

Understanding Your Clinical Trial Results Transcript

Part 1: Objective Response

If you go to a cancer clinic for treatment of a solid tumor, your doctor will tell you how you're doing based on their own interpretation of your test results and symptoms. They might consider things like how your tumor has changed in size over time, whether there are any new tumors, whether the cancer has spread to other parts of the body, changes in your symptoms or quality of life, and what the tumor cells look like under a microscope.

Exactly how they view your response to treatment can be subjective. In fact, another doctor might see things in a different light. But, when you're in a cancer clinical trial, the researchers running the trial have to report the results objectively. So, they need to measure each person's response to the experimental treatment the same way, using consistent language to explain what they're seeing.

To help make sure the researchers all report their results the same way, they follow a set of guidelines to gauge the progress or response of each of the trial participants. That way the Food and Drug Administration (FDA) can figure out whether a new treatment really works and should be approved for use.

Part 2: Response Evaluation Criteria in Solid Tumors (RECIST)

For cancers involving solid tumors, RECIST criteria are often used to determine how well a patient responds to an experimental treatment in a clinical trial. RECIST, or Response Evaluation Criteria in Solid Tumors, looks at whether a patient's tumor has disappeared, shrunk, stayed about the same size, or gotten bigger.

The patient's doctor measures the tumor using CT scans, MRI images, or PET scans taken before and after treatment. Based on these measurements, researchers can objectively report how each patient responded to a study treatment.

Part 3: Response to Therapy

Using the RECIST criteria, if CT, MRI, or PET scans indicate a tumor has disappeared after treatment, the researcher calls it a complete response. If a tumor has shrunk by at least 30% based on CT, MRI, PET scans, that's called a partial response. If a tumor has grown by at least 20%, it's considered progressive disease. Anything between partial response and progressive disease is noted as stable disease.

Let's take a closer look at what each of these responses really mean. While patients who have a complete response to therapy tend to have more positive results, a complete response to a cancer treatment does not mean the cancer has been cured, that the cancer will not recur, or that the patient will live longer.

Patients who have a partial response to a cancer treatment tend to have better results than patients who get worse or whose tumor increases in size. But a partial response does not necessarily mean that the cancer will not get worse in the future. If you have progressive disease on a cancer therapy, it may mean that the therapy isn't right for you, or that the drug needs more time to work. Talk to your doctor if you're concerned about your treatment.

Having stable disease doesn't mean that a therapy is or isn't working. The tumor may have slightly increased in size. It's also possible that the tumor shrunk slightly or was prevented from growing or spreading to another part of the body.

Patients who have a partial response or stable disease as a result of a cancer treatment may experience some benefits, but it can be hard to know for sure whether a treatment is having an effect on your cancer. Talk to your doctor if you have questions about your current therapy.

One way to figure out if a cancer therapy really works is to see if it increases the survival time of the patients in one or more clinical trials. It can sometimes take a while to see just how long a therapy may increase survival, so, the FDA allows pharmaceutical companies to use other markers. Two of these markers for survival are response rate and progression-free survival. The response rate is the percent of patients in a trial who experienced a complete response plus those who experienced a partial response. Progression-free survival is the length of time during and after the cancer treatment that a patient lives with the disease but doesn't get worse.

It's important to note that if a new therapy increases the response rate or progression-free survival of trial participants, there is no guarantee that the treatment will increase survival. And while the RECIST criteria only focuses on changes in tumor size, other factors like symptom relief, prevention of spread, length of survival, and quality of life may be just as important.

Always talk to your doctor about your condition, how you're feeling, and how you're responding to treatment.

A message from Incyte Corporation in collaboration with the Cholangiocarcinoma Foundation and Target Cancer Foundation.

You and your doctor are a team in your care. This video is for informational purposes only and is not intended to be a substitute for medical advice. Talk with your doctor to decide the right course of treatment for you.

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