

## ALTERNATIVES TO USING PLACEBOS IN CANCER CLINICAL TRIALS

By Amna Ibrahim, MD

Clinical trials can be an option for people with life-threatening illnesses to try new drugs in development. But some people might be concerned they'll go through the trial only to be part of the group that doesn't get the new drug – getting a placebo instead. Though the use of placebos in comparative clinical trials can be useful, they are not always practical or ethical, especially in patients with life-threatening cancer or other illnesses. Many trials do not use placebos. Instead, they compare investigational treatments to what is called “standard of care.” As a doctor working in the FDA’s Center for Drug Evaluation and Research, I know that patients have questions about the use of placebos in cancer clinical trials. Here are answers to some of the most common ones.

### Typically, what is a placebo in a clinical trial, and how is it used?

Placebos are like sugar pills. They do not have any effect on the disease itself. They are used in clinical trials, where a new drug is compared to the placebo. Placebos help prevent bias in how the trials are done and in how the results are interpreted.

### What is standard of care in a clinical trial?

Standard of care is what a doctor would typically use to treat a condition. If there is no beneficial treatment, standard of care may mean the doctor observes and monitors the patient to see how the disease progresses.

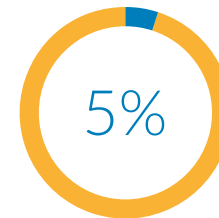
### How is standard of care different from a placebo in a clinical trial?

Unlike a placebo, standard of care—other than just observation—typically has some kind of effect on the condition. In a clinical trial, researchers may compare a new treatment to a standard of care to see whether the new treatment is as good as or better than the standard of care.

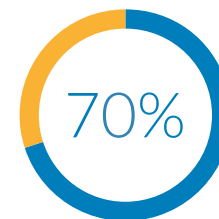
### When did cancer trials begin to move away from using placebos and to standard of care as a comparison treatment, and why?

In cancer patients, the use of placebo in place of an active treatment raises ethical concerns. It is not true that the FDA requires the use of a placebo in comparative trials. In fact, in many cases, using standard of care as a comparison may be more appropriate over a placebo, if one is available. As we develop more and more effective therapies, the use of placebos will decrease even further.

## BY THE NUMBERS



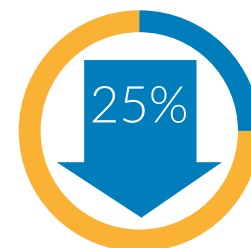
Estimated percentage of eligible adult cancer patients who participate in clinical trials.



Estimated percentage of Americans who are willing or inclined to participate in a trial.

# 1.7 million

Estimated number of new cases of cancer in the United States in 2018.



Percentage by which the overall death rate from cancer in the United States fell, from 1990 to 2014.



## CANCER TREATMENT AND CARE

**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.**

- Clinical Trial information is available through **www.clinicaltrials.gov**. The FDA does not conduct clinical trial research.
- Expanded Access is a program which gives patients the use of an investigational drug outside of a clinical trial. It's also known as Compassionate Use. Visit **www.fda.gov** and search Expanded Access for Patients for more information.
- If you're aware of a chemotherapy product for your type of cancer that has been approved in another country, but not in the United States, talk to your physician about obtaining the chemotherapy product through FDA's Personal Importation Program.
- Patient-friendly materials about cancer are available from the National Cancer Institute's "Patient Education Publications".

## CANCER TREATMENT AND CARE continued

- Cancer product approvals and more information about the FDA Oncology Center of Excellence can be found at: **www.fda.gov/oce**.
- A complete list of all FDA Public Workshops, can be found by searching online for at: **www.fda.gov/NewsEvents/Meetings**.

### Oncology Center of Excellence Contact Information

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ONCOLOGY CENTER OF EXCELLENCE

## Cancer Q&A

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