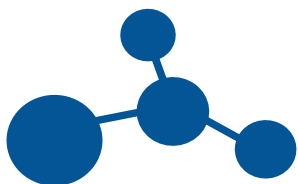




Global
Colon Cancer
Association

**KNOW YOUR
BIOMARKER**

MSS DPYD NRAS
TUMOR SIDEDNESS
TUMOR LOCATION
HER2 BRAF KRAS
PIK3CA UGT1A1
LYNCH SYNDROME MSI
ctDNA TMB FAI
CEA NTRK FUSION



PATIENT ADVOCACY TOOLKIT:
KNOW YOUR BIOMARKER

Welcome to the Global Colon Cancer Association's Know Your Biomarker Advocacy Toolkit!

Know Your Biomarker is an awareness, education, and advocacy campaign fighting for global access to colorectal (bowel) cancer biomarker testing. Through the Know Your Biomarker program, the Global Colon Cancer Association advocates for biomarker testing for all colorectal cancer patients, because where you live should not determine whether you can prevent or survive colorectal cancer.

Know Your Biomarker advocates for biomarker testing access at all levels by working with individual advocates, non-profit organizations, industry partners, and policymakers. Know Your Biomarker educates patients about biomarker testing and offers a discussion guide to support conversations about colorectal cancer biomarkers with their healthcare teams. And Know Your Biomarker provides adaptable educational and advocacy resources because we are all working toward the same goal. Let's work together.

The Know Your Biomarker Advocacy Toolkit was created to help you join the global effort to ensure all colorectal cancer patients have access to biomarker testing. On www.knowyourbiomarker.org, you'll find additional educational materials, patient stories, and more.

In this toolkit, you'll find focused colorectal cancer biomarker education to get you started. We have information about

- what a biomarker is
- how biomarkers are used in colorectal cancer care
- who should have biomarker testing
- specific colorectal cancer biomarkers
- the impact each biomarker can have on treatment

The toolkit contains a sample position statement for organizations and sample letters to send to the policymakers in your country. We've also included some tips for letter writing, and lessons from patient advocacy experts.

Finally, we've compiled a list of resources, both international and regional, to support your advocacy efforts toward colorectal cancer biomarker testing access.

Thank you for your valuable efforts on behalf of the colorectal cancer patient community.

Sincerely,

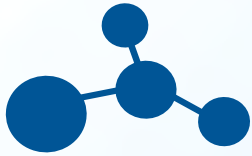


Andrew R. Spiegel, Esquire
Chief Executive Officer



Nicole Sheahan
President

P.S. As you read these materials, if you come across a colorectal cancer biomarker term that you're unfamiliar with, please see the Key Terms section at the end of this toolkit.



PATIENT ADVOCACY TOOLKIT: KNOW YOUR BIOMARKER

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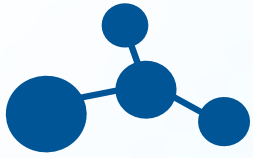
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Thank you to Pfizer for their
support of the Know Your
Biomarker Advocacy Toolkit.



SECTION 1:

COLORECTAL CANCER BIOMARKER FACT SHEETS

FACTS

WHAT IS A BIOMARKER?

A biomarker is a piece of information about your health. Biomarkers include your blood pressure, your blood type, and cholesterol or blood sugar levels measured in a blood test. Biomarkers can tell your medical team important information about you and your cancer.

For colorectal cancer specifically, relevant biomarkers include:

- Substances released by your cancer into your blood
- Location of your tumor (whether it is on the right or left side of your colon)
- Changes (mutations) in the genes of your tumor (tumour) cells, or in the genes of your whole body.

These mutations mostly occur in just you or your tumor, but some do run in families. 5% of colorectal cancers are hereditary.

**5% ARE
HEREDITARY**

HOW ARE BIOMARKERS TESTED?

Biomarker testing is done by analyzing tumor biopsy tissue, blood samples, or other body fluids. Biomarker information can also come from radiologic imaging (CT scans, X-rays), or surgical reports.

Laboratory techniques are different for testing each biomarker and may include IHC (immunohistochemistry), NGS (next-generation sequencing), PCR (polymerase chain reaction), and FISH (fluorescence in situ hybridization).



WHY TEST FOR COLORECTAL CANCER BIOMARKERS? WHAT ARE THEY USED FOR?

Colorectal cancer biomarkers can provide your medical team vital information about you and your cancer that is used to determine prognosis, guide treatment decisions, and monitor you after treatment. Biomarkers are also used in developing targeted therapies for colorectal cancer.

- **Prognosis:** Biomarkers can indicate the overall prognosis of your cancer and your risk of cancer recurrence.
- **Treatment decisions:** Biomarkers can reveal which treatments will be effective or ineffective against your cancer. Some biomarkers can indicate which treatments will cause you adverse or toxic side effects.
- **Screening and Monitoring:** Biomarkers can be used to screen people who are at high risk for colorectal cancer, and can be used to monitor you for cancer recurrence after treatment.
- **Treatment development:** Biomarkers are used to identify potential targets of colorectal cancer treatments.

WHO SHOULD HAVE BIOMARKER TESTING?

Everyone with colorectal cancer should have biomarker testing.

Everyone with colorectal cancer, no matter the stage at diagnosis, should have microsatellite stability / instability (MSS / MSI) biomarker testing. Microsatellite instability is also known as deficiency of mismatch repair (dMMR).

If you have stage IV / metastatic colorectal cancer, you should have testing for RAS (both KRAS and NRAS), BRAF, and HER2 biomarkers.

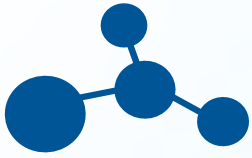
There are several biomarkers that don't currently have standardized recommendations for testing, including PIK3CA, tumor mutational burden, and NTRK gene fusion. Talk to your medical team about whether testing of these biomarkers would be beneficial for you.

Biomarker testing can give you and your medical team valuable knowledge about your cancer and help guide your treatment choices. For more information about colorectal cancer biomarkers, please visit knowyourbiomarker.org and talk to your medical team.

COLORECTAL CANCER (CRC) BIOMARKERS AND TREATMENT IMPACT

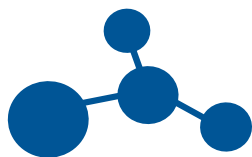
BIOMARKER	WHO SHOULD BE TESTED?	WHAT IS IT?	WHAT IS THE TREATMENT IMPACT?	
MSS	<ul style="list-style-type: none"> All colorectal cancer (bowel cancer) patients 	<ul style="list-style-type: none"> MSS is microsatellite stability MSS and MSI-High are assessments of your cells' ability to fix certain kinds of genetic mistakes. 	<ul style="list-style-type: none"> CRC with MSS is treated with traditional chemotherapy. CRC with MSS and TMB-High can be treated with immunotherapy. 	
MSI-HIGH	<ul style="list-style-type: none"> All colorectal cancer patients All patients with MSI-High results should also be tested for the hereditary Lynch Syndrome 	<ul style="list-style-type: none"> MSI-High is microsatellite instability-high (also known as deficient mismatch repair, dMMR). MSS and MSI-High are assessments of your cells' ability to fix certain kinds of genetic mistakes. 	<ul style="list-style-type: none"> Immunotherapy is effective in MSI-High colorectal cancer. 	
KRAS	<ul style="list-style-type: none"> All stage IV / metastatic CRC patients All patients being considered for EGFR inhibitor treatment 	KRAS is a gene involved in controlling cell growth and cell survival. Mutations in KRAS may allow cells to grow out of control and become cancer.	CRC without KRAS mutation (wild-type) is treated with EGFR inhibitors.	<ul style="list-style-type: none"> Colorectal cancer with KRAS mutation is treated with traditional chemotherapy with or without bevacizumab added. EGFR inhibitors are not effective in tumors (tumours) with KRAS mutation.
NRAS	<ul style="list-style-type: none"> All stage IV / metastatic CRC patients All patients being considered for EGFR inhibitor treatment 	NRAS is a gene involved in controlling cell growth and cell survival. Mutations in NRAS may allow cells to grow out of control and become cancer.	CRC without NRAS mutation (wild-type) is treated with EGFR inhibitors.	<ul style="list-style-type: none"> Colorectal cancer with NRAS mutation is treated with traditional chemotherapy with or without bevacizumab added. EGFR inhibitors are not effective in tumors with NRAS mutation.
HER2 (ERBB2)	All stage IV / metastatic CRC patients, unless a KRAS, NRAS, or BRAF mutation has already been identified	HER2 is a gene involved in control of cell growth and cell survival. An increased number of HER2 gene copies (amplification) and increased amount of HER2 protein (overexpression) can cause cancer by allowing abnormal control of cell growth and survival.	HER2 negative tumors are treated based on other patient and biomarker information.	<ul style="list-style-type: none"> CRC that is HER2 positive (has HER2 amplification or overexpression) may be treated with HER2 inhibitors with or without traditional chemotherapy. EGFR inhibitors are less effective in colorectal cancer with HER2 amplification.
BRAF (INCLUDING BRAF V600E)	All stage IV / metastatic CRC patients	BRAF is a gene involved in controlling cell growth. Mutations in BRAF may allow cells to grow out of control and become cancer.	Tumors without BRAF mutation (wild-type) are typically treated with EGFR inhibitors.	<ul style="list-style-type: none"> CRC with BRAF mutation is treated with targeted therapy (BRAF inhibitors plus MEK inhibitors) with or without traditional chemotherapy. EGFR inhibitors alone are not effective in BRAF mutant tumors but may be added to other targeted therapy.
CEA	All CRC patients	CEA is carcinoembryonic antigen, a substance produced by colorectal cancer cells and by intestinal cells in some other benign diseases.	A decreasing CEA level during treatment is a sign that the treatment is effective.	<ul style="list-style-type: none"> An increasing CEA level over time may indicate cancer progression on treatment or a return of cancer after treatment. Further testing is needed to confirm progression or recurrence.

BIOMARKER	WHO SHOULD BE TESTED?	WHAT IS IT?	WHAT IS THE TREATMENT IMPACT?	
TUMOR LOCATION (TUMOR SIDEDNESS)	<ul style="list-style-type: none"> All CRC patients as part of initial diagnosis Does not require separate biomarker testing 	Right-sided colon cancer is located in the cecum (caecum), ascending colon, hepatic flexure (right colic flexure) or transverse colon.	<ul style="list-style-type: none"> Immunotherapy is effective in right-sided tumors. When added to traditional chemotherapy, bevacizumab is more effective than cetuximab in right-sided colon cancer. 	
		Left-sided CRC is located in the splenic flexure (left colic flexure), descending colon, sigmoid colon, or rectum.	<ul style="list-style-type: none"> Adjuvant chemotherapy is effective in left-sided CRC. When added to traditional chemotherapy, cetuximab is more effective than bevacizumab in left-sided tumors. 	
PIK3CA	No standardized guidelines, patients should discuss with medical team	PIK3CA is a gene involved in controlling cell growth and migration. PIK3CA mutations may cause cancer as well as some rare diseases of abnormal growth.	For CRC without PIK3CA mutation (wild-type), treatment is guided by other patient and biomarker information.	<ul style="list-style-type: none"> Tumors with mutation in PIK3CA exon 20 are less responsive to EGFR inhibitor treatment. Colorectal cancer with PIK3CA mutation may have a good response to aspirin or other NSAIDs as neoadjuvant or adjuvant treatment, or as recurrence prevention.
TMB	No standardized guidelines, patients should discuss with medical team	TMB is tumor mutational burden, a measurement of how many genetic mutations are present in tumor cells in a specific amount of DNA (a megabase).	In colorectal cancer with TMB-Low, treatment is guided by other patient and biomarker information.	Immunotherapy is effective in CRC with TMB-High, even in some tumors with MSS.
NTRK FUSION	<ul style="list-style-type: none"> Patients with stage IV / metastatic CRC that is progressing on chemotherapy and has no KRAS, NRAS, or BRAF mutation No standardized guidelines for patients with stage IV / metastatic CRC with MSI-High, patients should discuss with medical team 	NTRK genes encode TRK proteins which are involved in control of cell growth and cell survival. When a type of mutation called NTRK gene fusion occurs, TRK fusion proteins are made. TRK fusion proteins can cause cancer by allowing uncontrolled cell growth and survival.	Tumors without NTRK fusion are treated based on other patient and biomarker information.	TRK inhibitors are used to treat CRC with NTRK fusion.
DPYD	<ul style="list-style-type: none"> All CRC patients experiencing severe toxic effects of 5-FU related chemotherapy (5-FU and its combinations, capecitabine and its combinations) No standardized guidelines for pre-treatment DPYD testing, patients should discuss with medical team 	DPYD is a treatment toxicity biomarker. DPYD is a gene encoding the enzyme DPD which is required to break down (metabolize) 5-FU related chemotherapy drugs. Mutations in DPYD may cause partial or complete DPD enzyme deficiency, leading to abnormal 5-FU metabolism and severe toxicity.	<ul style="list-style-type: none"> In patients with DPYD mutations causing partial DPD enzyme deficiency, doses of 5-FU related drugs may be reduced to lower the risk of severe toxic effects. In patients with DPYD mutations causing complete DPD enzyme deficiency, different drugs may be used to avoid 5-FU related chemotherapy. 	
UGT1A1	<ul style="list-style-type: none"> All CRC patients experiencing severe toxic effects of irinotecan chemotherapy No standardized guidelines for pre-treatment UGT1A1 testing, patients should discuss with medical team 	UGT1A1 is a treatment toxicity biomarker. It is a gene encoding the enzyme which is required to metabolize irinotecan. Mutations in UGT1A1 may cause decreased enzyme level or function, leading to abnormal irinotecan metabolism and severe toxicity.	In patients with UGT1A1 mutations, irinotecan dose may be reduced to lower the risk of severe toxic effects.	



SECTION 2:

SAMPLE POSITION STATEMENT



SAMPLE POSITION STATEMENT

Below is a sample position statement available to patient advocacy organizations who wish to support increasing access to colorectal cancer biomarker testing. You may edit the language below or use it as written:

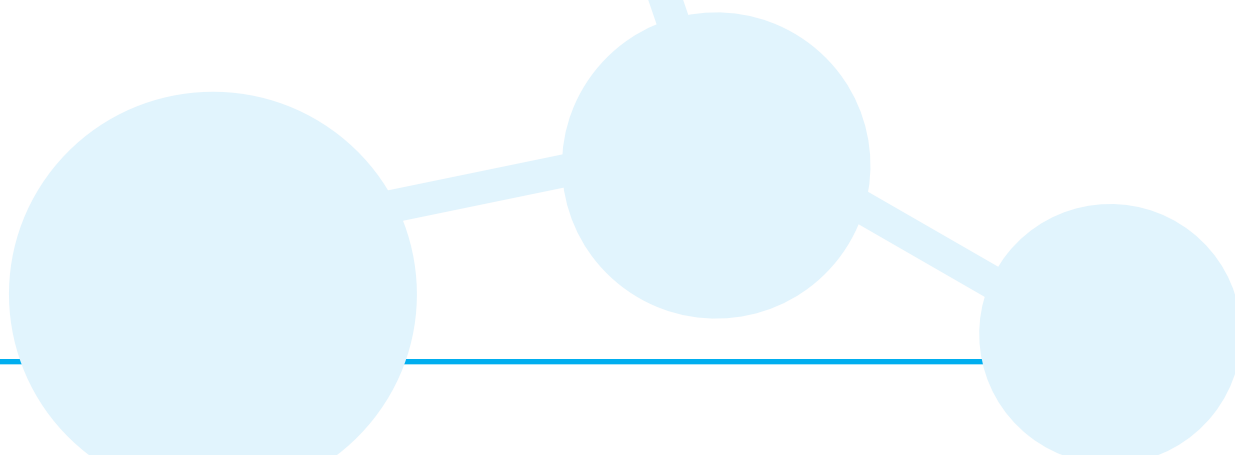
COLORECTAL CANCER BIOMARKER TESTING

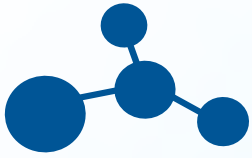
Biomarkers and biomarker testing are a fundamental part of precision medicine for colorectal cancer. Biomarkers provide vital information used to determine prognosis and risk of recurrence, guide treatment decisions, evaluate treatment response, and monitor for recurrence after treatment. Biomarker testing can help assess the need for adjuvant chemotherapy after surgery. Biomarker testing results help healthcare providers match patients with therapies targeted to their specific subtype of cancer, and even to clinical trials testing new therapies. Biomarker testing is also used to monitor patients for recurrence after treatment, often identifying recurrence earlier than imaging tests alone and allowing earlier therapeutic intervention.



[Organization name] supports the following core principles:

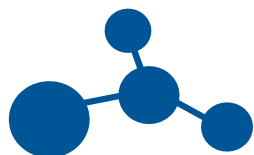
1. Growing awareness of precision medicine and cancer biomarker testing and their benefits among patients, healthcare providers, and policymakers.
2. Increasing education about cancer biomarkers, biomarker testing, and precision medicine for patients, healthcare providers, and policymakers.
3. Improving access to precision medicine, biomarker testing, and indicated targeted therapies for all colorectal cancer patients.
4. Securing coverage of biomarker testing and indicated targeted therapies for all colorectal cancer patients.
5. Supporting innovation in precision medicine and targeted therapies by increasing patient access to clinical trials.





SECTION 3:

SAMPLE LETTERS



SAMPLE LETTERS

A core function of a strong patient advocacy organization is communication with policymakers to express policy positions. This means supporting policies, such as increased colorectal cancer biomarker testing, which would improve patients' healthcare and opposing policies which raise concerns about quality of cancer care in your community. Policymakers must hear from patient organizations like yours to create patient-centered policies.

The following sample letters may be used as templates for your own advocacy on colorectal cancer biomarker testing in your country or region. You may need to adapt these for your organization and tailor them for the colorectal cancer patient community you represent. These communications can take the form of written or emailed letters, social media posts, newspaper editorials, or press releases.

If you have questions or would like assistance with customizing your letter, please email biomarkers@globalcca.org.

TIPS FOR LETTER WRITING:

- While a letter from one patient advocacy organization is useful, a letter signed by multiple groups is even more powerful. Consider asking your partners and ally organizations to sign on to your letter. If possible, have each organization write a letter based on your own. A collection of ten letters from ten patient organizations is a much stronger statement than a single letter signed by ten groups.

- In the first paragraph, state which policy you are writing about, and whether your organization supports or opposes it. Include this again in the final paragraph. This makes it much easier for the reader to quickly understand your position.
- Always include the name of your organization, the disease area it represents (e.g., colorectal cancer, digestive system cancer, hereditary cancer), and how many patients it represents (e.g., 500,000 patients have colorectal cancer in your country or region).
- If possible, reference supporting data. For example, several of these template letters cite physician survey data about colorectal cancer biomarker testing. You may find some resources like this in the "Additional Resources" section of this Toolkit.



SAMPLE LETTER TO POLICYMAKERS

Barriers to biomarker testing access exist worldwide. Challenges involving coverage of and reimbursement for cancer biomarker testing are nearly universal. In some countries, there are not enough qualified laboratories and not enough people trained to perform testing in these laboratories. Due to staff shortages, laboratories may not participate in quality assurance programs. Policies that support laboratory facility development and laboratory personnel recruitment and education can increase biomarker testing access. Additionally, there can be long periods of time between biomarker test and targeted therapy regulatory and reimbursement approvals. Healthcare providers may hesitate to order tests when they cannot act on the results, matching targeted therapy to the right patients. Policies that increase coordination between biomarker test approval and targeted therapy approval can increase access to testing. Below you will find a sample letter to use as a template for your own letter of support for laws and policies increasing access to cancer biomarker testing.

PLACE ON YOUR
ORGANIZATION'S
LETTERHEAD
FEATURING
YOUR GROUP'S
NAME, LOGO,
AND CONTACT
INFORMATION.

DATE

Lawmaker Name and Title

Lawmaker Address

Lawmaker Address Line 2

Re: [Name or number of policy supporting biomarker testing access]

Dear [Lawmaker name and title],

On behalf of [name of your organization] representing [number of patients represented] in [country or region], we are writing in support of [policy name or number] which would increase patient access to the cancer biomarker testing that ensures patients receive the correct treatment.

Precision medicine is improving cancer outcomes. Oncologists can make use of information about a person's cancer, their biomarkers, to assist diagnosis, to assess their prognosis, to inform treatment choices, and to monitor how well therapy is working. Biomarkers are also used to diagnose hereditary cancer syndromes, a key step in preventing cancer in affected families.

Scientific progress in biomarker testing and biomarker-related cancer treatments has led to targeted therapies that can improve patient survival and quality of life. Biomarker testing is fundamental to this precision medicine approach, but testing rates are not in line with evidence-based clinical cancer guidelines. Socioeconomic inequalities in the use of biomarker testing and targeted therapy contribute to health disparities.

- 60% of oncology drugs launched in the past 5 years require or recommend biomarker testing prior to use
- 66% of oncology providers reported that coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.

Access to biomarker testing and precision medicine is not keeping pace with medical progress. [Policy name or number] will [require reimbursement coverage, prioritize regulatory approval, increase laboratory capacity] for biomarker testing for diagnosis, treatment, and disease monitoring, as supported by medical and scientific evidence, including internationally recognized clinical practice guidelines. Access to indicated biomarker testing and precision medicine produces better health outcomes, improves quality of life for patients, and reduces costs to healthcare systems.

For these reasons, [ORGANIZATION NAME] urges your support for [policy name or number].

Sincerely,

[Name]

[Organization]

SAMPLE LETTER TO U.S. LAWMAKERS

In the U.S., many state governments have introduced legislation to require health insurers and their state's Medicaid plans to pay for biomarker testing, overcoming a common barrier to biomarker testing. It is important for patient advocacy organizations and individual patients to voice their support of these bills. Below you will find a sample letter to use as a template for your own letter of support. With state legislation, these letters are often sent to the chair and/or co-chair of the Senate or House Health Committees.

PLACE ON YOUR ORGANIZATION'S LETTERHEAD FEATURING YOUR GROUP'S NAME, LOGO, AND CONTACT INFORMATION.

DATE

Lawmaker Name and Title

Lawmaker Address

Lawmaker Address Line 2

Re: [Bill number support]

Dear [Lawmaker name and title],

On behalf of [name of your organization] representing [number of patients represented] in [state or region], we are writing in support of [bill number] which would require health insurers in [state] to increase patient access to cancer biomarker testing that ensures patients receive the correct treatment.

Precision medicine is improving cancer outcomes. Oncologists can make use of information about a person's cancer, their biomarkers, to assist diagnosis, to assess their prognosis, to inform treatment choices, and to monitor how well therapy is working. Biomarkers are also used to diagnose hereditary cancer syndromes, a key step in preventing cancer in affected families.

Scientific progress in biomarker testing and biomarker-related cancer treatments has led to targeted therapies that can improve patient survival and quality of life. Biomarker testing is fundamental to this precision medicine approach, but testing rates are not in line with evidence-based clinical cancer guidelines. Socioeconomic inequalities in the use of biomarker testing and targeted therapy contribute to health disparities.

[Enter information on why biomarker testing is important to your organization...Potential facts to include below:]

- 60% of oncology drugs launched in the past 5 years require or recommend biomarker testing prior to use
- 66% of oncology providers reported that insurance coverage is a significant or moderate barrier to appropriate biomarker testing for their patients.
- Many underserved communities are not benefiting from the latest advancements in biomarker testing: patients who are older, Black, uninsured, or Medicaid-insured are less likely to be tested for guideline-indicated biomarkers. Without action, this could increase existing disparities in cancer outcomes by race, ethnicity, income, and geography.

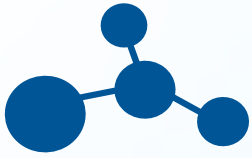
Healthcare coverage for biomarker testing is not keeping pace with medical progress. [Bill number] will require state-regulated plans [including Medicaid?] to cover biomarker testing for diagnosis, treatment, and disease monitoring, as supported by medical and scientific evidence, including nationally recognized clinical practice guidelines. Access to indicated biomarker testing and precision medicine produces better health outcomes, improves quality of life for patients, and reduces costs to healthcare systems.

For these reasons, [ORGANIZATION NAME] urges your support for [bill number].

Sincerely,

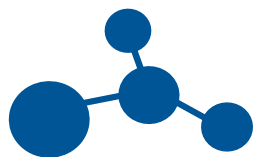
[Name]

[Organization]



SECTION 4:

SEVEN LESSONS FROM PATIENT ADVOCACY EXPERTS



SEVEN LESSONS FROM PATIENT ADVOCACY EXPERTS

In May 2022, the Global Colon Cancer and the World Patients Alliance convened a panel discussion, “Lessons from the Patient Advocacy Experts” as part of a two-day training program for patient advocacy organizations. This panel featured Gail Attara, CEO of the Canada-based Gastrointestinal Society, Hussain Jafri, Executive Director of the World Patients Alliance, Zorana Maravic, CEO of Digestive Cancers Europe, and Andrew Spiegel, Executive Director of the Global Colon Cancer Association. These lessons below, adapted from the panel discussion, will aid you in your advocacy efforts to increase patient access to colorectal cancer biomarker testing, and any other issues on which you work.

1. EDUCATION IS CRITICAL

Most patient advocates are regular people without special expertise in medicine, science, or policymaking. They have great passion but may need some education to be effective advocates on the important policy issues that affect patients worldwide. It’s important to educate ourselves. That’s why GCCA creates programs like Know Your Biomarker. This toolkit also contains resources to get you started in biomarker advocacy. Additional resources about colorectal cancer biomarkers are available at knowyourbiomarker.org. We encourage you to share these resources, as well as your knowledge and training, with others in your organization and patient community.

2. COLLABORATE WITH OTHER PATIENT GROUPS

Work with other patient advocates and patient advocacy organizations whenever possible. This has several benefits. First, we can all learn from each other’s experiences, including emerging biomarker policies affecting other countries or other cancers. Second, collaboration increases the impact of patient voices in policymaking: a letter signed by multiple organizations carries more weight with a policymaker than a letter signed by a single group. An organized campaign of similar letters from multiple groups asking for the same thing is even more powerful. Third, by presenting a united front, it makes it easier for policymakers to address patient concerns. Cooperation between multiple groups facilitates this.

3. IDENTIFY CHAMPIONS

Whenever possible, identify people within your patient community and among healthcare providers, government allies, and other stakeholders who share your passion and goals for patient-centered policy. Does a particular patient have a powerful story to share? Do respected healthcare leaders share your concerns? Does a prominent government official support your position? Let your members and policymakers know by elevating this individual’s voice. Work with these stakeholders to engage on policy solutions. If they have data that supports your position, consider incorporating it into your member communications. If they are willing to endorse your preferred policy solution, incorporate that into your advocacy campaigns.

4. ANECDOTES & DATA: EACH HAVE THEIR PLACE

Patient testimonials can personalize an abstract concern with a policy by giving a concrete real-world example. Representations of real patients’ experiences can add great emotional power to policy-related communications such as letters or testimony. However, they may also be dismissed as “anecdotal evidence”. Empirical data, such as patient or physician surveys or academic research studies supporting your policy positions, can add intellectual rigor to your arguments. But facts and figures alone can come off as cold and detached from the human consequences of a particular policy. Use both stories and data in your efforts to educate and persuade.

continued on next page

SECTION 4

SEVEN LESSONS (CONTINUED)

5. DEVELOP SPECIFIC POLICY REQUESTS

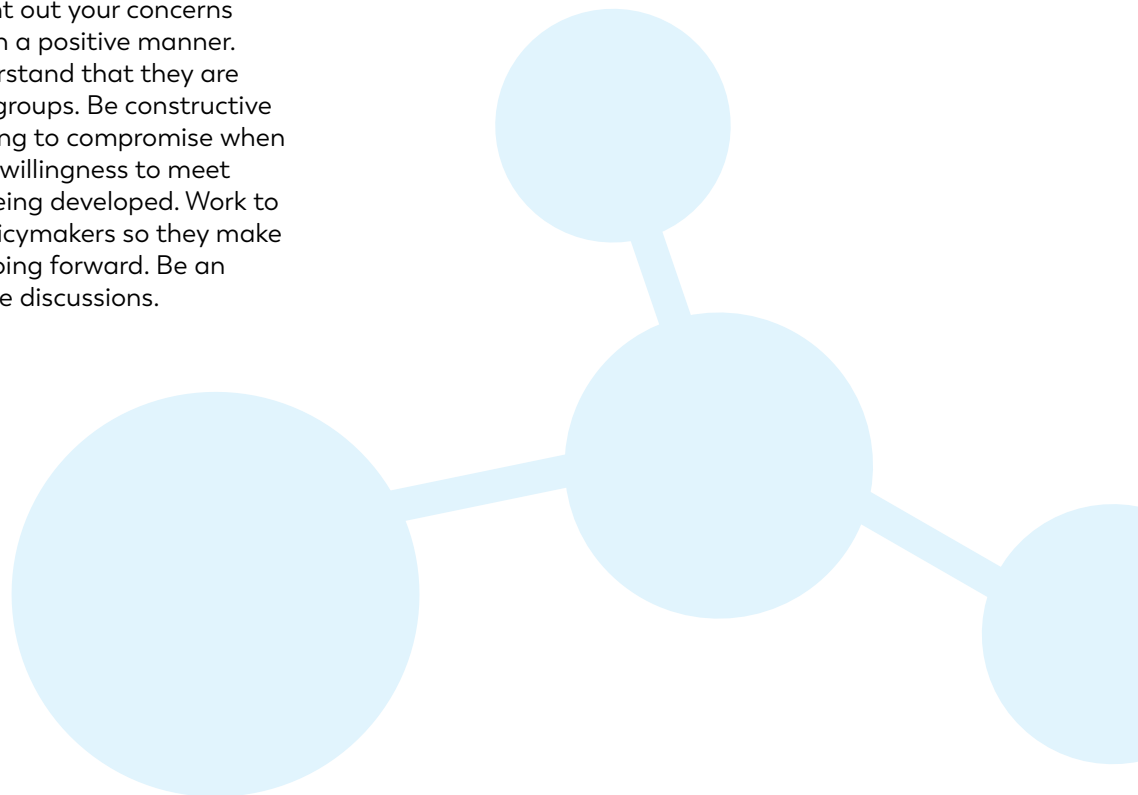
Your messaging should be simple and as clear as possible to your community, your allies, and especially to policymakers. Raise your concerns in a friendly but firm manner. Suggest solutions that are compatible with the policymakers' goals and that address your concerns. What do you want, ideally? Be specific and be realistic. Policymakers are balancing the concerns of many stakeholders, often with different interests and conflicting goals. What position would you be willing to accept as a compromise? They can't say YES if they don't understand what you want, or if it's an unrealistic request.

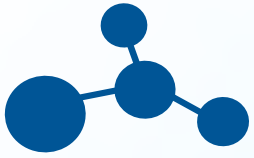
6. BUILD POSITIVE, LONG-TERM RELATIONSHIPS WITH POLICYMAKERS

An effective patient advocate is one that policymakers will listen to and consult on policies that affect them. We achieve this by cultivating long-term relationships built on mutual respect and constructive, positive engagement. Rather than attacking a policymaker for a harmful policy, respectfully point out your concerns and suggest potential solutions in a positive manner. Again, be friendly, but firm. Understand that they are balancing the concerns of many groups. Be constructive and solution-focused and be willing to compromise when it improves a policy. Express your willingness to meet and discuss future policy as it's being developed. Work to become a trusted resource to policymakers so they make more patient-centered policies going forward. Be an indispensable stakeholder in these discussions.

7. ADVOCACY IS AN ONGOING PROCESS

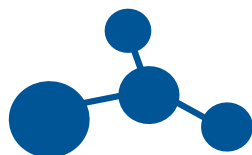
Advocacy doesn't end with issuing a position statement, sending a letter of opposition, or even declaring a policy victory. Those are the first steps in a long-term vocation. As with any area, effective advocacy means continual monitoring of policy developments, regular communication with allies and members, and continual engagement with policymakers. No single patient advocate and no single organization can do this alone. Consider membership in an international patient advocacy coalition such as the Global Colon Cancer Association and be sure to join coalitions in your own country and region. Through their members, these organizations gather information about emerging biomarker policy concerns around the world, and share with their members globally through newsletters, emails, and webinars. They also develop educational materials which you can adapt for your own country or region.





SECTION 5:

ADDITIONAL RESOURCES



ADDITIONAL RESOURCES

GLOBAL

GCCA Know Your Biomarker

- Patient Stories <https://www.knowyourbiomarker.org/patient-stories>
- Biomarker Information: What is a biomarker? How are biomarkers used? Why do biomarkers matter? This article answers these questions and more. <https://www.knowyourbiomarker.org/biomarkers/what-is-a-biomarker>
- Individual Colorectal Cancer Biomarker Fact Pages for Patients <https://www.knowyourbiomarker.org/biomarkers/colorectal-cancer>

From Testing to Targeted Treatments (FT3): Biomarker Testing for Cancer Treatment (adaptable resource) <https://www.fromtestingtotargetedtreatments.org/biomarker-resource/>

AMERICAS

UNITED STATES

National Comprehensive Cancer Network

- Guidelines for Patients
 - Colon Cancer: <https://www.nccn.org/patientresources/patient-resources/guidelines-for-patients/guidelines-for-patients-details?patientGuidelineId=8>
 - Rectal Cancer: <https://www.nccn.org/patientresources/patient-resources/guidelines-for-patients/guidelines-for-patients-details?patientGuidelineId=36>
- Biomarker Guideline Compendium (Requires a free account to access) <https://www.nccn.org/compendia-templates/compendia/biomarkers-compendium>
- Guidelines for Healthcare Professionals (Requires a free account to access)
 - Colon Cancer: <https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1428>
 - Rectal Cancer: <https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1461>

AMERICAS

UNITED STATES (continued)

FORCE: Facing Hereditary Cancer EMPOWERED

- Hereditary Colorectal Cancer <https://www.facingourrisk.org/portal/people-with-colorectal-cancer>
- Biomarker Testing and Targeted Therapies Biomarker Testing and Targeted Therapies <https://www.facingourrisk.org/portal/biomarker-testing-and-targeted-therapies>

LATIN AMERICA

Oncoguia

- Targeted Therapy for Colorectal Cancer <http://www.oncoguia.org.br/conteudo/terapiaalvo-para-cancer-colorretal/1721/180/>
- Immunotherapy for Colorectal Cancer <http://www.oncoguia.org.br/conteudo/immunoterapia-para-cancer-colorretal/11406/180/>

Radar do Câncer: Colorectal Cancer Information for Brazil <http://radardocancer.org.br/painel/colorretal/>

La Asociación Mexicana de Lucha contra el Cáncer

(AMLCC): Colorectal Cancer Patient Guide <https://www.amlcc.org/biblioteca-de-consulta-sobre-el-cancer/recursos-digitales-de-consulta-para-pacientes-con-cancer-colorrectal-metastasis/>

CANADA

Colorectal Cancer Canada: “Get Personal” Biomarker Program for Patients <https://www.colorectalcancercanada.com/what-we-do/our-programs/#section1>

AUSTRALIA

Bowel Cancer Australia: Biomarker Information <https://www.bowelcanceraustralia.org/biomarkers>

continued on next page

SECTION 5

ADDITIONAL RESOURCES (CONTINUED)

EUROPE

Digestive Cancers Europe: Patient Guide to Biomarkers in Metastatic Colorectal Cancer <https://digestivecancers.eu/publication/why-getting-personal-can-be-lifesaving-a-patient-guide-on-biomarkers-in-metastatic-colorectal-cancer/>

European Society for Medical Oncology

- Personalized Medicine in Colorectal Cancer Guide for Patients and Policymakers <https://www.esmo.org/for-patients/personalised-medicine-explained/colorectal-cancer>
- Personalized Medicine Guide for Patients <https://www.esmo.org/for-patients/patient-guides/personalised-cancer-medicine>
- Biomarker Fact Sheets for Healthcare Professionals <https://oncologypro.esmo.org/education-library/factsheets-on-biomarkers>

UNITED KINGDOM

Bowel Cancer UK: “Get Personal” Biomarker Program for Patients <https://www.bowelcanceruk.org.uk/campaigning/get-personal/>

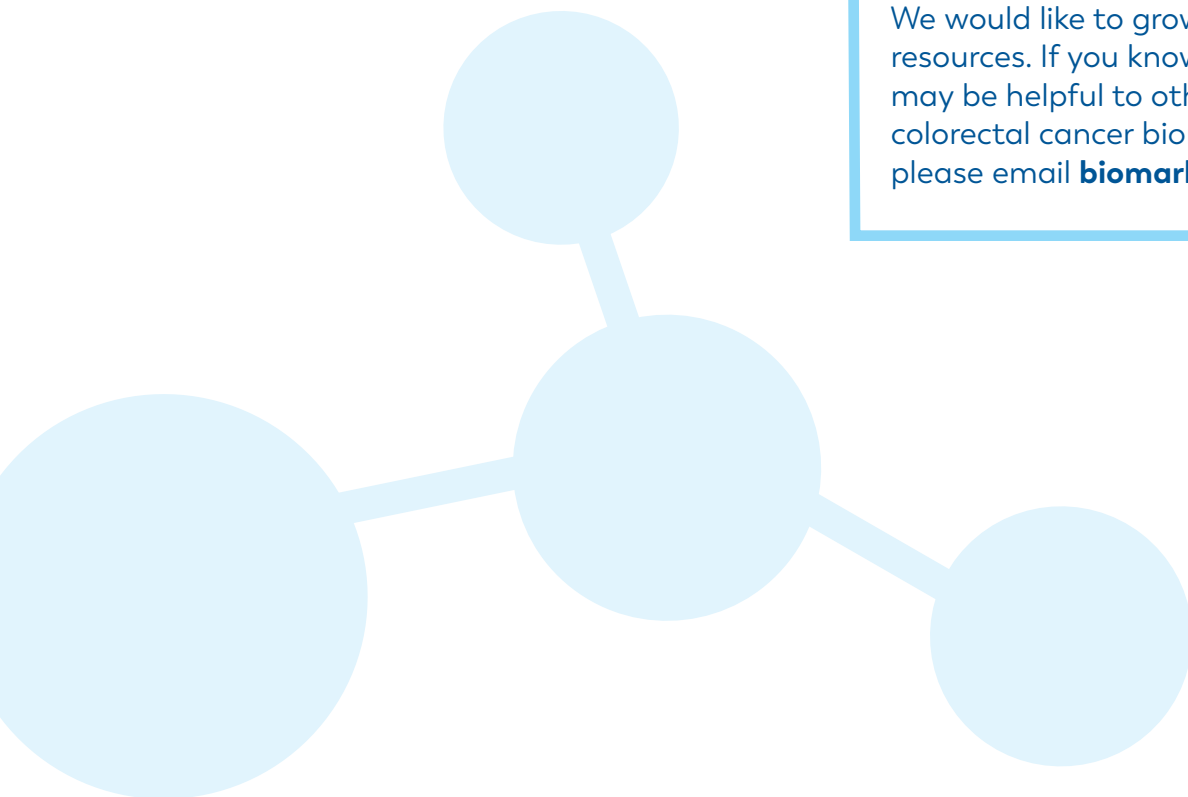
National Health Service England: National Genomic Test Directory National Genomic Test Directory <https://www.england.nhs.uk/publication/national-genomic-test-directories/>

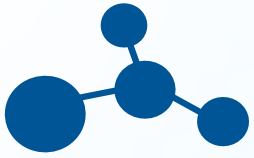
ASIA

JAPAN

Japanese Society for Cancer of the Colon and Rectum: Guidelines for Health Professionals <https://www.jscrr.jp/en/guideline.html>

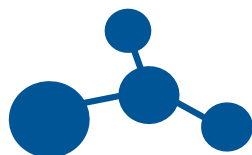
We would like to grow this list of resources. If you know a resource that may be helpful to other advocates for colorectal cancer biomarker testing, please email biomarkers@globalcca.org.





SECTION 6:

KEY TERMS



KEY TERMS

- **Acquired resistance:** When a treatment that once worked against a tumor stops working. This can be due to new resistance mutations in tumor cells, or due to an increase in the number of cells with an existing resistance mutation.
- **Adenocarcinoma:** Malignant tumor derived from glandular cells in the epithelial layer of different organs, for example the epithelium that lines the intestines.
- **Adenoma:** Benign tumor derived from glandular cells in the epithelial layer of different organs, for example the epithelium that lines the intestines.
- **Adjuvant therapy:** Treatment given after the primary treatment, such as drug therapy or radiation after surgery. This prevents recurrence of the cancer by treating cancer cells that may remain in the body after surgery.
- **Benign:** Non-cancerous. Benign tumors do not invade locally or spread to other parts of the body.
- **Biomarker:** A piece of information about your health. Colorectal cancer (bowel cancer) biomarkers include substances released by the tumor, genetic changes (mutations) in the cancer cells (or the whole body), and tumor location.
- **Biomarker testing:** Measurement or analysis of biomarkers. The results of biomarker testing can provide information about prognosis, guide treatment decisions, and assist in the development of new treatments. Also known as tumor testing or profiling, molecular testing or profiling, or genetic testing or profiling.
- **Bowel cancer:** see Colorectal cancer.
- **Chemotherapy:** Drug treatment of cancer. The term is often used to refer to drug treatment with traditional anti-cancer drugs rather than targeted therapy drugs or immunotherapy drugs.
- **Colorectal cancer:** Cancer located in the colon, including the rectum. The majority (90-95%) of colorectal cancers are adenocarcinoma.
- **ctDNA (circulating tumor DNA):** Small pieces of DNA from tumor cells that are found in blood. Tumor cells release these bits of DNA when they die.
- **DNA (deoxyribonucleic acid):** The molecule that carries genetic information in the cell.
- **Exon:** A segment of DNA that is the instructions for the cell to make RNA and protein. A sub-segment of a gene.
- **Familial adenomatous polyposis (FAP):** An inherited syndrome of increased cancer risk most often caused by a mutation in the APC gene. FAP is characterized by many (usually hundreds to thousands) colorectal adenomatous polyps. Polyps will become cancerous if not removed, and patients with FAP are at very high risk of colorectal cancer. Patients with FAP are also at high risk of cancer of the stomach (gastric), small intestine, pancreas, liver (hepatic) and biliary tract, adrenal glands, thyroid gland, and brain.
- **Fusion gene:** A gene made up of parts of two different genes. It is created by gene fusion, when a part of one gene becomes attached to another gene.
- **Fusion protein:** The protein product made from a fusion gene.
- **Gene:** A segment of DNA containing instructions for the cell, usually instructions to make a protein.
- **Gene amplification:** An increase in the number of copies of a gene.
- **Gene fusion:** A genetic change in which a part of one gene becomes attached to another gene. This happens when a piece of a chromosome, the structure that carries genes, breaks off and attaches to another chromosome.
- **Germline mutation:** A change in DNA that is present in reproductive cells (sperm and eggs). These mutations can be passed on to children. Inherited mutations are then present in all body cells of the offspring.

KEY TERMS (CONTINUED)

- **Hereditary:** Describes genetic information, traits, or diseases passed from parents to children.
- **Immunotherapy:** Treatment that helps the body's own immune system kill cancer cells.
- **Juvenile polyposis syndrome (JPS):** An inherited syndrome of increased cancer risk caused by a mutation in the SMAD4 or BMPR1A genes. JPS is characterized by multiple juvenile polyps in the gastrointestinal tract. Patients with JPS are at increased risk of developing colorectal cancer as well as cancers of the stomach (gastric), esophagus, small intestine, and pancreas.
- **Liquid biopsy:** A test performed on blood that analyzes circulating cancer cells and ctDNA (circulating tumor DNA).
- **Lynch Syndrome:** An inherited syndrome of high colorectal cancer risk caused by mutations in DNA mismatch repair genes. Lynch Syndrome also causes higher risk of other cancers including endometrial (uterine) cancer, stomach (gastric) cancer, and ovarian cancer. Also known as hereditary non-polyposis colorectal cancer (HNPCC).
- **Malignant:** Cancerous. Malignant tumors can invade locally and spread through the body.
- **Metastatic:** Cancer that has spread from its original location to other organs of the body.
- **Mutation:** A change in the sequence of DNA. Mutations can be somatic (not inherited, occurring in some body cells, such as tumor cells) or germline (inherited, occurring in reproductive cells which carry them on to all cells of offspring).
- **Neoadjuvant therapy:** Treatment given before the primary treatment, such as drug therapy or radiation before surgery. This treatment shrinks the tumor that is then removed in surgery.
- **Personalized medicine:** An approach in which a person's tumor biomarkers are used to help in the diagnosis of cancer, cancer treatment planning, treatment outcome monitoring, and follow-up care. Also called precision medicine.
- **Polyp:** An abnormal growth that sticks out from a mucous membrane, for example the lining of the intestines. Benign polyps include adenomas (adenomatous polyps) and juvenile (hamartomatous) polyps. Benign polyps may transform into malignant polyps. Malignant polyps contain colorectal adenocarcinoma.
- **Precision medicine:** see Personalized medicine.
- **Prognosis:** The likely course or outcome of a disease.
- **Rectal cancer:** Cancer located in the rectum. The majority (90-95%) of rectal cancers are adenocarcinoma.
- **RNA (ribonucleic acid):** A molecule that carries genetic information copied from DNA in the cell. RNA exists in several forms with different functions, including messenger RNA (mRNA) which guides the cell process of using the DNA instructions of a gene to make a protein.
- **Somatic mutation:** DNA changes that occur in non-reproductive cells of the body, including tumor cells. These mutations are not inherited.
- **Targeted therapy:** Treatments that work on specific cancer cells, causing less damage to a patient's normal cells. This can include drugs that inhibit the function of cancer growth genes and proteins, drugs that help a patient's immune system recognize and kill cancer cells, or drugs that inhibit the development of a tumor's blood supply.
- **Wild-type:** Describes a gene that has the normal sequence. The gene has no mutation.