

## UNDERSTANDING PRECISION MEDICINE:

Before we explain the concept of precision oncology, let's begin by defining the term precision medicine:

Precision medicine is about matching the right drugs or treatments to the right people, based on a genetic or molecular understanding of their disease. It's an approach to patient care that's based on the idea that one person's disease isn't necessarily exactly the same in someone else who seemingly has the same disease.

The genes you inherited from your parents and the environment you live in can influence your health, the symptoms you experience, and even how well treatments might work. Precision medicine attempts to understand more about how variations in our genes, proteins and other factors influence our health. The area of precision medicine that addresses treatments for various cancers is called precision oncology.

### Why Is Precision Oncology Important To Me?

Changes in our DNA sequence can be inherited or be a result of lifestyle or environmental factors, like smoking, sunlight and radiation. While genetic variations contribute to physical characteristics like height and hair color, they also influence our likelihood of getting certain diseases like cancers. Some genetic variations protect us from disease, while others make us more susceptible. Tumors have genetic changes that cause cancer to grow and spread. The changes that occur in one person's cancer may not occur in others who have the same type of cancer. Every person's cancer is unique to them, comprised of a distinct combination of gene mutations and other cellular changes. Precision oncology is important to understand because a treatment that helps one person's cancer doesn't always work for somebody else.

### What's the Beneficial Potential of Precision Oncology?

The precision oncology strategy takes your individual genetics in consideration to create treatment options designed specifically for you and others with similar molecular changes. This could involve analyzing your blood and your tumor and as appropriate using "targeted treatments", which are drugs or other substances that attack specific cells to help stop the cancer from growing or spreading. Unlike chemotherapy, targeted treatments may be less prone to harm your healthy cells, causing fewer and less severe side effects. Precision oncology is transforming the way doctors are thinking about treating cancer patients. It offers possible alternatives to sometimes unnecessary or ineffective treatments.



### What Are Some of the Challenges Associated With Precision Oncology?

It's a relatively new and growing field of scientific study. Health care providers and scientists need to have a good understanding of genetics and biochemistry. Some of the necessary technologies to make precision oncology an everyday practice in most health care settings are still being developed. The National Institutes of Health, US National Library of Medicine suggests three main challenges: consent, collection and cost.

### How Will My Privacy Be Protected?

Protecting patient privacy and keeping health information confidential is always a crucial issue. That means researchers will have to develop a rigorous process of informed consent. People who decide to participate by donating their genetic materials to a large database will need to understand the risks and benefits of participating in scientific research. You can find more information about Privacy and Trust Principles as part of the US Precision Medicine Initiative. Data Security Policy Principles and Framework for the initiative are also available by conducting an online search.

### How Do Doctors Collect and Manage Genetic Material Donations?

One goal of the Precision Medicine Initiative is to collect clinic and hospital data from more than a million US volunteers. Doctors and researchers are working to find better ways to standardize the collection process. They've designed enormous databases to efficiently store large amounts of patient data. Donated samples are sent to biobanks with no information in it that would tie it to an individual.

### Will Precision Oncology Treatments Cost More Than Other Cancer Drugs?

Cost is an important issue with precision oncology and precision medicine in general. The Precision Medicine Initiative will require Congress to approve many millions of dollars in funding over multiple years. Technologies to sequence large amounts of DNA are expensive to develop but are less costly as technology evolves. Additionally, drugs that are developed to target a person's genetic or molecular characteristics are likely to be expensive. Reimbursement from third-party payers (such as private insurance companies) for these targeted drugs is also likely to become an issue.

## BY THE NUMBERS

# 14 Approvals

of new anticancer therapeutics by the FDA.

from Aug. 1 2018, to July 31, 2018

# 11 Uses

of previously FDA approved anticancer therapeutics were expanded to include additional types of cancer.

from August 1, 2017, to July 31, 2018

# OVER 1.7 Million

Estimated number of new cases of cancer diagnosed in the United States in 2019.

As of July 25, 2019

# 2.4 Million

Estimated number of cancer deaths avoided.

from 1991 to 2015

<https://cancerprogressreport.org/Pages/cpr18-cancer-in-2018.aspx#driving>



26%

Estimated decline in US cancer death rate.

from 1991 to 2015

## RESOURCES ON PRECISION MEDICINE

Your Oncologist or Healthcare Provider may recommend that you start treating your cancer with an approved cancer treatment that could include drugs, biologics, or medical devices. If there are no approved cancer treatments available for the type of cancer that you have, or if you have failed approved cancer treatments for your cancer, talk to your Healthcare Provider about participating in a clinical trial. Here's some additional information.

### Precision Oncology Program

[FDA.gov/OCE](https://www.fda.gov/OCE)

### NIH All of Us Research Program

<https://allofus.nih.gov/>

### Genetics Home Reference

<https://ghr.nlm.nih.gov>

### Genomics and Health Impact Blog

<https://www.CDC.gov/genomics/>

### “Precision Medicine is Already Working to Cure Americans”

<https://obamawhitehouse.archives.gov/blog/>

### Oncology Center of Excellence Contact Information

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www.fda.gov/oce

ONCOLOGY CENTER OF EXCELLENCE

# Cancer Q&A

## What Is Precision Oncology?

