Initiative, University of Rochester, who presented on **Biomarker Testing in Non-Small Cell Lung Cancer: A Consensus Statement**. The objective of the consensus statement project is to identify similarities and disparities in biomarker testing recommendations in three different areas: 1) patient eligibility criteria to undergo predictive biomarker testing; 2) identification of the specimen type and adequate collection; and 3) criteria for adequate testing and reporting processes (tests, platforms, and turnaround times). To achieve the goals of the consensus statement project, a comprehensive, multidisciplinary panel of individuals from different academic and community centers used the modified-Delphi process called the RAND Appropriateness Method (RAM) to identify areas of consensus among a panel of experts based on the NCCN, ASCO, and CAP/IASLC/AMP guidelines. In the first of three rounds of voting, they identified 70 pairwise recommendations across the three described areas. The group expects to continue with two more voting rounds and to summarize the consensus guidelines in a statement that will be published in a peer-reviewed journal to be disseminated among all NLCRT member organizations and health systems and cancer centers that are participating in the NLCRT biomarker testing ECHO series.

Next, **Dr. Farhood Farjah**, NLCRT Triage for Appropriate Treatment Task Group Vice Chair, University of Washington, presented on **Acquiring Tissue for Lung Cancer Diagnosis and Comprehensive Biomarker Testing**. He described the goals of tissue acquisition, which are to establish the histopathologic diagnosis of lung cancer, to stage the lung cancer, and to do comprehensive biomarker testing. He highlighted the necessity of maximizing timeliness while minimizing patient risk during the tissue acquisition process. Hence, the best procedure is the one that exposes the patient to the least amount of risk while yielding enough tissue to accomplish all three goals. Dr. Farjah illustrated this concept with several clinical cases in which patients had multiple lesions that could be biopsied. He concluded that there is no single right procedure for all patients; the best procedure must be determined on a case-by-case basis. This manuscript was recently published in *CA: Cancer Journal for Clinicians*.

Dr. Ignacio Wistuba, Co-chair of the NLCRT Biomarker Initiative, MD Anderson Cancer Center, presented on the development of a **Process Map and Assessment Tools to Reduce Biomarker Testing Turnaround Time**. The presentation highlighted the factors that can prevent or delay the use of biomarker testing for NSCLC patients, such as access to testing, tissue adequacy, turnaround time, and insurance coverage. One of the approachable pre-analytical factors that affect turnaround time is the timeliness of test orders. Dr. Wistuba suggested that timeliness can be improved by healthcare physicians by ordering molecular testing at the time of initial clinical diagnosis or by pathologists through directed reflex testing based on stage and histology. Next, he described some compliance and financial barriers to reflex testing and highlighted that although single-gene testing is faster, there is a preference for panel-based comprehensive testing. Dr. Wistuba concluded that reducing comprehensive biomarker testing turnaround time for NSCLC is a challenge and requires a multidisciplinary effort. He proposed starting with adequate tissue collection by a pulmonologist, interventional radiologist, or surgeon and using a platform that provides the most information in a short period of time. Finally, he emphasized the need for a robust quality assurance program to monitor implementation success for each of the steps affecting turnaround time.

Dr. Pierre de Delva, Chair of the Mississippi Lung Cancer Roundtable, University of Mississippi Medical Center, spoke about **Addressing Lung Cancer Biomarker Testing Using Project ECHO and State-Based Coalitions** in Mississippi. He described the expansion of biomarker-driven care in the last decade thanks to the effort put into basic scientific research and the translation of discoveries into effective clinical treatments. Today, most patients have better outcomes because of biomarker testing options and therapies to personalize their care. However, patient, provider, and institutional barriers to biomarker testing exposed knowledge gaps. Dr. de Delva explained that Project ECHO was designed as a knowledge-sharing network to bring expert information to communities through collaborative interactive video conferencing. The NLCRT launched this Project ECHO in Mississippi as a 3-state pilot study (along with Kentucky and Georgia) in May 2021 and involved eight hospital systems and one oncology group. He emphasized the need for multiplier effects by going beyond academic medical centers to reach the community programs that treat most lung cancer cases. According to survey results from the 3-state pilot report, Project ECHO implementation improved the knowledge and confidence of multidisciplinary participants in understanding testing biomarker testing barriers. Finally, Dr. de Delva described how a coalition of clinician champions and ACS colleagues modeled the *Mississippi Lung Cancer Roundtable* after the American Cancer Society National Lung Cancer Roundtable.

Finally, **Ms. Hilary Gee Goeckner**, American Cancer Society Cancer Action Network (ACS CAN), presented on **State Legislative Trends: Expanding Access to Biomarker Testing**. She described the ACS CAN as a non-profit, non-partisan advocacy affiliate of the American Cancer Society that works on advancing evidence-based policies to help with cancer prevention, detection, treatment, and research. She underscored the disparities in access to biomarker testing and showed that Black, older, or Medicaid-insured patients, as well as those in community oncology settings, are less likely

to receive comprehensive biomarker testing. Then, she listed the barriers to accessing biomarker testing, including insurance coverage issues that directly impact the receipt of targeted therapy based on test results. An ACS CAN survey revealed that two-thirds of oncology provider participants had concerns about patient costs and insurance test coverage. In general, insurance policies are more restrictive than the guidelines for biomarker testing. For example, they are more likely to cover single-gene testing than multigene panel tests. To address coverage gaps, the ACS CAN organization works with other partners to align insurance coverage policies with evidence that indicates that biomarker testing must be covered for diagnosis, treatment, management, and monitoring. The new legislation has been passed in four states and is expected to be passed by more states in 2023.

Session 3 - Biomarker Testing Workflow Perspectives

This session began with a presentation by **Dr. Raymond Osarogiagbon**, NLCRT Steering Committee Member, Baptist Memorial Healthcare Corporation, on the **Determinants of Access to Biomarker Testing and Therapy & Strategies to Deliver Care in Underserved Areas**. He first showed published data that demonstrated that the survival probability of patients with lung cancer is significantly higher among those who are tested for biomarkers, especially when they receive targeted treatment. Likewise, race and socioeconomic factors also suggest that there might be a relationship between those factors and cancer mutation profiles. However, two other studies showed that there were no significant differences in the somatic mutation patterns of lung cancers in Black and White populations. This suggests that targeted therapies could benefit both Black and White patients equally. Unfortunately, the evidence indicates that Black patients receive worse healthcare quality, which hinders their access to appropriate and timely treatment. Dr. Osarogiagbon concluded by stating that the solutions with the highest impact will be those involving changes in healthcare and social policies.

Next, **Dr. Adam Fox**, Medical University of South Carolina, shared his presentation on **Predictors of Who Does Not Receive Biomarker Testing: Can Incorporating Reflex Testing Help?** He shared predictors of absent testing, including race, older age, comorbid conditions, fewer socioeconomic means, and treatment in less specialized settings. Predictors of non-treatment are the same, with the addition of advanced-stage cancer. Given that not testing for biomarkers means not benefiting from targeted therapy, Dr. Fox highlighted the need to evaluate the inclusion of cancer biomarkers as reflex tests. Reflex testing should be established as a standard of care for all patients who are eligible for biomarker testing. Reflex testing reduces disparities in testing, improves the timeliness of testing, and consolidates the need for knowledge across the clinical multidisciplinary team. Then, Dr. Fox described some technical, operational, and compliance barriers to reflex testing. Finally, he presented data showing that reflex testing was successfully implemented in some institutions, increasing the number of patients being tested and decreasing the turnaround times. However, there are still no published results about the implementation outcomes.

Dr. Nicholas Pastis, The Ohio State University, presented on **EBUS and the Proceduralist's Role in Acquiring Tissue for Biomarker Testing**. Endobronchial ultrasound (EBUS) is a landmark test for the diagnosis and staging of lung cancer. Dr. Pastis described the diagnostic algorithm for NSCLC, which starts with the collection of tissue that is then split into two pieces. One piece is prepared for histology, while the other is processed for cytology and biomarker testing. Dr. Pastis commented that next-generation sequencing (NGS) is the preferred biomarker technique because it allows for complete genome sequencing. The NCCN guidelines recommend broad-based testing for most types of lung cancers, but the amount of DNA mass obtained from EBUS is usually insufficient for doing all biomarker tests. This barrier can be overcome by doing more passes, but more evidence is needed to determine the minimal number of passes that give the highest yield of DNA. The standard approach for DNA purification is from a cell block. He said that peripheral ultrasound could provide good-quality DNA for NGS in more than 90% of the cases. He concluded with evidence that EBUS is also a validated tool to check for PD-L1 and candidacy for immune checkpoint inhibitor therapy.

Dr. Haresh Mani, Inova Health System, presented on the **Challenges with Specimens, Tissue Acquisition, and Platform Selection in the Community Setting**. He explained that biomarker testing on bone specimens requires the creation of a cell block of the soft tissue obtained from the aspirate to overcome the problem of nucleic acid degradation due to the decalcification process. He described the current difficulty of doing a rapid onsite evaluation (ROSE) to ensure specimen adequacy because of insufficient staff levels in community settings. Hence, they use a telepathology platform through which a pathologist in an office can give a rapid evaluation. He said that cell blocks are preferred to smears because the samples must be sent out for biomarker testing to other companies. He also discussed some technical concerns, such as which pass to use for ROSE, which fixative is adequate for biomarker testing, how many blocks his health system uses for core biopsies, and how they select the material for testing. At the community level, it is a significant challenge to procure molecular orders. Finally, Dr. Mani discussed billing difficulties and how his health system attempted to overcome that issue.

Dr. Sinchita Roy-Chowdhuri, MD Anderson Cancer Center, presented on **Metrics for Success on Timing of Ordering, Quantity, and Turnaround Time**. She began by identifying the necessities for successful biomarker testing, which include the availability of adequate tissue, the timely ordering of tests, comprehensive biomarker testing, and the availability of quality metrics to monitor the process. The turnaround time between the tissue arriving at the lab and sending results should be ten days or less. However, in most cases, oncologists order biomarker tests when patients come back with histopathological results, which is a process that can delay the molecular diagnosis for two or more weeks. Reflex testing is the optimal choice for reducing turnaround time. Dr. Roy-Chowdhuri emphasized the importance of collecting sufficient tissue for both cancer diagnoses and biomarker testing. She recommended NGS versus single-gene analyses to maximize the information gained from tissue masses. She concluded that improving turnaround times can be achieved by working together in multidisciplinary teams.

Dr. H. Jack West, City of Hope Cancer Center, presented on the **Disparities in Molecular Testing and Delivery of Targeted Therapies In NSCLC**. He emphasized that the increase in molecular target and therapy advances has widened the gap between specialized care centers and broader community centers. He described one study in which only 22% of patients with lung cancer received biomarker testing in 2019 and another study that showed under-testing had not improved much over time. Moreover, about half of patients start a first-line treatment before testing results are back. Dr. West highlighted that 30% to 70% of NSCLC patients with identified targets do not receive appropriate treatment. This problem is due to long turnaround times and drug costs but also because sometimes the sequencing test reports are not seen or understood. Hence, he called for the simplification of NGS reports by separating the signal from the noise and for the development of tools that can help oncologists to interpret results and explain them to patients. Finally, he discussed the need for new models to broaden the distribution of new subspecialist inputs, such as Project ECHO, virtual molecular oncology tumor boards, and providing asynchronous expert case reviews.

Finally, **Dr. Aakash Desai**, Mayo Clinic Rochester, presented on the **Financial Burden of Precision Oncology**. He started by identifying two sets of financial burdens for biomarker testing and targeted therapy. He showed that even though Medicare NGS testing coverage had increased the number of early testing orders, the expansion of Medicare coverage is not equally distributed among insurance types, and the gaps in NGS testing have widened. Therefore, policies beyond coverage are needed to ensure equitable access to care. Dr. Desai explained that even though market competition has increased because of more drugs coming into the market, the costs of targeted therapies for NSCLC between 2015 and 2020 have risen above the inflation rate and consumer price indexes. Likewise, the out-of-pocket expenses for patients have also increased in the past decade. He concluded by emphasizing that the financial burden of precision oncology affects both patient mortality and quality of life.

Session 4 - Partnerships to Optimize Biomarker Testing

This session began with a presentation by **Dr. Liora Sahar**, American Cancer Society, on **Access to Biomarker Testing: A Geospatial Approach**. Dr. Sahar started by stating that her presentation was part of a larger project called the Multilevel Inventory of Resources for Lung Cancer Care Delivery, which has a goal of analyzing factors that impact lung cancer outcomes. She explained that the general strategy for estimating geographical access to biomarker testing is to overlay the areas of testing demand with areas where tests are provided. She discussed strategies to identify the providers, including specialists and institutional approaches. Finally, she highlighted some challenges of integrating data from diverse sources, including temporal and location-level differences at the county, hospital, and provider levels.

Ms. Claudia Miller, Medical University of South Carolina, presented her **Thoracic Nurse Navigator Experience in South Carolina.** She described the role of oncology nurse navigators, which includes overcoming social and system barriers to ensure equitable and timely care from diagnosis to

treatment and beyond, patient education, and the management of patient expectations and anxieties. Navigators can also help to bridge critical gaps in precision medicine, such as identifying patients who need testing and facilitating the processes of tissue collection and testing, reporting results, and educating patients about the importance of waiting for these results. Ms. Miller manages and coordinates care for about 25 incoming patient referrals and interacts with a multidisciplinary team. Her facility uses EPIC as the EMR system, and she is responsible for entering biomarker testing orders into the system and communicating with pathology staff for everything related to testing. Her key messages were the need to integrate ctDNA into practice, the importance of EMR systems, the translation of genomic data into diagnosis, prognosis, and therapy, and the need for ongoing profiling of patient tumors.

Ms. Andrea Ferris, LUNGevity Foundation, presented on **It Takes a Community - Collaborative Efforts to Advance Precision Medicine.** The LUNGevity Foundation defines precision medicine as biomarker-driven care throughout the cancer care process, from pre-diagnosis through potential progression. LUNGevity implements a collaborative approach to ensure that patients diagnosed with lung cancer have access to precision care. In collaboration with others, LUNGevity developed a biomarker testing awareness campaign to reach key audiences, and Ms. Ferris highlighted the need to simplify biomarker test reports to facilitate interpretation by both community oncologists and patients. LUNGevity also carries out policy work, including work around reimbursement and payment. She introduced the "No One Missed" biomarker campaign, which brought together private and public organizations with the goal of ensuring access to testing for every patient with a lung cancer diagnosis. The campaign began as a general national campaign, but now they are focusing on medically underserved populations that include Black and Hispanic-Latino communities. They are also expanding the campaign to other countries. Finally, she described the Cancer Precision Medicine Commons, a project that allows patient advocacy organizations to convene and share ongoing activities related to precision medicine.

Mr. Daniel Saez, GO2 For Lung Cancer, presented on **Barriers to Biomarker Testing Among GO2 Foundation's Centers of Excellence**. He highlighted the approach of the GO2 For Lung Cancer to address barriers to biomarker testing. His data showed that although the next generation sequencing (NGS) technique can capture all types of genetic variants, it is used less than 60% of the time in academic centers. About 80% of community cancer centers are still conducting single-gene testing. Next, he discussed a survey that identified insufficient tissue samples as the most common barrier for biomarker testing. The survey showed that patients understood the need for precision medicine and that most of them preferred to delay treatment while they sought testing first. In another survey performed by GO2 for Lung Cancer involving both Centers of Excellence (COE) and non-COE facilities, healthcare providers reported that the largest barriers were turnaround times, financial burdens and reimbursement, and insufficient tissue samples. Mr. Saez concluded by showing that opportunities to dismantle these barriers included reinforcing care pathways that encourage timely biomarker testing, adopting electronic prior authorization into workflows,

providing biomarker education, and advocating for legislative changes that support broader biomarker testing coverage.

Dr. Pablo Gutman, Holy Cross Health, presented on the **Operational Pathways for Molecular Testing in the Community Setting**. He began by highlighting that the NCCN Guidelines V5.2022 mentioned the need for biomarker testing. Hence, conducting biomarker testing has both health and legal implications. He discussed three main issues to address in the community settings: 1) determining how to increase awareness of the need for biomarker profiling, 2) how to ensure sufficient tissue is procured, and 3) how to ensure that the results of testing are readily accessible to healthcare providers in a timely fashion. Actions to address these issues include patient and professional education, balancing the amount of tissue used for diagnosis versus molecular profiling, assuring appropriate tissue procurement and preservation, following standard operating procedures for small specimens, ensuring rapid contact with oncologists to order biomarker testing, and being proactive about receiving test results. He concluded by noting that many of the barriers are found in both community and academic settings.

Dr. Michael Kelley, Duke University, presented on the **Department of Veterans Affairs Lung Precision Oncology Program (LPOP)**. This program aims to give VA clinicians a range of tools to proactively address and treat lung cancer in Veterans and covers the continuum of care (prioritizing early detection, offering biomarker testing, improving access to precision-oncology clinical trials, increasing the number of clinical trials available, and enabling rapid translation of discoveries into clinical care). He stated that the VA healthcare system is the largest integrated healthcare system in the USA and that they treat around 50,000 new diagnoses of cancer every year, about 3%-3.5% of total cases in the country. He described the program's *Clinical Pathways* for lung cancer care, which can be found at www.cancer.va.gov and inserted into the EMR system. The *National Precision Oncology Program (NPOP)* began in 2015 with the mission to bring tailored therapeutic options to Veterans, guided by individual molecular maps of their tumors. The NPOP also provides a smarter clinical trial design to stratify patient populations most likely to benefit from treatment. Dr. Kelley highlighted that molecular testing is purchased from vendors and is paid for centrally. He mentioned the available resources of NPOP and described the facility-level tool they developed to track lung cancer testing in their electronic records system. Finally, he described some additional interventions to optimize biomarker testing.

Session 5 – Panel Discussion on Industry Initiatives and Challenges

Dr. Melissa Lowder, AstraZeneca, opened the panel with a presentation on **Optimizing Lung Cancer Biomarker Testing in Practice**. She stated that AstraZeneca was committed to overcoming biomarker testing barriers, such as tissue insufficiency rates, slow turnaround times, and healthcare disparities. One of their projects is to create resources and facilitate expert-led forums to help address tissue proceduralists, especially in the community setting, with a key strategic goal of

creating standardized testing processes for patients with NSCLC. A key priority for AstraZeneca is evidence generation, which they achieve by partnering with institutions and programs, such as the MYLUNG Consortium, the GOAL consortium, the Lung Ambition Alliance, and LUNGevity Foundation, among others.

Ms. Kathryn Chandra, Genentech, presented on **Tackling Disparities in Access to Biomarker Testing.** She highlighted that Genentech focuses on partnerships and that they know local action has the most impact on patients. Genentech supports both the ACS CAN state legislative initiative and the NLCRT's Addressing Lung Cancer Biomarker Testing Through Project ECHO as ways to improve health outcomes, achieve health equity, and increase access to biomarker testing. The company prioritized local engagement by reorganizing its field teams to move both patient and provider education from the national to the local level. They also enhanced direct patient engagement through a new tool called My Care Roadmap. Finally, Genentech is working to generate new data on the role biomarker testing plays in clinical outcomes.

Dr. Byeong Yoon, Amgen, presented on the **AMGEN Initiatives to Support Comprehensive Biomarker Testing.** AMGEN is focused on education, operational barriers, and evidence generation. The biggest challenge in community settings where most patients with lung cancer are being treated is education. Thus, the company's education program is partnering with different groups that have a far reach into the community to ensure that communities are up to date on biomarker testing. To overcome operational barriers, AMGEN is working with the ACCC to establish operational pathways that can be templates for how community centers might be able to adopt biomarker testing. AMGEN has copay programs for commercially insured patients and provides access to free testing related to their therapies or for biomarkers that are directly tied to their therapies. Finally, Dr. Yoon described how AMGEN improves evidence generation by partnering with organizations such as US Oncology, Community Oncology Alliance, and others to determine the best practices that can meaningfully impact testing.

Dr. Lee James, Bristol Myers Squibb, presented on the **Bristol Myers Squibb (BMS)** efforts to reduce health disparities by accelerating disease awareness and education programs while improving access to care in medically underserved communities. BMS is working to increase clinical trial diversity in terms of the location of clinical trial enrollment, the people involved in the enrollment, the investigators, and internal representatives. The company is also tackling health disparities through partnerships. Finally, BMS makes direct health equity grants to support community healthcare workers and patient navigators.

Dr. Mia Levy, Foundation Medicine, presented on **Industry Initiatives and Challenges** and stated that Foundation Medicine has strong commitments to diversity, inclusion, and overcoming the disparities that have emerged in biomarker testing. She stated that there is a need to extend comprehensive biomarker profiling to patients with early-stage disease who could benefit from inclusion in clinical trials or the identification of alterations that drive their tumors in cases of quick

recurrence. Foundation Medicine is also working to overcome the financial barriers to testing that face both physicians and patients. They support clinical decisions with interpretive reports, comprehensive molecular tumor boards, and direct access to more detailed information for physicians. Finally, Foundation Medicine partners with biopharma and clinical organizations by giving them back their data to help them learn more about their populations. The company then works with the organizations to understand the aggregated data, which can have a great impact on cutting-edge clinical trials.

Ms. Rebecca Nagy, Guardant Health, presented on **Biomarker Testing in Lung Cancer: Barriers and Solutions**. She started by describing the Guardant Health financial assistance program to address the financial barriers of patients. To improve order and report efficiencies, the company is implementing a solution that consists of a bi-directional interface to EMR systems at the point of care. Finally, to overcome health disparity barriers, Guardant Health is working on partnerships to improve access to clinical trials for underserved populations and to educate those populations about the benefits of participating in the trials.

Session 6 - What We Learned Today and Plans for the Future

Dr. Ella Kazerooni thanked the Biomarker Summit planning committee, NLCRT staff, speakers, guests, and industry partners for their enthusiastic participation and emphasized that the goal of convening experts from many communities and organizations was to benefit patients affected by lung cancer and their families.

Dr. Gerard Silvestri presented an overview of key ideas and messages from the summit presentations. He emphasized the importance of always thinking from a patient perspective. He celebrated that the time between targeted therapy discoveries and patient treatment with new therapies has significantly decreased since 2000 and underlined the necessity of unifying guidelines and overcoming barriers, such as access, adequacy, turnaround time, coverage, diversity, and reflex testing. Finally, he highlighted the importance of having high-quality metrics for evaluation.

Next, the co-chairs of the NLCRT Biomarker Initiative shared their opinions about which actions to prioritize for the next year.

Dr. M. Patricia Rivera proposed simplifying the initiation of biomarker testing, standardizing testing reports, and promoting the content of established biomarker testing guidelines in ways that are harmonized, modernized, and accessible to everyone.

Dr. Bruce Johnson proposed establishing standards for diagnostic biopsies, developing tools to reduce testing turnaround time, and unifying Medicare testing coverage across the country.

Dr. Ignacio Wistuba proposed improving patient navigation resources at a local level beyond the boundaries of academic and community healthcare institutions. He proposed coordination of

partnerships between foundations, organization, and healthcare providers to create and disseminate professional and patient education. Dr. Wistuba also emphasized the success of the NLCRT Biomarker Testing ECHO as a model that should be promoted and scaled up across the country. Finally, he proposed working with Association of Molecular Pathology to simplify biomarker testing reporting and to finish the project in a year and a half.

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