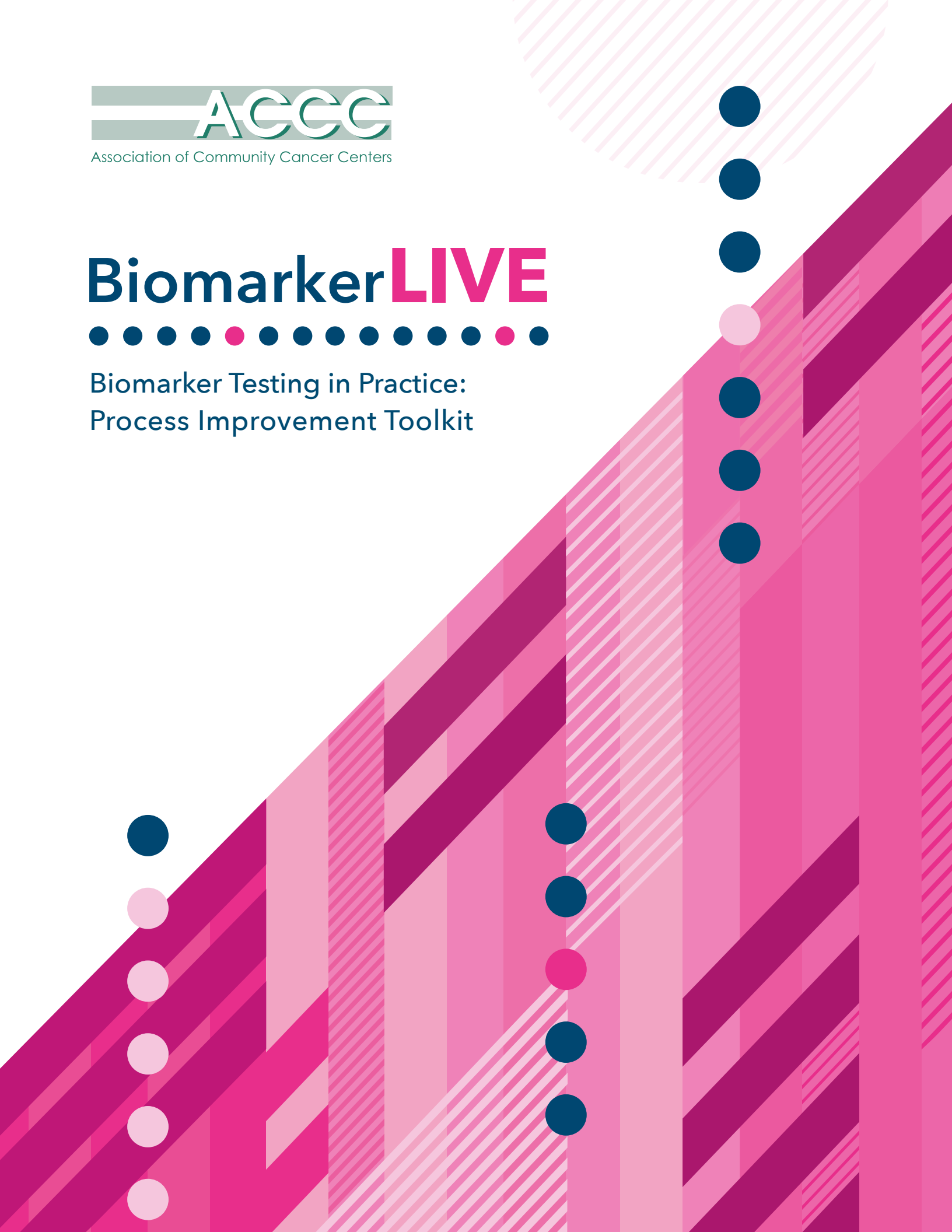


# BiomarkerLIVE



Biomarker Testing in Practice:  
Process Improvement Toolkit



# INTRODUCTION

Multiple challenges arise when attempting to integrate biomarker testing into community oncology practices. This toolkit focuses on four key elements that must be taken into account when developing a precision medicine program that incorporates biomarker testing:

1. Provider Education
2. Patient Education
3. Infrastructure
4. Staffing and Services

When implementing biomarker testing, a comprehensive strategy is crucial. Different practices may perform better in one category than in another, but all elements must be considered in order to ensure a successful program. Individual practices should evaluate their strengths and weaknesses relative to each category to better understand—and be prepared for—the challenges their new biomarker programs may confront.

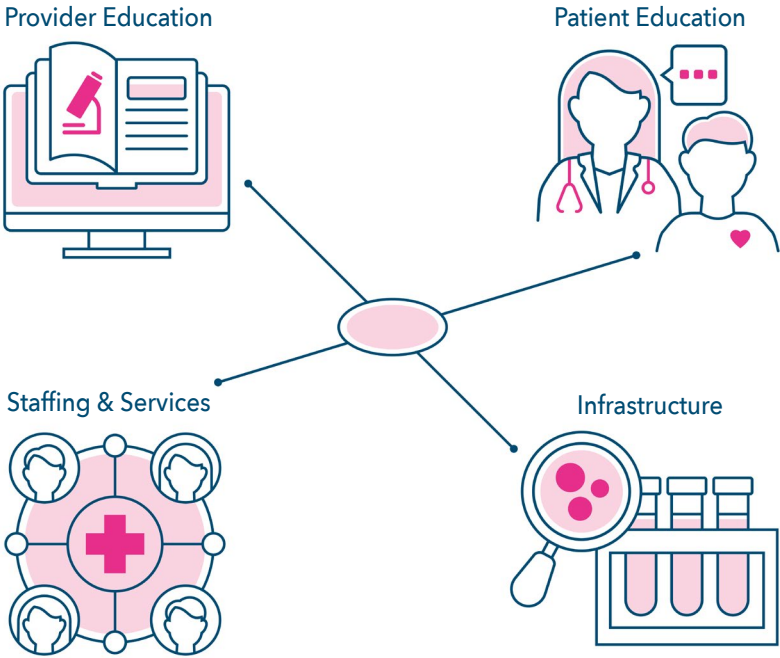
This toolkit is a guide for multidisciplinary cancer care team members who are implementing—or plan to implement—biomarker testing in their cancer centers.

Download resources for providers—and to share with patients—by clicking the italicized links throughout the toolkit.

# KEY ELEMENTS

To determine the most important considerations when developing a biomarker testing program, as part of its BiomarkerLIVE education initiative, the Association of Community Cancer Centers (ACCC) performed a comprehensive literature review, conducted member surveys, and facilitated focus groups with community oncology practices with the goal of understanding the challenges of creating an inclusive precision medicine program and exploring potential remedies for those challenges.

This effort resulted in the articulation of four key elements that are fundamental to the success of any viable biomarker testing program.





## Provider Education

Prescribers must have sufficient knowledge of biomarker testing and its role in cancer prognosis, diagnosis, and treatment to ensure all patients are tested when appropriate and that their results are interpreted in a timely manner to optimize treatment planning. A practice's leadership should encourage its providers to prioritize education about biomarker testing and precision medicine treatment options.

### Declare an area of interest

Biomarker testing and treatment alternatives are changing and evolving all the time. No one person can be an expert in all areas. Programs are the most successful when providers specialize in one area of interest and serve as an expert in that area whom their colleagues can consult as necessary.



*"All oncologists in our system have declared one to three areas of special interest. This allows our practitioners out in the community to have an in-system resource, because the actual process of deciding on who needs testing, ordering it, curating it, and getting results back is a very time-consuming process."*

– **JAMES WEESE, MD, FACS**, VICE PRESIDENT, AURORA CANCER CARE

*"We are using biomarker [results] as a possibility for enrollment in clinical trials. We've partnered with a few companies and we are able to open 'just-in-time' clinical trials\* to enroll our patients based on a particular biomarker."*

– **ABHINAV CHANDRA, MD**, MEDICAL DIRECTOR, YUMA REGIONAL MEDICAL CARE CENTER

\*Just-in-time trials build on a methodology to provide a wide array of trials within a short time frame to reduce the administrative burden on research sites.

### Consider clinical trials

Understand the role of biomarker testing as it relates to clinical trial eligibility. This is an important way to expand both testing and treatment options for your patients.

[Learn more about ACCC's clinical trial resources](#) | [Explore The Clarity Foundation Trial Finder Tool](#)

### Establish an external consultation network

Collaborate with other practices, advisory groups, or third-party testing facilities to obtain guidance outside of your practice's expertise. Alternatively, some testing companies provide access to molecular tumor boards as a service to their clients. One example is [Foundation Medicine](#).



## Patient Education

Experts and patient advocates participating in the National Lung Cancer Roundtable say that one of the challenges to implementing large-scale biomarker testing is a lack of patient awareness and understanding about it at the time of diagnosis or disease progression.<sup>1</sup> The abundance of cancer education materials available combined with the emotions brought on by their cancer diagnosis makes it easy for patients to feel overwhelmed and confused. Physicians, nurses, case managers, and pharmacists can all play an important role in educating patients.

### Assess where your patients are in terms of their educational needs and readiness

Not all patients have the same knowledge base from which to start to learn about their diagnosis and treatment. Providers must learn how to have conversations with their patients in a manner that assesses the patient's level of medical knowledge and ability to comprehend complex topics such as biomarker testing. From there, providers can determine the patient's health literacy level and how to best convey important information without adding confusion to an already stressful situation.

#### One Simple Question to Start the Conversation: How much do you know about your cancer?

Learn more about the *ACCC's health literacy program, Let's Be Clear: Communicating to Improve the Cancer Patient Experience.*

### Keep messaging simple

Explain the importance and potential impact biomarker testing may have on patients' treatment plans. There are many resources that provide guidance on the use of plain language in patient education. The *Consistent Testing Terminology Working Group*—which is composed of more than 50 patient advocacy organizations; professional societies; pharmaceutical, biotech, and diagnostics companies; and testing laboratories—has published a white paper on the need for consistent terminology about biomarker testing, including results from a patient survey on the topic and recommendations for keeping messaging simple.

#### Further Reading

***"A White Paper On The Need For Consistent Testing Terms In Precision Medicine."***

*"We have colleagues at different institutions who we can call on for very complex issues. We go outside the usual structure to get help on these very tricky cases. This happens throughout medicine in a collaborative environment."*

— **MIKE THOMPSON, MD, PHD, FASCO,**  
CO-DIRECTOR, PRECISION MEDICINE,  
AURORA CANCER CARE CENTER

### Be prepared to provide appropriate patient education materials

Organizations such as LUNGeVity Foundation, Fight CRC, Living Beyond Breast Cancer, and The Clarity Foundation are just some of the groups that have free materials that provide information for patients and caregivers on biomarker testing and precision medicine.



According to a recent discussion from the the ACCC Operational Pathways for Molecular Testing in NSCLC Advisory Committee, one of the biggest challenges in patient education is teaching patients that it may be appropriate to wait for the results of biomarker testing before making any decisions about treatment, including starting standard first-line, or subsequent, systemic anti-cancer therapy. Patients may experience a perceived loss if they are told that they need treatment but should consider waiting to start it until further test results are obtained.

#### **Additional Resources for Providers**

- [\*Consistent Testing Terminology Working Group Health Provider Information Card\*](#)
- [\*Cancer Support Community, Resources for Precision Medicine\*](#)
- [\*Center for Disease Control and Prevention Plain Language Materials & Resources\*](#)
- [\*Plain Language Action and Information Network \(PLAIN\)\*](#)

#### **Resources to Share with Patients**

- [\*LUNgevity What You Need to Know about Biomarker Testing\*](#)
- [\*Living Beyond Breast Cancer Guide to Understanding Genetics and Family Risk\*](#)
- [\*The Clarity Foundation Tumor Blueprints\*](#)
- [\*National Society for Genetic Counselors About Genetic Counselors\*](#)

You can access these resources and others in the [\*ACCC BiomarkerLIVE Resource Library\*](#).



## Infrastructure

Having the right infrastructure allows for smoother processes in tumor biopsy acquisition, biomarker testing, results interpretation, and treatment planning. Process inefficiencies in these areas can create barriers to effectiveness. Practices should review their institutional guidelines on a regular basis to ensure best practices are implemented and maintained.

### Establish guidelines for tumor and/or serum biopsies

Ensure you provide appropriate training for clinicians and local pathologists in obtaining and handling tissues to minimize delays due to insufficient or unacceptable biopsy samples. Align this educational training with the requirements of the pathology lab that performs or orders the biomarker testing.

#### Resources

- [Liquid Biopsy Consortium](#)
- [College of American Pathologist Preanalytics for Precision Medicine Project Team](#)
- [College of American Pathologists \(CAP\) Guidelines](#)

### Ensure that technical and human resources are present

It is critical to have the right fixative and microtome procedures in place to ensure optimal biomarker detection without contamination. Sufficient personnel must be trained and available to handle the multiple procedures involved in processing the tissue, such as acquiring blocks from archival storage, cutting slides, circling tumors, and estimating tumor percentage. The latter step requires significant pathologist training for reproducible results.



*“Our laboratory has multiple point-people who coordinate the sending out of specimens for all the testing. That communication can be very difficult if you don’t have an organized group for that process.”*

– JENNIFER GODDEN, PHARM.D., BCOP, CO-DIRECTOR, ONCOLOGY PRECISION MEDICINE PROGRAM, AURORA CANCER CARE

*“One of the most important parts of precision medicine is making testing a system priority and having reflex testing whenever possible. Unless reflex testing is implemented as a systems approach, even very good providers can miss testing a significant part of the time.”*

– MICHAEL P. MULLANE, MD, DIRECTOR OF HEREDITARY MEDICINE AND PREVENTION CENTER, AURORA CANCER CARE



### Implement and periodically update reflex testing protocols

A multidisciplinary team of pathologists, oncologists, radiologists, laboratory personnel, and hospital administration should agree on which testing you want to offer your patients and under what circumstances.<sup>2</sup>

### Optimize test ordering processes and results protocols within your electronic medical record (EMR)

There are now more opportunities to work with EMR vendors and third-party testing facilities to automate the flow of data related to biomarker testing.<sup>3</sup>

### Establish molecular tumor boards (MTB) that meet regularly in person or virtually

In smaller practices, it may be challenging to create and maintain internal MTBs. There are opportunities to work with virtual MTBs either through vendors or by establishing relationships with larger cancer treatment centers.<sup>6,7</sup>

*Learn more about ACCC's tumor board resources.*

#### Further Reading

***"Reflex Testing of Oncotype Dx Recurrence Score: A Single Institution Review of a Quality Improvement Protocol."***<sup>4</sup>

***"West Cancer Center to get more precision treatment options from Foundation Medicine-One Oncology initiative."***<sup>5</sup>

Please check out these additional BiomarkerLIVE resources and tools.

#### On-Demand Webinars

- ***Pathology 101***  
Addresses the role of laboratory medicine professionals and pathologists in biomarker testing, incorporating a review of testing techniques and applications, lab-specific regulations, and the impact of those regulations on biomarker testing.
- ***Biomarker Testing: Cost and Coverage***  
Review current policies and regulations that drive costs related to biomarker testing.
- ***Genetic vs Genomic - Knowing the Difference for Patients with Inherited Cancers***  
Deep dive into the differences between germline and somatic mutations, with case examples, and presentation of findings from the LUNGeivity/ FORCE patient survey.
- ***Biomarkers 101***  
Introduction to cancer biomarkers, relevant terminology, and implications for cancer care.

#### ACCC CANCER BUZZ Podcasts

- ***Episode 37: Financial Barriers to Biomarker Testing***  
Learn about the role of financial navigation in helping patients and providers understand the options available to patients in need of biomarker testing.
- ***Episode 55: What You Need to Know about Liquid Biopsy***  
Learn about the current clinical applications of liquid biopsies, associated reimbursement issues, and what you can do to implement these tests at your program.





## Staffing and Services

The complexities of a precision medicine program are best managed by a multidisciplinary care team that incorporates dedicated leadership. The team should steer the overall direction of the program based on current science and treatment developments. Team members should include physicians such as molecular pathologists and surgical pathologists as well as computational biologists and geneticists. These individuals should be jointly responsible for recruiting and engaging relevant practice stakeholders and providing continual education and support to the clinicians who provide precision medicine services.<sup>8</sup>

### Passionate and committed administrative leadership is critical

Your administration's support is essential to be able to advocate for the resources necessary to create and maintain a successful precision medicine program.

### Ensure you have adequate personnel and services

Oncology nurse navigators, genetic counselors, financial counselors, and billing personnel can help patients navigate the complexities of the testing and treatment process and overcome related challenges, such as patient education needs and financial constraints.

#### Additional ACCC Resources

- [Making the Case for New Staff Briefs](#)
- [Integration of Pathology with the Cancer Care Team Assessment Tool](#)

### Dedicate personnel for enrolling patients into clinical trials

Clinical research coordinators can help develop treatment pathways that might not otherwise be available to your patients.

### Create a culture of consistent and thorough interdisciplinary communication

This culture should be a routine part of daily interactions. The complexity of precision medicine makes each team member's role essential, requiring an attention to detail that only disciplined collaboration can provide.



*"As a leader, you have to justify getting the money needed for the program and continually demonstrate how it brings value to the system when it's not always an issue of dollar return on investment."*

– **JAMES WEESE, MD, FACS**, VICE PRESIDENT, AURORA CANCER CARE

*"Patient navigator/case management would be an area where we could use more help. Also, we are looking at one of our providers to get additional training on genetic counseling."*

– **RAJU VADDEPALLY, MD**, MEDICAL ONCOLOGIST, YUMA REGIONAL MEDICAL CARE CENTER

Offering your patients quality precision medicine services requires a comprehensive strategy that incorporates the education, process improvement, system integration, and staffing considerations that are essential to building a successful program.

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## ACKNOWLEDGMENTS

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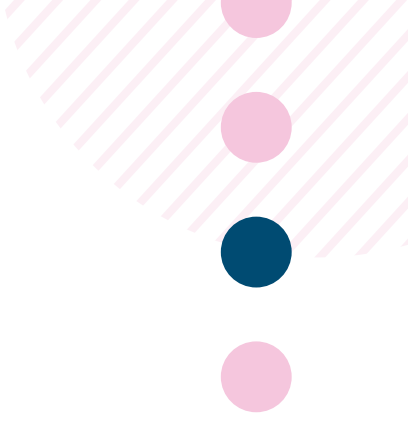
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[Learn more at acc-cancer.org/biomarkerlive.](http://acc-cancer.org/biomarkerlive)

The Association of Community Cancer Centers (ACCC) is the leading education and advocacy organization for the cancer care community. Founded in 1974, ACCC is a powerful network of 28,000 multidisciplinary practitioners from 2,100 hospitals and practices nationwide. As advances in cancer screening and diagnosis, treatment options, and care delivery models continue to evolve—so has ACCC—adapting its resources to meet the changing needs of the entire oncology care team. For more information, visit [acc-cancer.org](http://acc-cancer.org). Follow us on social media; read our blog, ACCCBuzz; tune in to our CANCER BUZZ podcast; and view our CANCER BUZZ TV channel.

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