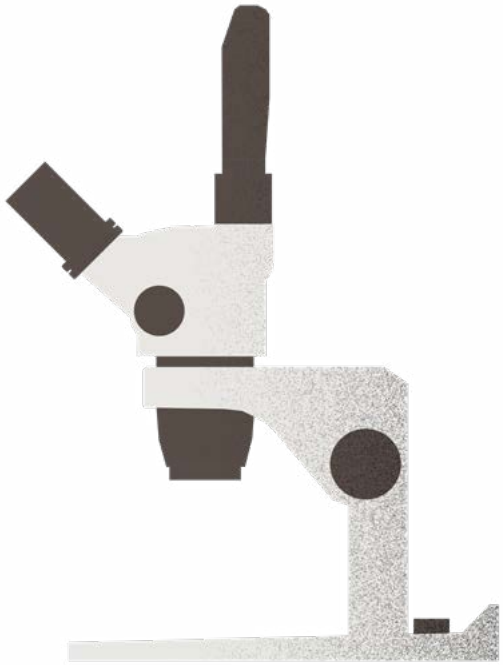
Precision Medicine and You:

Biomarkers in Solid Tumors

Johnson&Johnson

Your guide to precision medicine in cancer



What is precision medicine?

Not all cancers are the same.
Precision medicine considers the individual features of your specific tumor to select a treatment. These features are called **biomarkers.**

What is a biomarker?

A biomarker is any molecule produced by your body that can be measured as the sign of a normal or abnormal process. Some biomarkers are molecules that drive the tumor's growth and spread.

Precision medicine provides a way for your doctors to decide on **your personalized treatment plan** based on your tumor's specific features.

With precision medicine, you and your doctor can:

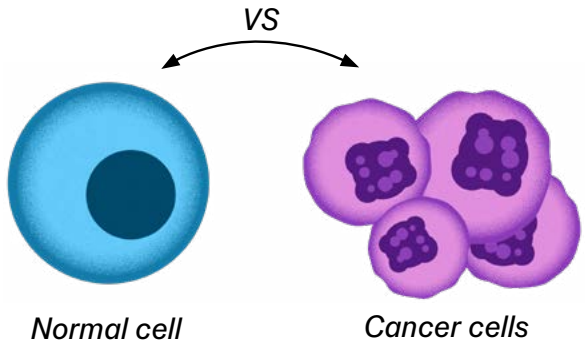
- Determine what's making your cancer grow and spread
- Select the appropriate treatment for you
- Understand the likelihood of your cancer responding to certain treatments
- Understand your and your family's risk of developing cancer or similar conditions

Table of contents

In this resource, you will explore how precision medicine may be involved in your care, with topics including:

Basics of cancer

Cancer occurs when new cells grow rapidly in parts of the body where they are not supposed to be

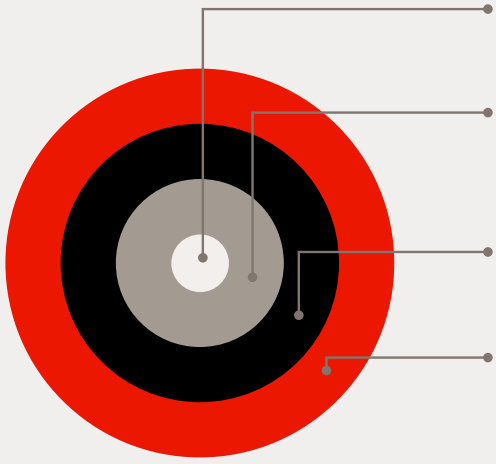


Key terms

Cells—the units that make up the tissues of the body and contain DNA

DNA—the genetic information needed for a person to develop and grow, which is passed from one generation to the next

Cancer can be described by how much it has grown or spread



In situ
Cancer cells have not spread beyond where they started.

Localized
Cancer cells have grown within the organ where they started, but have not spread beyond that organ.

Regional
Cancer cells have spread to nearby areas of the body.

Metastatic
Also called “distant”: Cancer cells have spread to more distant areas of the body.

You are not alone:
More than 2 million people are expected to be diagnosed with cancer in 2025.

Changes in your genes can cause normal cells in your body to become cancerous

What is a gene?

A gene is a unit of DNA that is passed from parent to child (hereditary). Genes carry instructions for making **proteins** (see above).

When cells in your body divide to make new cells, genes must be copied. Sometimes mistakes are made when genes are copied. These mistakes may be harmless, **or they may cause normal cells to become cancer cells.**

What is a protein?

A **protein** is a molecule made by your body that carries out a specific purpose. Proteins are essential to keeping your body functioning.

However, when **gene changes** happen in your body's cells, the **proteins** those genes produce may not function properly, or may be altered in ways that cause cancer to develop and spread.

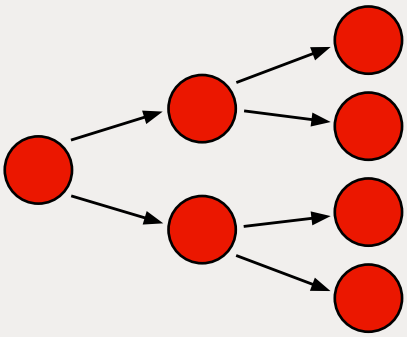
Gene changes usually occur in cancer cells, but in some cases may have been inherited

Gene changes can be classified based on whether they were inherited **(germline)** or occurred later in life **(somatic).**

Germline changes

These are genetic changes that are inherited from your parents and are present in all the cells of your body, including cancer cells.

Germline changes are present in all cells.

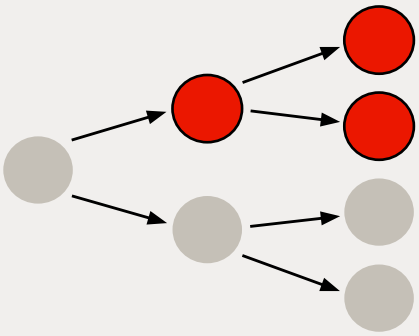


Knowing whether your cancer has **germline gene changes** helps determine whether **your family members** may be at increased risk of cancer, as well as tailor your treatment to your type of cancer.

Somatic changes

These are genetic changes that cause cancer to develop and spread. They are seen in cancer cells but not in other cells in your body.

Somatic changes are present in some cells.



Knowing whether your cancer has **somatic gene changes** helps you and your doctor tailor **your treatment** to the features of your cancer.

Precision medicine for your cancer

As mentioned, biomarkers are gene changes or protein changes that can help your doctor better understand your tumor.

Biomarkers can:

- Help diagnose a particular kind of cancer
- Help understand how likely it is that you or your family members may get cancer (germline biomarkers)
- Help determine your treatment options

Certain treatments for cancer are designed to work against particular gene or protein changes

This means treatments may be:

- **More effective than other treatment options** against tumors that have a particular biomarker
- **Less effective than other treatment options** against tumors that do NOT have a particular biomarker

Talk to your doctor—depending on what type of tumor you have, biomarker information could be important at the time you are diagnosed, later on in your treatment journey, or both.

Certain biomarkers indicate whether a particular treatment may work for you

Your biomarker results can help determine a treatment choice that's tailored to your tumor's specific features.

Targeted therapy

Some biomarkers show that changes in genes are driving the growth and spread of your cancer. It may be possible to target those genes with medicine—this is called "targeted therapy."

Example biomarkers for targeted therapy:

EGFR
BRCA1/2
FGFR

Immunotherapy

Some biomarkers show that your cancer may be vulnerable to your immune system, if your immune system is boosted to recognize and attack the cancer. This is called "immunotherapy."

Example biomarkers for immunotherapy:

PD-L1
MMR deficiency
Tumor mutational burden

Other treatments, such as **chemotherapy**, are available if your tumor does not test positive for biomarkers that would suggest a specific treatment

Key term

Chemotherapy—treatment that stops cancer cells from growing by killing them or stopping them from dividing

Many types of cancer are known to have biomarkers that can inform treatment decisions

Below is a partial list of cancers and the biomarkers that can inform treatments.
If you have one of these types of cancers, it's important to talk to your doctor about finding out whether your cancer has a biomarker that may inform your treatment plan.

Cancer type		Biomarker
	Breast	ER, PR, HER2, *BRCA1/2*
	Prostate	PSA, *BRCA1/2*
	Lung and bronchus	PD-L1, *EGFR, ALK, BRAF,* HER2, *KRAS, MET, ROS1, RET, NTRK,* c-Met
	Colon and rectum	*KRAS, NRAS, BRAF*, HER2, MSI-H, dMMR
	Melanoma	*BRAF*
	Bladder	*FGFR,* HER2
	Kidney and renal pelvis	CA-IX
	Uterus	MMR, TMB, MSI-H, HER2, *NTRK*
	Non-Hodgkin lymphoma	B2-MG, LDH
	Pancreas	CA 19-9, *BRCA1/2*

Knowing whether your cancer has a biomarker is essential to selecting the treatment that's right for you.

The ins and outs of biomarker testing

Biomarker testing involves several steps

Step 1: Biopsy → Step 2: Testing → Step 3: Treatment decision

Step 1 Biopsy

To perform biomarker testing, your doctor will collect a sample of your tumor or your blood or urine.

Step 2 Testing

Your tumor biopsy samples will be sent to a laboratory where a doctor called a pathologist conducts biomarker testing.

Step 3 Treatment decision

Depending on the type of testing performed, after 1 to 3 weeks, your doctor will get a report of what biomarkers your tumor has.

You and your doctor can use the information to choose the right treatment for your cancer.

While testing can sometimes take longer, it is important to wait for all the results to help choose the right treatment.

Step 1

Biopsy

In most cases, the best way to determine whether your cancer has biomarkers is to test a sample of the **tumor**. Taking this sample is called a **biopsy**, which can be done using one of the methods below.

Surgical biopsy is a type of biopsy where a piece of your body with suspicious cells is removed.

Needle biopsy is a type of biopsy where a special needle is inserted through the skin to collect cells from a suspicious area.

Endoscopic biopsy is a type of biopsy where your healthcare provider uses a thin, flexible tube called an endoscope, with a light on its end to see structures inside your body. Your healthcare provider uses special tools to take small samples for testing.

Skin biopsy is a type of biopsy where cells from your skin are removed.

Liquid biopsy is a type of biopsy where your blood sample is collected instead of, or in addition to, a tumor biopsy.

Key terms

Tumor—an abnormal growth or lump in the body. Tumors may or may not be cancerous.

Tumor biopsy—a procedure where a sample of cancer cells is collected to be tested in a laboratory

Step 2 **Testing**

Your tumor biopsy samples will be sent to a laboratory where a doctor called a pathologist conducts biomarker testing.

Biomarker testing may assess a single biomarker at a time or multiple biomarkers at once

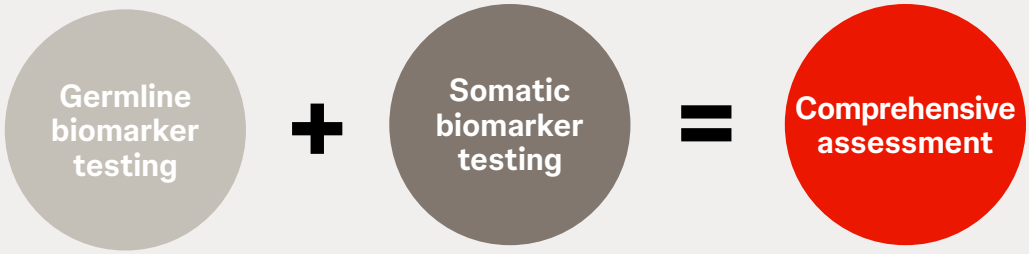
	Individual biomarker testing			Comprehensive biomarker testing
	Test 1	Test 2	Test 3	Test 1
Biomarker 1	✓			✓
Biomarker 2		✓		✓
Biomarker 3			✓	✓

Comprehensive biomarker testing

This is an efficient way to test for multiple biomarkers at once to provide a more holistic view of your collective biomarkers

Biomarker testing may assess germline or somatic biomarkers

Depending on what type of cancer you have, you may need **germline** biomarker testing, **somatic** biomarker testing, or **both**.



Getting germline and somatic testing helps you get a fuller picture of your cancer, when appropriate

Step 3 Treatment decision

After 1 to 3 weeks, your doctor will get a report of what biomarkers your tumor has.

Results of biomarker tests can **help doctors choose the treatment** that will be most appropriate for your type of cancer and avoid treatment that won't be helpful. Waiting for all your results will guide this decision.

Sometimes, your tumor may be positive for a certain biomarker, but there isn't an approved treatment for it yet. If that's the case for your cancer, there may still be options like clinical trials. Ask your doctor what that could mean for your cancer treatment.

Key terms

Comprehensive biomarker testing may also be referred to as:

- Comprehensive genomic profiling (CGP)
- Next-generation sequencing (NGS)

Some tests can be performed more quickly than others, but it is important to wait for all results, so that you and your doctor can determine the appropriate treatment for your specific cancer.

What can you do while you wait for your biomarker test results?

Educate yourself

Learn about your cancer type and understand the basics of your diagnosis from reputable and trusted sources like:

- **CancerCare: Biomarkers** https://www.cancercare.org/biomarkers

A page with educational resources, like worksheets, videos, and patient stories, to help you talk about biomarkers with your doctor

Stay in touch with your care team

Proactively communicate with and prepare for conversations with your healthcare providers by:

- Scheduling appointments
- Preparing questions for your doctor like those on the next page
- Clarifying the timeline of your treatment
- Requesting support from a nurse navigator or social worker to help you through the next steps
- Contact a Genetic Counselor
- Consulting with a nutritionist to guide you with healthy food choices

Focus on mental and emotional health

A cancer diagnosis can be mentally and emotionally stressful, but you do not have to go through this alone:

- Join a Patient Advocacy Group like **Biomarker Collaborative** https://biomarkercollaborative.org/
  - A global network dedicated to introducing patients and care partners to biomarker support groups and other resources
- Talk with a therapist
- Talk with friends and family
- Research and try out some stress management and coping strategies

Questions for your doctor

What type of cancer do I have? Does this kind of cancer have biomarkers I should be tested for?

What type of biopsy and biomarker test will I need?

When can we expect to get my biomarker results back?

What gene or protein changes did my tumor show, and how will those change my treatment plan?

Based on my tumor biomarker results, should my family be tested? Who in my family should be tested?

Solutions start with a conversation

Take action and speak with your doctor about cancer biomarker testing

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