



# **Advancing Standing Order-Based (“Reflex”), Comprehensive Biomarker Testing in Lung Cancer Care**

## **LUNGeivity Precision Medicine Summit Summary Report**

### ***Executive Summary***

LUNGeivity convened its fourth Precision Medicine Summit in Washington, DC, bringing together approximately 75 clinicians, pathologists, hospital and health system leaders, professional society representatives, payers, researchers, patient advocates, and industry stakeholders. The meeting focused on "standing order-based biomarker testing" — ensuring that NSCLC patients receive comprehensive biomarker testing before treatment decisions are made, regardless of the method or channel used. Participants moved through a structured agenda of presentations, panels, and large-group discussions, followed by breakout action groups charged with converting shared understanding into concrete plans.

#### **The Problem**

Modern lung cancer care encompasses more than ten actionable genomic alterations — EGFR, ALK, KRAS, MET, RET, and others — each with targeted therapies that directly influence survival. Biomarker testing as an integral part of completing a diagnosis is not a refinement of care; it is foundational to it. Yet the gap between what is clinically possible and what patients routinely receive remains wide and consequential.

Laurie Seligman, an eight-year NSCLC survivor, opened the meeting with her own story: diagnosed in 2018 without ever being told about biomarker testing; unable to access a thoracic oncologist in a major U.S. city; and forced to self-advocate against a physician who discouraged testing over cost. Comprehensive biomarker testing in 2020 identified a KRAS G12C mutation, opening the door to targeted therapies she credits with keeping her alive. Her message: biomarker testing gives patients a chance to live longer, and every patient deserves access to it.

Research across six institutions confirmed the problem is systemic: wide variation in who orders tests, how tissue is handled, and whether results actually reach the treating oncologist in time; widespread misapplication of the CMS 14-day rule (only 29% of providers apply it correctly, and 64% wrongly apply it to privately insured patients); coverage and reimbursement barriers that leave early and advanced-stage patients without access to comprehensive NGS; and payer denials stemming from regulatory ambiguity about who qualifies as an "ordering physician." The result: clinicians may begin treatment before biomarker results return or NGS panels may go unordered entirely.

### **What the Meeting Established**

Across all sessions, several points of convergence emerged that represent genuine progress toward coordinated action:

- Timely testing is a patient safety issue, not merely a quality metric. Patients have a six-to-eight week window from diagnosis before risking disease progression. That window must be actively managed.
- A diagnosis is not complete without molecular characterization. All major guideline-writing bodies reaffirmed that comprehensive NGS testing — paired with histologic assessment at diagnosis, not sequenced after the patient reaches the oncologist — should be strongly recommended, not merely suggested.
- The term "reflex testing" is increasingly counterproductive. The meeting moved editorially toward "standing order-based testing" as a cleaner, more implementation-friendly alternative that avoids regulatory and payer complications, although this should be further discussed as part of ongoing efforts to better define precision oncology terms.
- The CMS 14-day rule for molecular tests in cancer care must be eliminated. There was agreement that it is a major inhibitor of timely testing and that coordinated multi-society advocacy to CMS is both warranted and urgent.
- No single organization can solve this alone. Amplified, non-duplicative collaboration across societies, payers, health systems, and patient advocacy groups is the only path to systemic change.

### **Eight Strategic Recommendations**

The meeting closed with eight recommendations for collaborative action by organizational leadership:

- **Endorse standing order-based biomarker testing** as the system-wide standard, replacing models that depend on individual clinician initiation.
- **Formalize a cross-sector collaborative** to convene societies, payers, health systems, diagnostic companies, and patient groups under shared leadership.
- **Support cross-society harmonization of definitions** for comprehensive, sufficient, and actionable biomarker testing.
- **Advance health system adoption of SOPs** by integrating biomarker testing into EMR pathways, tumor board workflows, and pre-dispensing verification for targeted therapies.
- **Invest in discrete genomic data infrastructure**, moving results out of PDFs and into formats usable for decision support, quality measurement, and research.
- **Expand evidence generation** for early-stage biomarker testing through multi-center studies and real-world data efforts.
- **Lead unified multidisciplinary education** across clinicians, pathologists, nurses, pharmacists, and patients on the value and timing of comprehensive testing.

- **Champion elimination of the CMS 14-day rule for molecular tests for inpatients** through a coordinated multi-society advocacy effort directed at CMS.

### **Five Action Groups: From Conversation to Plans**

Five breakout groups developed concrete action plans, each with defined visions of success, stakeholder maps, and timelines:

- **Data and Evidence Gathering:** A phased roadmap through the first half of 2028, including stakeholder mapping (2026), interviews and assumption-based data gathering (2027), and gap analysis and packaging (2028) — aimed at gathering data so patients have comprehensive testing results by their first oncologist visit.
- **Defining Terms:** Build consensus definitions for “standing order-based,” “comprehensive,” and “sufficient,” testing through data support, quality measures, and multi-stakeholder engagement.
- **Society Partnerships and Guidelines:** Eight action steps for all participating societies to embed SOPs and guideline-concordant care into checklists, guidelines, education materials, studies, and advocacy goals — with specific assignments to named individuals.
- **Health System Engagement:** Implement biomarker testing workflows to get results to all NSCLC patients within 21 days of diagnosis, using ACCC Learning Collaboratives, recognition programs, and a consensus publication as implementation vehicles.
- **Payer and CMS Engagement:** Pursue state-level action (commissioner guidance, Medicaid engagement, new legislation) and federal action (direct CMS email requesting 14-day rule change; expanded provider education). Success defined as enhanced state law access and revision of the inpatient 14-day rule.

### **The Moment**

*This meeting represented a pivotal moment: the collective recognition that comprehensive biomarker testing is not just a clinical recommendation — it is a foundational requirement for modern cancer care. The consensus reached, combined with the practical solutions offered and the action groups formed, positions the field to turn these insights into measurable progress. The goal is unchanged and unambiguous: every patient receives the right test at the right time — and consequently, the right treatment.*

# Advancing Standing Order-Based “Reflex”, Comprehensive Biomarker Testing in Lung Cancer Care

## LUNGeity Precision Medicine Summit Summary Report<sup>1</sup>

### *Precision Medicine Summit Overview*

On February 23 and 24 LUNGeity convened the fourth Precision Medicine Summit in Washington, DC. Disrupted by a winter storm, the Summit included some 60 in-person participants, along with 10-15 participants who joined virtually. The participants included clinicians, hospitals and health systems, patient advocates, researchers, professional societies, academics, payers, opinion leaders, and industry. The focus of the meeting was on “reflex biomarker testing”—the process of ensuring that, by whatever method and through whatever channel, non-small-cell lung cancer (NSCLC) patients receive a comprehensive genomic test before treatment decisions are made and treatment begins. The objectives were:

- To build and expand a shared understanding across the leadership of major clinical organizations of reflex testing opportunities, challenges, and potential solutions.
- To share insights into how societies, payers, hospitals, and advocacy groups view their roles and expectations of one another.
- To build commitments from major societies to prioritize reflex testing in their guidelines.
- To create a roadmap for collaborative advocacy with CMS and payers, grounded in leadership-level perspectives.
- Following the meeting, to convene ongoing multi-stakeholder “action group(s)” to carry the work forward.

The meeting was divided in two major parts: a series of presentations, panels, and large group discussions to reach a common understanding of reflex testing and breakout sessions to establish “action groups”—teams that are motivated and willing to carry the work forward into action. The learning/discussion sessions included:

- 1) Reflex Testing—Why Does It Matter
- 2) One Patient’s Biomarker Testing Story
- 3) Realities of Reflex Testing at the Site Level
- 4) Policy and Reimbursement—Implications for Stakeholders
- 5) Guidelines Review: Current Positions on Reflex Testing

The interactive work included:

- 1) Landscape Mapping—Where Do We Align on Reflex Testing
- 2) Action Group Sessions
- 3) Roundtable Discussion—Action Planning and Next Steps

### ***I. Why Reflex Testing Matters***

Dr. Frank Weinberg, oncologist at the University of Illinois, opened with a presentation that gave a clear imperative for quality NSCLC care: get patients the right treatment at the right time, and

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<sup>1</sup> Report prepared by LUNGeity Foundation with input from artificial intelligence

treat each patient with the best available therapy. Modern lung cancer care now encompasses more than ten actionable genomic alterations — EGFR, ALK, KRAS, MET, RET, and others — each with corresponding targeted therapies that directly influence survival. The implication is powerful: biomarker testing is not a refinement of care, it is foundational to it.

Four themes ran through the entire discussion:

- Biomarker testing leads to increased survival — distinct diseases require targeted therapies.
- Reflex testing ensures patients receive results in a timely manner.
- Delays erode patient trust in the system and create coverage uncertainty.
- All patients must receive equitable care — "it's not extra, it's team-based; it's about getting a fair chance."

### **The Case for Timeliness**

Timely testing is not simply a quality improvement goal — it is a patient safety issue. Delays or missed testing lead to inferior treatment choices, unnecessary toxicity, and the loss of critical therapeutic windows. Dr. Weinberg shared real-world data from his institution, which implemented a reflex model triggered automatically upon new lung cancer diagnoses. The results were striking: testing was ordered rapidly, turnaround times were consistent with national benchmarks, and racial disparities in test completion were eliminated.

Participants noted that patients typically have a window of six to eight weeks from initial scans to initiate treatment before risking disease progression — time that must not be wasted. Non-small cell lung cancer does allow somewhat more runway than other cancers, but urgency remains. A recurring challenge: how do you explain the wait to patients who are emotionally overwhelmed by a new diagnosis? Dr. Weinberg emphasized that clear early communication, structured care plans, and transparent timelines help patients understand that a brief wait leads to more effective and personalized treatment. When that explanation is absent, patients experience delays as confusion and loss of trust.

### **The "Treater" and "Orderer" Problem**

A practical friction point surfaced: who is actually responsible for triggering biomarker testing? The distinction between the treater—the oncologist managing the patient's care—and the orderer—whoever places the test order—is often unclear and varies significantly between institutions. This ambiguity creates gaps where testing can fall through the cracks. The current payment model was described as antiquated and in need of reform, and a multi-stakeholder approach was called for to advocate for approaches explicitly include discussion of reflex testing benefits.

### **Defining "Reflex Testing" — A Contested Term**

One of the meeting's central challenges was the absence of a shared, standardized definition of "reflex testing." The word "reflex" carries different meanings across professional communities. The facilitator introduced a trial definition—"An automatic, standardized process in which predefined biomarker or genomic tests are ordered during diagnosis to inform treatment"—but this framing prompted significant and productive debate.

Several important concerns emerged:

- *Absence of "pathologist-initiated" language.* Some settings rely on this phrase, but naming a single profession risks creating barriers to multistakeholder collaboration.

- *Regulatory implications.* The term "reflex" has formal meanings under CLIA and CMS; misalignment could complicate policy advocacy.
- *"Complete" vs. "sufficient" testing.* Completeness is impossible to define universally given variation in DNA, RNA, and IHC testing needs and rapidly evolving biomarkers. Alternatives such as "necessary," "sufficient," or "actionable" were proposed.
- *Predefined panels.* Biomarker needs vary by institution, clinical trial, and physician practice, making a national predefined panel difficult to specify.
- *NCCN's position.* NCCN, whose guidelines inform treatment, coverage, and reimbursement for many providers and payers, does not use the term "reflex testing" and offers no guidance on how testing should be initiated.

Despite these tensions, consensus points emerged: timeliness is central to any working definition; standardized language across the field is essential; and any shared definition must support — not restrict — multistakeholder collaboration.

### **Tentative Working Terminology: “Standing Order-Based Testing”**

The session closed with the group acknowledging that it does not yet have a shared definition — and that establishing one is a critical first step before broader advocacy can be mounted. An action group was later formed to address terminology, but did not reach agreement during the meeting.

At the risk of stirring further controversy, but also in service of moving the conversation beyond simply continuing to use “reflex testing” as the default term, we adopt the term “standing order-based testing” for the remainder of the report. Note that although there was not a full consensus of the group, this was the most accepted term.

## ***II. One Patient's Story***

The meeting continued with a compelling patient narrative from Laurie Seligman, an eight-year lung cancer survivor and advocate for biomarker-guided care. Her story illustrates both the life-saving potential of biomarker testing and the systemic barriers patients face in accessing it — and it set the tone for everything that followed.

### **Diagnosis and Initial Challenges**

Diagnosed in 2018, Laurie's path was marked by gaps that should not exist. Her oncologist never mentioned biomarker testing, and her initial biopsy was limited to EGFR, ROS1, and PD-L1 — omitting the broader genomic analysis that might have led her to targeted therapies far earlier. It was not until 2019, at LUNGeivity's Hope Summit, that she learned about biomarker testing at all — a full year after diagnosis.

Despite living in one of the largest cities in the United States, Laurie could not access a thoracic oncologist within her insurance network. When new medical issues arose in August 2020 and she sought testing, her oncologist discouraged it over cost concerns. Laurie pushed back — reasoning that her retirement savings would be of no use if she did not survive. That determination proved pivotal.

### **The KRAS G12C Discovery and Its Impact**

Comprehensive testing in 2020 revealed the KRAS G12C mutation — a discovery that changed everything. Specialist access remained out of reach in Texas, so Laurie relocated to Florida to connect with a thoracic oncologist who is also an active researcher. Sotorasib (2021–2025) and

later adagrasib followed, and Laurie credits biomarker testing directly with her survival. Earlier testing might also have enabled clinical trial enrollment and possibly prevented severe complications, including recurrent lung collapse.

When tissue samples are insufficient, her team now initiates a liquid biopsy immediately upon any new progression. The 10-to-20-day turnaround is manageable when built into the treatment planning process from the start.

### **Key Themes**

- *Biomarker testing is foundational to precision oncology.* Without a molecular profile, patients risk months on treatments not matched to their disease.
- *Access to specialists matters enormously.* Geographic and systemic barriers are real — Laurie's inability to see a thoracic specialist in a major U.S. city is not an outlier.
- *Patient self-advocacy should not be required — but it is.* Patients should not have to fight this hard for standard-of-care testing.
- *The field must keep evolving.* Targeted drugs do not work indefinitely; continued development of new options for KRAS and other actionable mutations is essential.

Delays in testing translate directly to delays in optimal treatment, and gaps in system design carry profound consequences for real patients. Her message is unambiguous: biomarker testing gives patients a chance to live longer, and every patient deserves access to it.

### **III. Realities of Reflex Testing at the Site Level**

Julia Trosman, PhD, of the Center for Business Models in Health Care presented findings from a LUNGeivity-sponsored, 6-site qualitative study of approaches to standing order-based testing. Eric Konnick, pathologist, at the University of Washington Medical Center and Kevan Simms EVP of Precision Medicine, at Ochsner Health participated in a panel conversation to put in context the findings of the study.

The study elucidated how standing order-based biomarker testing is actually ordered, implemented, and made available to patients—and what stands in the way. The evidence base to date is largely based on research in large academic systems. The goal is to understand practice in a broader range of institutions, including what good practice looks like and what it takes to get there.

#### **Disparities and Delays in Test Ordering and Workflow**

Research across the six institutions revealed wide variation in testing workflows and persistent, compounding delays. Incomplete staging, reimbursement ambiguity, slow or inconsistent prior authorization, and uncertainty about who should place the order all contribute to delays. The 14-day rule, discussed in the next section of this report, presents a notable logistical challenge; some institutions have simply chosen to disregard it. Internal resistance compounds the problem: some pathology teams are hesitant to assume ordering responsibility, while some oncologists are reluctant to delegate it. The result is fragile, inconsistent processes that vary not just across institutions but across service lines within the same institution.

Four major reflex testing models were identified, including two *two-step processes* — where pathology or pulmonology initiates, but a centralized team places, the final order and two *one-step systems* where a pathologist or oncologist places the order directly in a centralized function

either before or after final histology is done. One size does not fit all—no single model suits all institutions; sites must adapt to local constraints, workforce capacity, and laboratory infrastructure. The key to success is to have a deliberate design rather than engage in ad hoc practice.

### **The Necessity of Structured, Cross-Disciplinary Collaboration**

Institutions with the most successful biomarker workflows shared several qualities: explicit role assignment, systematic communication channels, and high-functioning cross-disciplinary teams. Timely testing cannot rely on linear, sequential workflows — steps such as test ordering, authorization, and tissue processing must occur in parallel. Systematic communication channels dramatically reduce delays and ensure results reach the correct clinicians without repeated manual intervention.

Clinical and/or administrative champions emerged as indispensable. Whether a pathologist, oncologist, pulmonologist, or administrator, successful sites depended on individuals who continually advocate for the process, ensure adherence, and troubleshoot friction. Institutions without champions frequently stall or regress.

### **Laboratory Variation and Result Delivery**

Another recurrent theme was the fragmented nature of biomarker result reporting. Many oncologists maintain individual preferences for different commercial laboratories—of which there are nine to ten major players—creating logistical challenges in result routing. Some institutions have adopted unified laboratory arrangements, but these agreements remain difficult to sustain when competing physician preferences or referral patterns intervene. External reports arriving via fax or PDF, particularly from patients traveling from long distances, add additional complexity and often require supplementary testing, delaying treatment decisions further.

One of the most concerning findings from the multi-institution research was that even when biomarker results return promptly, they do not always reach the treating oncologist in a timely or systematic manner, sometimes requiring multiple appointments or additional follow-up for the patient. This operational gap remains under-recognized and represents a significant patient-care vulnerability.

### **"Sufficient" vs. "Complete" Diagnostic Testing**

As testing technologies expand and targeted therapies proliferate, the meeting participants expressed strong caution against defining testing requirements based on “minimum sufficiency” criteria. Many argued that such an approach risks entrenching outdated testing panels, particularly in a field where new actionable mutations and targeted therapies emerge rapidly.

Participants advocated instead for comprehensive next-generation sequencing (NGS) as a standard, emphasizing that failing to identify actionable mutations early can misdirect therapy, limit eligibility for trials, and compromise survival. Several stakeholders asserted that for many cancers, particularly lung cancer, a diagnosis is not complete without molecular characterization, reinforcing the need to pair histologic and genomic assessment at diagnosis.

## ***IV. Policy and Reimbursement: Implications for Stakeholders***

Nikki Martin presented the results of a survey conducted with 285 healthcare providers about the policy and reimbursement barriers to standing order-based biomarker testing. She was joined by four panelists to further discuss the barriers:

- Michael Ryan, Partner, JD, McDermott Will & Schulte
- Gabriel Bien-Willner, MD PhD, Palmetto GBA
- Barb Liwosz, Blue Cross Blue Shield Association
- Bruce Quinn, MD PhD, Bruce Quinn Associates

The survey identified three primary barriers that framed the discussion:

- Coverage and reimbursement for broad multi-gene panels across both early- and late-stage NSCLC
- CMS 14-day rule
- Payer denials stemming from tests ordered by pathologists.

The panel's consistent message: solutions are attainable, but only through deliberate, evidence-based, multi-stakeholder advocacy.

### **Reimbursement and Coverage Constraints**

CMS's National Coverage Determination (NCD) 90.2 restricts broad NGS testing to advanced-stage cancer, leaving early-stage patients ineligible even when the clinical case is strong. Private insurers frequently mirror CMS policy. An important distinction the panel emphasized: reimbursement and coverage are not the same concept, and conflating them obscures where the actual barriers lie. Some payers technically "cover" testing while making reimbursement so administratively burdensome that providers effectively abandon attempts to bill certain panels.

A further misalignment: some payers require "stepwise" testing — mandating single-gene assays before broader NGS panels are reimbursed. This is inconsistent with clinical guidelines and can be a major contributor to delayed or incomplete diagnoses. A striking survey finding: over half of respondents reported experiencing no reimbursement barriers, a result that may be viewed as an actual absence of barriers or as reflecting inadequate awareness of actual barriers.

Proposed solutions:

- Mobilize stakeholders to communicate directly with CMS to update NCD 90.2.
- Engage senior HHS leadership to elevate visibility and urgency.
- Approach policymakers with data-driven arguments demonstrating fault in existing policy.
- Frame advocacy clearly: NCCN guidelines create clinical standards but do not carry the force of law and do not automatically bind payers.

### **Ambiguity in Ordering Authority**

Regulatory language defining who qualifies as an "ordering physician" remains a significant source of confusion and inconsistent adjudication. Under federal regulation, pathologists are often *not* recognized as ordering physicians unless they meet specific case-level exemption criteria. In practice, this leads to denials when pathologists order molecular tests—even when the tests are integral to confirming or completing a diagnosis. Twenty percent of respondents reported payer denials on this basis, highlighting the need for national clarification .

Participants acknowledged that resolving this issue would require regulatory—not simply payer—action. This is further complicated by the distinction between diagnostic versus treatment-driven testing, a line that is clinically outdated but still embedded in regulatory frameworks.

Proposed solutions:

- Develop and disseminate educational resources on available exemptions.
- Document scenarios where exemption criteria have been met to build the case for reform.
- Pursue regulatory change as the only durable long-term solution.

### **Misapplication of the CMS 14-Day Rule**

One of the most pervasive administrative barriers discussed was the misapplication of the Medicare 14-day rule. Although CMS carved out an exception in 2018 for outpatient molecular testing, data show that many institutions continue applying the rule broadly—some to all inpatient and outpatient cases, and many even to commercial insurers where the rule has no relevance. Only 29% of respondents apply the rule correctly, while 22% apply it incorrectly to all settings, 27% do not apply it at all, and 20% are unsure. Most striking, 64% report applying the rule to privately insured patients, causing entirely unnecessary delays in testing and treatment .

The consequences are significant. Due to delays stemming from misapplication of the rule, over half of clinicians begin treatment before biomarker results return, and more than a third report that NGS panels go unordered entirely, or are replaced with single-gene testing—undermining the very precision medicine approaches that have become the standard of care in oncology.

Proposed solutions:

- Pursue formal regulatory change to exempt oncology biomarker testing from the rule altogether.
- Implement targeted provider education on exemption criteria and the date-of-service standard.
- File systematic appeals to challenge denials and build an evidence base for reform.

### **Forward Actions**

The panel's consistent view: solutions are attainable. The path forward requires effective advocacy, evidence-based policy engagement, and targeted education — pursued simultaneously and in coordination across stakeholders.

## ***V. Guidelines Review: Strategic Insights***

This session brought together experts from leading lab, oncology, and pathology societies, as well as NCCN, to address challenges in biomarker testing guidelines, clinical language, and implementation strategy. The panel comprised:

- Annette Kim, MD PhD, University of Michigan and College of American Pathologists
- Robyn Temple-Smolkin, PhD, Association for Molecular Pathology
- Ali Brown, MD, American Society for Clinical Pathology
- Jennifer King, PhD, International Association for the Study of Lung Cancer
- Janette Merrill, DHA, American Society for Clinical Oncology
- Jessica Bauman, MD, Fox Chase Cancer Center and National Comprehensive Cancer Network

A key framing observation: guidelines are written for a wide variety of target audiences, making it genuinely difficult to write them in ways that work equally well for all. That gap — between guideline intent and bedside practice — ran through the entire discussion.

## **Terminology and Guideline Clarity**

As mentioned above, one of the sharpest points of consensus was that the term "reflex testing" is increasingly counterproductive. It carries regulatory and payer implications, is actively avoided by some institutions, and is frequently misinterpreted. The field is moving toward neutral, implementation-friendly alternatives — "sequential testing strategy," "standing order," and "protocol-based testing" all surfaced, with "standing order" emerging as the panel's preferred (if not consensus) language.

The shift is not merely semantic: cleaner language is expected to facilitate payer alignment, reduce audit exposure, and support more uniform institutional adoption.

## **Strong Support for Comprehensive Biomarker Testing**

All major guideline-writing bodies reaffirmed the necessity of comprehensive biomarker testing in NSCLC, typically anchored in broad NGS panels and key IHC markers such as PD-L1 and MET. The forthcoming 2026 updates will further strengthen this language and transition to living guidelines, with revisions as frequently as every six to eight months. The panel called for guidelines to "strongly recommend" biomarker testing rather than use weaker phrasing — word choice matters when clinicians and payers are making treatment and coverage decisions.

The panel also recommended reframing biomarker testing as *completing* the diagnosis — not as an optional add-on. A practical constraint: sequential or exhaustive testing risks consuming limited tissue samples, making upfront, parallel, comprehensive testing a clinical necessity in many cases.

## **Evidence-Driven Implementation**

Guidelines can only move as quickly as the supporting evidence allows. Any expansion — especially into early-stage disease — requires a stronger published evidence base, not just clinical intuition. A parallel proposal — a Standing Order-Based Testing Toolkit or Playbook — would compile solutions already available in the field, updated every six to eight months. The panel also recommended monitoring the WHO biomarkers working group, currently forming.

## **Recommended Actions**

- Discontinue use of the term "reflex testing" in clinical and guideline communications; adopt "standing order-based testing."
- Reframe biomarker testing as completing the diagnosis, not an optional enhancement.
- Strengthen guideline language to "strongly recommend" comprehensive biomarker testing; transition to living guidelines updated every six to eight months.
- Develop a standard operating procedure for biomarker testing in NSCLC.
- Develop a Standing Order-Based Testing Toolkit or Playbook.
- Monitor the WHO biomarkers working group.
- Ensure education reaches oncologists on the clinical benefits of biomarkers — uptake will not follow guidelines clinicians do not understand or trust.

## ***VI. Framing for Action Groups—the Opportunity Landscape***

The landscape discussion reframed persistent barriers instead as opportunity areas where multi-institutional collaboration can drive meaningful progress. Organized as a visual affinity map, the session identified five major thematic pillars for advancing comprehensive biomarker

testing across the lung cancer care continuum. The map reflects strong alignment across data advocacy, terminology standardization, professional society engagement, health system integration, and payer reform.

### **1. Data and Evidence Gathering for Guidelines Advocacy**

Building a rigorous evidence base remains the foundation for any durable advance in guideline policy. Priorities include ensuring guidelines are grounded in clinical utility data — particularly for early-stage testing — developing systems to verify that tests capture relevant biomarkers, and building confidence in liquid biopsy as it moves toward mainstream use. Patient education is also part of this pillar: patients need to understand both the value of biomarker testing and why waiting for results before beginning treatment is a prerequisite for optimal care, not a delay.

### **2. Defining Terms**

Shared definitions and standardized language are prerequisites for effective advocacy — a theme that echoed across every session. The group called for a dynamic definition of comprehensive biomarker testing that avoids conflating terminology with specific methodologies, and for clinically grounded definitions of comprehensive biomarker testing that reflect real-world practice. Related: what patient gains represent a meaningful success threshold? What are the right KPIs — measurable and actionable? Alignment on these questions is a precondition for measuring whether the field is making progress.

### **3. Society Partnerships and Guidelines**

Professional medical societies are essential partners, and several goals emerged for deepening engagement: aligning societies on SOPs and definitions; encouraging guideline alignment across all stages of lung cancer; and pursuing a joint statement to the relevant stakeholders and policy makers on SOPs for testing. Societies also need to educate their members as well as policy makers that improvements in biomarker testing lead directly to improved patient outcomes — that link must be made explicit and compelling.

### **4. Health System and Hospital-Level Engagement**

Workflow fragmentation in lung cancer remains a significant problem. While breast cancer operates on a stable, SOP-driven biomarker testing model, lung cancer practice varies widely across institutions — in who initiates testing, how tissue is handled, lab capabilities, turnaround times, and clinical pathway integration. Priorities for the key institutions:

- Improve molecular diagnostic governance across pathologists, interventional radiologists and pulmonologists, and clinical teams.
- Establish tumor board structures for initiating biomarker testing.
- Develop multi-disciplinary training modules on biomarker testing.
- Examine workflows from other tumor types to identify applicable best practices.
- Eliminate inter-provider variability and set standards health systems are required to meet.
- Educate nurses to feel confident advocating for biomarker testing.
- Create widely available, discrete (not PDF-based) genomic data accessible to everyone in the care process.

### **5. Payer and Coverage/Access Management Engagement**

Participants unanimously identified the CMS 14-day rule as a major inhibitor that must be removed. Priorities for this pillar:

- Educate payers and address their fears related to payment risk.
- Pursue joint statements with payers and societies to dispel myths about coverage.

- Advocate that health plans pay for each comprehensive biomarker test.
- Push for compliance enforcement of state biomarker laws.
- Align across stakeholders to eliminate the 14-day rule through formal regulatory and legislative engagement.

Participants worked in breakout “action groups” to advance each of these opportunities. Each group was charged with identifying and defining success metrics and developing action plans, including identifying stakeholders, putting actions on a timeline, and naming specific next steps. The notes and conclusions from each action group are in Appendix 1.

## ***VII. Eight Strategic Recommendations for Collaborative Leadership***

Given how closely related the charges to several groups were, there was a substantial degree of overlap among the actions. We have synthesized the conclusion

Early directional examples from the groups included: requiring biomarker test verification before a pharmacy dispenses targeted drugs; advocating for standardized SOPs across health systems; and developing consensus definitions for "comprehensive" and "sufficient" biomarker testing grounded in actionable mutations and available therapies.

- 1) Endorse a system-wide move to "standing order-based biomarker testing."** Through both individual organizational initiatives and collective action and advocacy, adopt and publicly support standardized, standing order-driven testing models that do not rely on individual clinician initiation.
- 2) Strengthen the national leadership position.** Formalize a cross-sector collaborative that convenes the right partners—societies, payers, health systems, diagnostic companies, and patient groups—and accelerate national alignment.
- 3) Support development of cross-society guidelines and shared definitions.** Play a catalytic role in harmonizing definitions of comprehensive biomarker testing, sufficient testing, and actionable testing, and other frameworks.
- 4) Advance health system adoption of standard operating procedures.** Integrate biomarker testing into EMR-driven pathways, require testing verification before targeted therapy dispensing, and embed biomarker processes into tumor board workflows.
- 5) Invest in data infrastructure for discrete genomic reporting.** Move genomic outputs from PDFs to discrete data elements—essential for decision support, quality measurement, guideline implementation, and research acceleration.
- 6) Expand the role in evidence generation.** Increase individual and collective research investment in early-stage utility studies, facilitate multi-center data collection, and support real-world evidence efforts to demonstrate the value of timely biomarker testing, including for early NSCLC.
- 7) Lead in multidisciplinary education and messaging.** Develop a unified education and communication strategy across societies and advocacy groups delivering consistent messaging to clinicians, pathologists, nurses, pharmacists, and patients about the value of standing order-based biomarker testing.
- 8) Champion national efforts to eliminate the CMS 14-day rule.** Use the organizations’ advocacy platforms—LUNGeivity, CAP, AMCP, ASCO, AMP, IASLC, NCCN, along with ACS CAN, ACS-NLCRT and others — to press CMS for reform.

**Conclusion**

This meeting represented a pivotal moment: the collective recognition that comprehensive biomarker testing is not just a clinical recommendation—it is a foundational requirement for modern cancer care. The consensus reached, combined with the practical solutions offered and the action groups formed, positions the field to turn these insights into measurable progress. The goal is unchanged and unambiguous: every patient receives the right test at the right time—and consequently, the right treatment.

## **Appendix 1: Action Group Plans: Summary**

Five action groups convened at the close of the meeting, each working from a common framework: name the initiative, define what success looks like, and map concrete action steps. What follows summarizes each group's output, with detail proportional to what was captured on the planning sheets.

### **Action Group 1: Data and Evidence Gathering for Guidelines Advocacy**

*Note: The initiative was explicitly broadened beyond guidelines. Reflex testing was defined here as a way to get test results before the patient meets with the oncologist.*

#### **Vision of Success**

Gather the data (per relevant stakeholders) that supports earlier testing, so patients have comprehensive — DNA, RNA, and protein ("actionable") — testing results by their first visit with the oncologist.

#### **Action Steps**

This was the most detailed of the five action plans, with a sequenced, multi-phase roadmap and named leads for each step.

- **Step 1 — Stakeholder ID: Mapping and Assumptions** (*Lead: Jennifer Quigley; When: H1 2026*) — Map the "why and what" of the data needed, identify the motivator for success, and define preliminary stakeholders and preliminary data categories.

Preliminary stakeholders identified:

- Clinical care team / MDT
- Lab / pathology
- C-Suite
- Payers
- Policy makers
- Pharma / biotech
- Patients and families

Preliminary data categories:

- Economic outcomes
- Time to treatment
- Outcomes
- Test concordance with treatment
- Turnaround time (TAT) from biopsy to test result

- **Step 2a — Stakeholder Interviews** (*Leads: Jen, Dana, and Frank; When: H1 2027, time TBD*) — Conduct interviews with stakeholders identified in Step 1. Budget preferred but not required. A pressure check involving all participants is planned for H1 2027.
- **Step 2b — Assumption-Based Data Gathering** (*Lead: John Fox; When: H2 2027*) — In parallel or if interviews are not feasible, gather data based on mapped assumptions from Step 1.

- **Step 3 — Gap Analysis, Packaging, and Stakeholder Engagement** (*Lead: Kellie Well; When: H1 2028*) — Analyze gaps identified through the data gathering process, package findings, and engage stakeholders with results.

## **Action Group 2: Defining Terms**

### **Vision of Success**

Proposed definition for reflex testing: Standardize guideline-supported biomarker testing to inform initial treatment decisions for newly diagnosed NSCLC patients, and develop operationalized procedures at the time of tissue procurement or diagnosis.

### **Action Steps**

- **Data support** — compile and leverage existing, emerging, and projected data to underpin agreed-upon definitions.
- **Implement quality measures** — establish metrics that can assess whether definitions are being applied consistently in practice.
- **Work with all stakeholders (consensus building)** — engage payers, societies, clinical guideline developers, quality metric developers, the laboratory industry, and health systems in reaching shared definitions.

## **Action Group 3: Society Partnerships and Guidelines**

*Note: Many staff will need to bring proposals back to leadership for buy-in before implementation. Two key terms used throughout: SOP = standardized ordering protocols; GCC = guideline-concordant care.*

### **Vision of Success**

One overarching message, with two supporting actions:

- Locally optimized NSCLC biomarker ordering workflows — including standard ordering protocols — should be developed by the multidisciplinary care team.
- Societies will continue to generate data on guideline implementation that incorporates evaluation of standard ordering protocols and guideline-concordant care.
- Societies will collaborate wherever possible to amplify the message and impact of their work without duplicating efforts surrounding NSCLC biomarker testing.

### **Eight Action Steps for All Societies Going Forward**

- Incorporate biomarker testing into checklists, guidelines, synoptic reports, education materials, and performance improvement tools for pathologists. (All societies)
- Incorporate biomarker testing into guidelines, education materials, and related resources for providers. (All societies)
- Incorporate biomarker testing into patient-facing education and communication materials. (All societies)
- Perform studies as broadly as possible across diverse practice settings to incorporate and address barriers to care. (All societies)

- Advocate within organizations to collaborate with sister societies — across committees, leadership, and other bodies — and align messaging around SOPs and GCC. (All societies)
- Create a "who to call" list for inter-society collaboration contacts. (*Assigned: Robyn*)
- Engage funders (foundations and industry) to align funding and activities with members and stakeholders around joint objectives related to SOPs and GCC, with specific focus on biomarker ordering at the point of care. (*Assigned: Julie and Bridgette*)
- Incorporate GCC and SOP — along with identifying and addressing barriers to achieving them — into society advocacy goals collaboratively wherever possible. (*Assigned: Aster and Bridgette; all societies*)

### **Society Roles: Who Is Doing What (Document 3b)**

The reverse side of the societies planning sheet mapped current activities and roles by organization. A circled note captures the group's shared identity: "Everyone is a strong educator in the space."

- **CAP — Guideline Developer:** Biomarker 1 Source, synoptic reports, guidelines, checklists, educational work, genomic report recommendations (underway).
- **ASCP — Guideline Implementation:** Implementation of guidelines, personnel training, Biomarker Testing Navigator Program (AZ-funded), biomarker ordering data collection grants (Pfizer-funded), educational work.
- **ACCC — Guideline Implementation:** Uber convener, cross-practice/multidisciplinary collaboration, educational work, Precision Medicine lexicon, pilot collaborative on pan-tumor reflex testing (multi-society), emphasis on community providers, oncology nurse navigators, connections to 25 individual societies and ASCO state societies, geographic targeting capability, education for PharmDs.
- **ASCO — Guideline Developer:** Guidelines, quality measures, learning collaborative QI projects (not specific to reflex QI), insight into state societies.
- **IASLC — Guideline Implementation:** Collaborative guidelines, global projects only; biomarker testing focus means reflex is "along for the ride"; pilot data generation; collaborates on US initiatives under US lead; education.
- **AMP — Guideline Developer:** International and US-implementable guidelines and education, US advocacy, patient-facing resources/website, reflex testing implementation success stories webinar series (sponsored), patient-friendly molecular biomarker reporting template (coming), provider-friendly molecular biomarker reporting template (published), long biomarker webinars and implementation work.

#### **Organizations not currently represented:**

Association of Community Cancer Center Directors, HOPA, APSHo (apps in onc), Commission on Cancer, CEO Roundtable, COA, surgical oncologists, CHEST, pulmonologists, pulmonary pathologists, ONS, AONN.

## ***Action Group 4: Health System and Hospital Level Engagement***

### **Vision of Success**

All lung (NSCLC) cancer patients receive a biomarker-informed treatment decision.

## Action Steps

The group's primary action step is to implement a biomarker testing workflow for all NSCLC patients within 21 days of diagnosis. Three sub-steps structure how to get there:

- **a. Identify key decision makers within the system (WHO?)** — understanding who holds authority and influence over testing workflows at the institutional level.
- **b. Align the testing protocol to key decision maker goals and pain points (WHY?)** — framing biomarker testing in terms of what matters to those decision makers, not just clinical best practice.
- **c. Build consensus across institutional leaders to coordinate and enable execution of workflow change (WHAT?)** — including agreement on KPIs and tactics.

## Tactics

- **ACCC 'Collaboratives'** — leverage ACCC's existing collaborative infrastructure as an implementation vehicle.
- **Add measures to nationally recognized Recognition Programs (led by Lynelle / ASCP)** — embed biomarker testing standards into existing accreditation and recognition frameworks.
- **Develop funding sources for Center of Excellence (COE) consultations (ACCC)**, including:
  - Stakeholder mapping for white paper dissemination (*assigned to Emily*)
  - Create consensus document to support publication (*assigned to Nikki*)

## Action Group 5: Payer and CMS

### Vision of Success

- **Enhanced state law access**
- **Revise inpatient 14-day rule (described as a "one word" change)** — suggesting the fix is administratively simple if the political will is there.

### Action Steps

The group organized its steps across two tracks — state-level and federal/CMS.

#### State track:

- Commissioners should issue guidance — guidance has been issued in 4 states so far; expand this effort.
- Engage Medicaid in Medicaid states — bring state Medicaid programs into alignment on biomarker testing coverage.
- Pass more state laws — build on existing state biomarker laws to expand coverage mandates.

#### Federal/CMS track:

- Request CMS change the 14-day rule — by email (a concrete, immediate first step).
- Increase education for hospitals and providers on the 14-day rule — address widespread misapplication through targeted outreach.

## ***Observation Across All Five Groups***

The five action groups reflect both the breadth of the challenge and the seriousness with which participants engaged with it. The Data Gathering group produced the most detailed roadmap, with named leads, sequenced phases, and timelines extending to 2028. The Payer and CMS group was notably concrete about near-term steps, including a direct email to CMS requesting change to the 14-day rule. The Health System group grounded its work in a practical who/why/what framework. And the Societies and Defining Terms groups built the cross-organizational scaffolding that all the others depend on. Taken together, the plans represent a credible, multi-front effort to move from shared diagnosis to shared action.