

Evolving Biomarkers: *Strategies for Keeping Up with Precision Medicine*

A cancer program's ability to pivot and adapt is increasingly important in the ever-changing precision medicine landscape each year. As new and emerging biomarkers are introduced, oncology programs must launch new protocols and additional processes, and increase staff. In rural and underserved areas, the challenges are even more pronounced. Here, implementation of new molecular therapies and immune-directed biomarkers presents complex hurdles, including financial and operational limitations. A lack of access to experts and multidisciplinary teams for collaboration and oversight is an additional problem, as are lengthy turnaround times for biomarker test results.

In 2020, the Association of Community Cancer Centers (ACCC) conducted a survey to gauge the readiness of cancer programs to establish and provide biomarker testing. Findings revealed that respondents from more than 50% of programs believed that their processes and procedures for established and emerging biomarkers needed improvement. Study results have also shown that more than 70% of patients treated at community cancer programs do not receive guideline-concordant biomarker testing. Also, study results have shown striking disparities in the utilization of molecularly targeted treatments among patients from racial and ethnic minorities. For example, compared with White patients, African American patients with non-small cell lung cancer were less likely to be tested to determine whether their cancer was caused by an EGFR mutation, and they were less likely to be treated with EGFR-targeted therapies.¹

Further, research and development for new biomarker-driven therapies and immune checkpoint inhibitors for patients with advanced or metastatic non-small cell lung cancer are progressing rapidly. This underscores the critical need for increased comprehensive biomarker testing for mutations

in certain genes (eg, KRAS, EGFR, ALK, ROS1, BRAF, RET, MET, NTRK) at community cancer programs, which can mean the opportunity for advanced treatments via new targeted therapy drugs.²

In December 2022, the US FDA granted accelerated approval for new therapies for adult patients with KRAS G12C–mutated non-small cell lung cancer.³ Because KRAS mutations are found in about 20% to 30% of non-small cell lung cancer cases⁴ and 13% of patients with nonsquamous non-small cell lung cancer have an actionable KRAS G12C mutation,^{5,6} the capacity of a cancer program to test for the KRAS G12C mutation is important and relevant.

This rapidly evolving landscape has created a formidable gap for community cancer programs, particularly those located in rural and underserved areas, that seek to incorporate newly actionable biomarkers into clinical practice. To address these disparities, ACCC, with its partners the Association for Molecular Pathology and LUNGeVity, and with support by Amgen, launched an education program called “**Evolving Biomarkers in Non-Small Cell Lung Cancer.**” It examines these challenges and develops strategies to improve the capability of community cancer programs to quickly incorporate and adapt to new testing innovations. The program builds upon the important work ACCC and its partners conducted in 2022 to develop the “**Biomarker Testing Implementation Roadmap for Advanced NSCLC,**” an innovative learning tool designed to help multidisciplinary cancer care teams implement, expand, and sustain biomarker testing.

In this article, ACCC shares a closer look at how 6 community cancer programs worked to assess and

improve their biomarker testing programs, which can serve as a guide for any other cancer program seeking to improve its ability to provide comprehensive biomarker testing for less-common driver mutations and to act swiftly as new treatments become available.

Virtual Workshops: Expert Insights

To understand the complexities that community cancer programs face when establishing or expanding comprehensive biomarker testing services, ACCC designed a series of virtual workshops led by experts to gauge current processes and workflows, current level of multidisciplinary collaboration among practices, and individual and organizational readiness to implement testing.

Collaborating with 6 cancer programs across the country from January to March 2022 and October to December 2022, the workshops brought together multidisciplinary providers and expert faculty to discuss common challenges and to pinpoint strategies to improve testing processes for evolving biomarkers.

Participating cancer programs were CaroMont Hematology and Oncology in Gastonia, North Carolina; Englewood Health in Englewood, New Jersey; Fairfield Medical Center's Cancer Care and Infusion Center in Lancaster, Ohio; Glens Falls Hospital's C.R. Wood Cancer Center in Glens Falls, New York; Ochsner Medical Center's St. Tammany Cancer Center in Covington, Louisiana; and Thompson Cancer Survival Center, part of the Covenant Health System, in Knoxville, Tennessee.

Workshops were led by expert faculty: Adam Fox, MD, pulmonologist, Medical University of South Carolina, Charleston; Pablo Gutman, MD, MBA, chairman of the pathology department and medical director, Holy Cross Hospital Cancer Institute, Silver Spring, Maryland; Dana Herndon, RN, MSN, ONN-CG, CPHQ, thoracic oncology nurse navigator, Cone Health Cancer Center, Greensboro, North Carolina; Alexander Spira, MD, PhD, FACP, Virginia Cancer Specialists Research Institute, Fairfax; and Yifan Tu, MD, Mercy Hospital South, David Sindelar Cancer Center, St. Louis, Missouri.

Organizational Pre-Assessment

Prior to the workshops, participants were provided with an opportunity to complete an organizational pre-assessment to measure their cancer program's readiness and capacity to conduct testing, and to evaluate current organizational practices related to testing. Participants included administrators, oncologists, advanced practice providers, nurse navigators, nurses, pathologists, and other multidisciplinary staff.

Notwithstanding the diversity of participating programs, outcomes from the pre-assessment showed that all 6 sites shared common strengths, including:

- Commitment to comprehensive biomarker testing
- Organizational culture oriented toward precision medicine
- Established relationships with external laboratories to execute biomarker testing
- Regular use of practice guidelines (eg, those of the National Comprehensive Cancer Network and College of American Pathologists)
- Utilization of biomarker test results as part of shared decision-making with patients

While all programs faced challenges related to the lack of a standing, multidisciplinary team to regularly review advanced non-small cell lung cancer biomarker testing procedures, as well as to the lack of biomarker testing integration with electronic health record systems, programs were in varied states of readiness regarding the following areas:

- Availability/use of established reflex protocols
- Appropriate technical expertise to implement comprehensive biomarker testing
- Appropriate financial resources to conduct biomarker testing on site
- Availability of patient navigators to educate and support patients and caregivers regarding biomarker testing and to mitigate distress while waiting for results
- Availability of staff to navigate reimbursement for biomarker testing

Workshops: Lessons Learned

During the workshops, participants had the opportunity to discuss current challenges and gain expert insights on how to overcome clinical and operational hurdles. Groups also focused on identifying opportunities for improvement and determining whether those opportunities could be addressed within the next 3 months (ie, high and low feasibility) as well as anticipated level of impact (ie, high and low) for patients with advanced non-small cell lung cancer.

Common themes discussed across workshops included:

- Clinical guidelines
- Protocols and challenges related to obtaining adequate tissue for testing
- Patient navigation
- Creation of biomarker testing workflows
- Utilization of ACCC's "Biomarker Testing Implementation Roadmap for Advanced NSCLC"

High-feasibility/high-impact opportunities for improvement identified during workshops included:

- Reviewing current workflows related to tissue collection to ensure that adequate tissue is obtained
- Reviewing turnaround times from tissue collection to send-out for testing
- Determining roles and responsibilities for test ordering and results tracking
- Reviewing processes related to reimbursement and prior authorization requirements
- Leveraging navigators to improve communication and alleviate patient distress around biomarker testing process
- Incorporating liquid biopsy to help inform decision-making while waiting for tissue results

From Opportunities to Action

After the virtual workshops, each program set out to develop an action plan for a process improvement that could be implemented over a 3-month period. Programs were asked to identify goals, activities, measures of success, deadlines, and the resources and responsible parties needed to support each activity. Following a 3-month period, ACCC revisited these programs through guided interviews to gauge progress and successes.

The action plan goals identified by individual programs included:

- Develop a process for blood draw for liquid molecular testing for patients with suspected locally advanced or metastatic lung cancer
- Develop and implement the "Future State Workflow Process" for obtaining biomarker testing for patients with non-small cell lung cancer
- Implement new lung biopsy processing protocol (ie, split tissue between 2 cassettes for immunohistochemistry/diagnosis and molecular studies)
- Review non-small cell lung cancer biomarker testing processes and procedures, and convene a multidisciplinary group to begin developing a new comprehensive biomarker testing workflow
- Develop new process for tissue collection and slide preparation to improve completion rates for comprehensive biomarker testing
- Review current non-small cell lung cancer biomarker testing practices and develop a workflow plan for implementation across all practices with consensus from other disciplines

While progress on these goals varied across programs, participants reported successes in gaining buy-in and commitment from multidisciplinary staff and leadership to support these goals. Participants also reported overwhelming satisfaction with the expert insights and key takeaways from the workshop series (more than 75% satisfaction across reported gains, confidence, attitudes, and intent to change practices related to comprehensive

biomarker testing). For more information on this workshop series and a closer look at program outcomes, access the complete report here.

Webinar: Practical Insights

Expanding on the success of the virtual workshop series, in April 2023 ACCC developed an on-demand webinar, “Practical Insights on How to Improve Comprehensive Biomarker Testing in Advanced Non–Small Cell Lung Cancer.” The webinar highlights how community cancer centers can improve biomarker testing processes by showcasing strategies to obtain sufficient tissue for testing, create efficient workflows, improve communication, and assess program readiness. It is led by workshop experts Dr Fox and Dr Gutman and an expert team from Fairfield Medical Center in Lancaster, Ohio: Chad Stoltz, MBA-HM, BSN, director of Cancer Services, Pharmacy, Imaging, Palliative Care, and Research; Celeste Schmelzer, MSN, RN, clinical research coordinator; and Roopa Srikantiah-Saha, MD, oncologist.

Supplemental Resources for Biomarker Testing Implementation

The “Evolving Biomarkers in Non–Small Cell Lung Cancer” education program joins a suite of powerful resources curated by ACCC to aid multidisciplinary cancer care teams in their journey to implement, expand, and sustain patient biomarker testing. The “**Biomarker Testing Implementation Roadmap for Advanced NSCLC**” is an online learning tool that provides step-by-step guidance across 4 areas: laying the groundwork for biomarker testing, training and preparing care teams to offer testing, implementing the program, and evaluating progress.

In addition to the Roadmap, ACCC has curated a comprehensive **resource library** with helpful tools, solutions, and guidance on key topics related to implementation of biomarker testing. These resources include articles and toolkits regarding program evaluation, process improvement strategies, testing guidelines, biomarker basics, patient navigation, reimbursement, and more.

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Association of Community Cancer Centers

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