

A guide to understanding Immuno-oncology Clinical Trial Results

This resource is for patients and
caregivers who are living with cancer.

How can this resource help me?

This resource explains key concepts about immuno-oncology and clinical trials, to help you have meaningful conversations with your healthcare team.

How should I use/read this resource?

This resource is divided into **four levels**. Each level is a complete story. You can start at whichever level you want.

Keep this document for your reference. We've provided space for you to take notes and write down any questions you may have as you read through it.

Level 1

**Starting the conversation about
new treatment options**

Level 2

**Understanding clinical trials:
finding information about
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**Taking a closer look at what clinical
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**Evaluating a treatment using
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level

1

**Starting the conversation about
new treatment options**

Level 1

Starting the conversation about new treatment options

There is now a variety of treatment options available for cancer. You and your healthcare team will weigh the risks and benefits of a new treatment, before making any changes to your current treatment plan.



What treatment options are available to me?

You may already know about some of the treatment options available for cancer, such as: surgery chemotherapy, radiation, or targeted therapy. With advances in science, there is now another way to treat certain cancers: **immuno-oncology (I-O)**.

Immuno-oncology (I-O)

Immuno-oncology uses drugs to help your body's immune system fight cancer. 'Immuno' in immuno-oncology refers to your immune system. The immune system is your body's natural defense against illness and diseases such as cancer.



How does my healthcare team decide if a new type of treatment, like immuno-oncology, may be right for me?

You and your healthcare team will work together with the goal of developing the best treatment plan for you. Your healthcare team will think about what works best with your body to help you fight your disease, and to improve your quality of life.



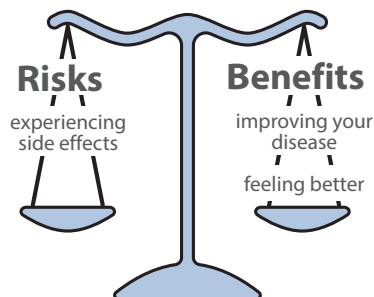
It is important to know that a treatment plan acts like a road map. It includes decisions around what medications you will receive when and how often you will receive them, updates to your lifestyle, nutrition, and more.

Your healthcare team will decide on the medications you will receive based on available options or clinical trial availability.

Treatment plans are fluid — they can evolve and change with your needs. Before considering a new type of treatment, like immuno-oncology, you and your healthcare team will weigh its risks and benefits.

Risks can be any side effects that you might experience.

Benefits can be seen as something that helps improve your disease, or helps you feel better.



In the next level we will look at clinical trials to understand where the information about a treatment's risks and benefits comes from.



level

2

**Understanding clinical trials:
finding information about
treatment benefits and risks**

Level 2

Understanding clinical trials: finding information about treatment benefits and risks

Your healthcare team is experienced at translating clinical trial results. By learning what was studied, your team can decide whether a treatment has the right balance of benefits and risks for you.



Where does my healthcare team get the information about treatment benefits and risks?

One way that your healthcare team gets information about treatment benefits and risks is from research studies also known as clinical trials. Before any treatment becomes available to patients, it is thoroughly studied by researchers in clinical trials.

Immuno-oncology and Clinical Trials

There are many clinical trials happening right now that look at how immuno-oncology can treat different types of cancer. Because of clinical trials, there are more options for patients living with certain cancers.

What are clinical trials?

A clinical trial is when researchers study a treatment with patient participants. Clinical trials may include healthy volunteers or those with the disease being studied. Researchers take and record measurements of what happened to each participant in the trial.

Researchers consider a lot of things before they start a trial. They think about what treatments to give the participants and what measurements to take.

They also think about how to separate the participants. For example, a common clinical trial set-up is to divide participants into two groups:

Group 1 would receive the standard treatment for their disease.

Group 2 would receive a new treatment (with or without the standard treatment).

Researchers take and record measurements. They compare the groups to see what the benefits and risks are for the new treatment. This information is published as clinical trial results.

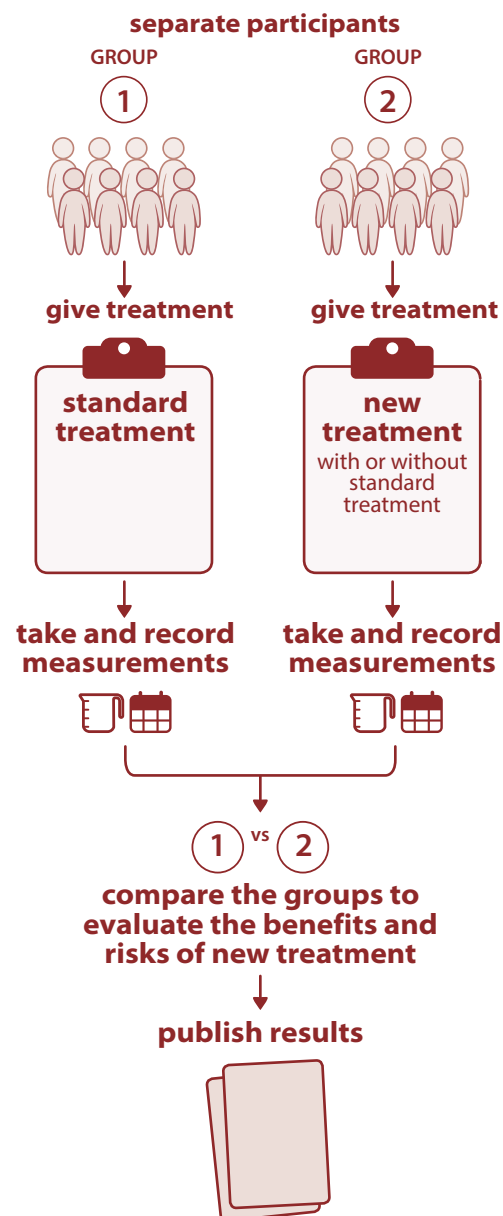


It is important to know that some clinical trials may only have hundreds of participants while others can have thousands of participants.

Clinical trials also vary in the way they are designed depending on the treatment being studied.

Clinical trials can be done in the United States or across multiple countries.

What Researchers Do In Clinical Trials:



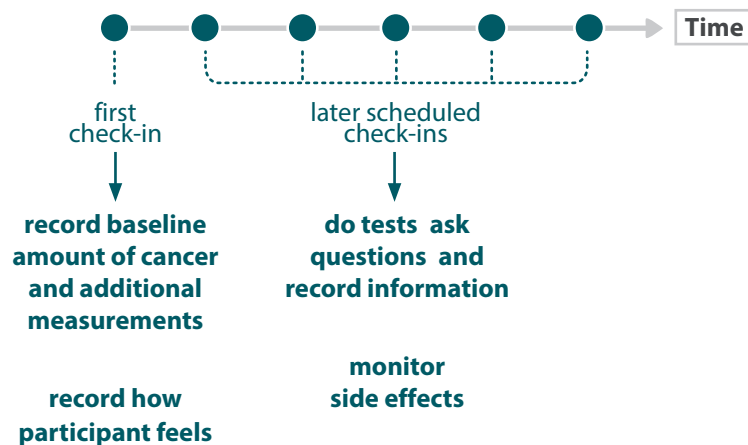
What do researchers record in clinical trials, and when?

Before a trial begins, researchers decide how often they will take measurements (like scans or blood tests). In order to take these measurements, they'll schedule regular check-ins with the participants.



At the first check-in, researchers will record a participant's starting amount of cancer, called the baseline amount of cancer, as well as other measurements. They will also record how a participant feels and what their daily activities are like. They will compare this information to what happens later in the trial.

At check-ins, researchers will do tests ask questions and then record what they find. The tests and questions will be different depending on the type of disease and the treatment being studied. If a participant feels any change that is strange, worrisome or bothersome it will also be recorded as a side effect.



All of this information will help researchers determine how a new treatment may affect patients in the future.

In the next level we will take a closer look at how treatment benefits and risks are measured.





level

3

**Taking a closer look at what
clinical trials measure**

Level 3

Taking a closer look at what clinical trials measure

Treatment goals for every patient are unique. Your healthcare team will look at the clinical trial results that are important to your goals. By understanding the different ways the results are measured, you can have a more complete picture of how a treatment may affect you.

How are risks and benefits measured in clinical trials? And how does that information help me?



Trials look at a lot of things, like how much a treatment has lowered the amount of cancer or how long a person has lived without the cancer getting worse.

The experiences other patients have had in clinical trials will give us clues to how it may work for you.

What types of measurements are there?

For every participant in a clinical trial, there are two common types of measurements that researchers usually take to evaluate benefits:

Amount



change in the
amount of cancer

Time



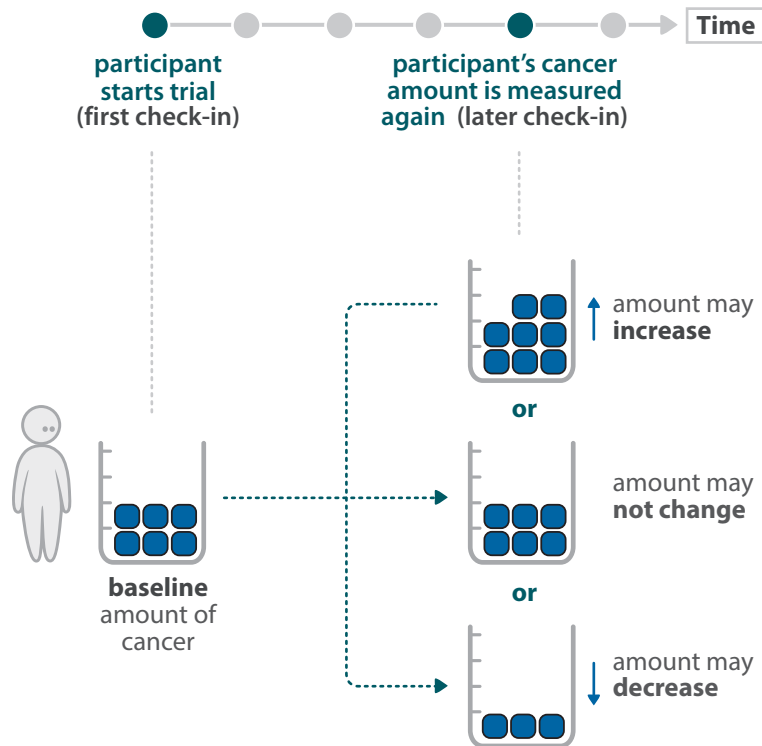
time it takes
to experience a change

In addition to measurements of benefit, side effects are also captured from each clinical trial. The results of benefit and side effect measurements are analyzed and reported as clinical trial results.



How do researchers figure out the change in the amount of cancer?

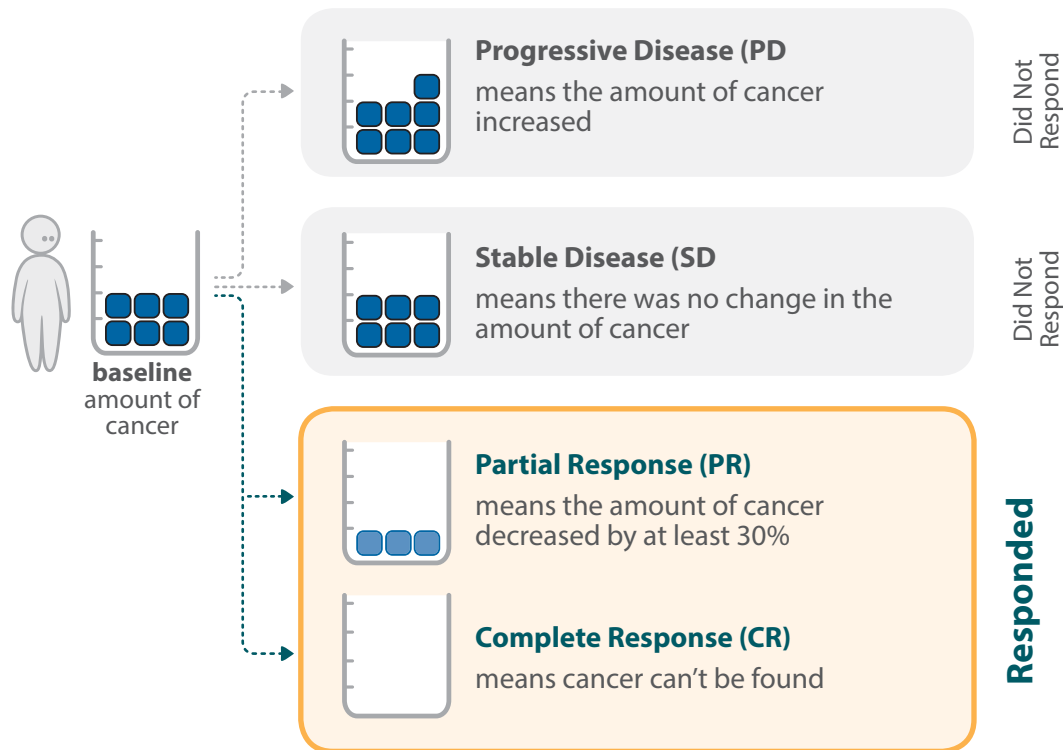
In clinical trials, researchers measure the change in the amount of cancer by looking at the difference between the baseline amount, taken at the first check-in, and the amount of cancer at a later check-in.



At the scheduled check-ins, researchers will measure if there was an increase, a decrease, or no change in the amount of cancer. This measurement helps researchers see if a clinical trial participant has had a response to the treatment that is being studied.

What does “response to treatment” mean?

When researchers say that a participant responded to treatment, they mean that the participant’s amount of cancer decreased by at least half of the baseline amount. A clinical trial participant can fall into any of the following categories:



It is important to know that each participant’s baseline amount of cancer is different. The researchers will record each participant’s category of response based on their individual starting amounts.

How are these measurements reported?

First, the researchers add the partial respondents and the complete respondents to get the total number of participants who responded to treatment. Then, they divide this number by the number of all participants in the trial.

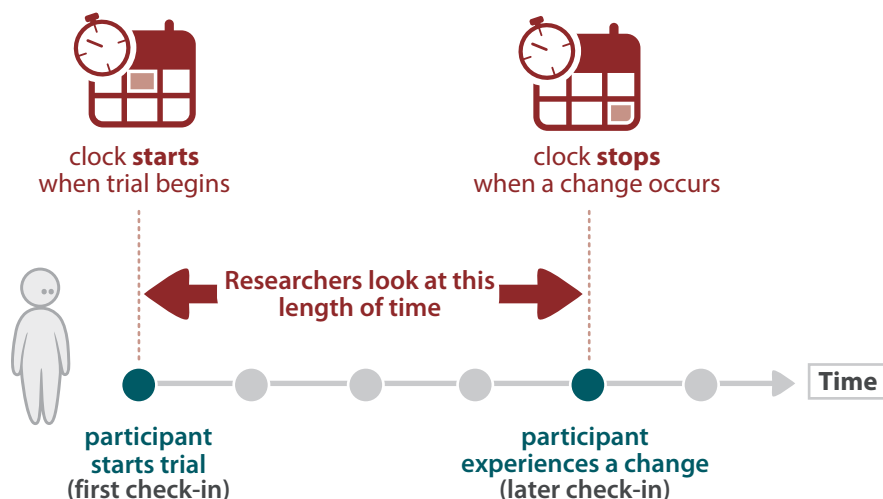
The result is a percentage called the Objective Response Rate (ORR) — number of people who responded to treatment out of all trial participants.

$$\frac{\text{number of respondents PR+CR}}{\text{number of all participants}} = \text{ORR (\%)}$$



How do researchers figure out the **TIME** for a change to occur?

In addition to measuring amount of cancer, researchers will also measure time by starting the clock when the trial starts and then stopping the clock when a participant experiences a change.



What does “experience a change” mean?

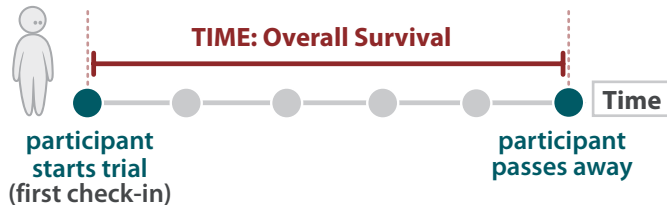
When measuring time, researchers consider that a change has occurred when there has been either an increase in the amount of cancer or the participant passed away.



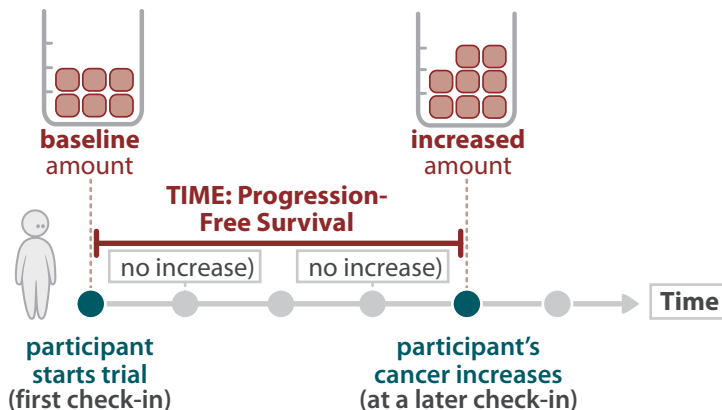
It is important to know that in addition to evaluating benefit researchers also monitor the side effects. They record specific measurements (such as laboratory results) as well as information about how the participant feels.

What time-related measurements do researchers take?

One measurement that researchers take is the length of time a participant lives while in a trial. This length of time is called Overall Survival. This measurement does not look at changes in the amount of cancer.



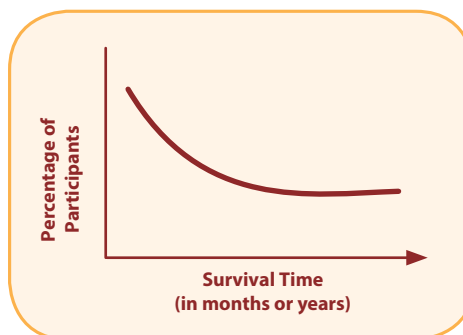
Another measurement is the length of time a participant lives without the cancer increasing while in a trial. This length of time is called Progression-Free Survival. This measurement does require researchers to consider the amount of cancer.



How are these measurements reported?

The researchers collect everyone's survival information and turn it into a graph.

This information is reported as Overall Survival and Progression-Free Survival results, usually shown in months or years.



In the next level we will see how clinical trial results are used to evaluate treatments.





My Notes

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level

4

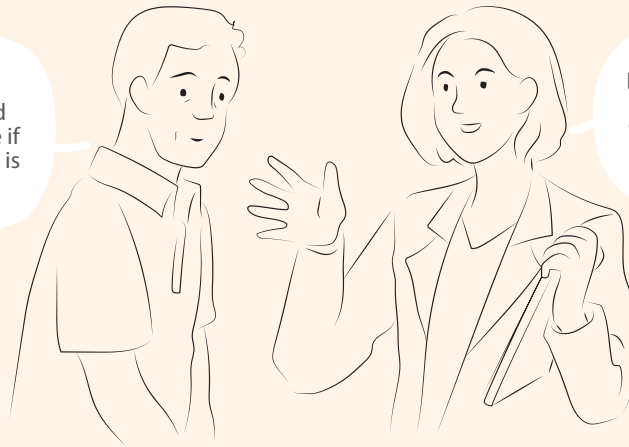
**Evaluating a treatment
using clinical trial results**

Level 4

Evaluating a treatment using clinical trial results

Your healthcare team will look at clinical trial results to see if a new treatment, like immuno-oncology (I-O), may work for you. They will look at the big picture and also focus on the details of the results that may apply to your treatment goals.

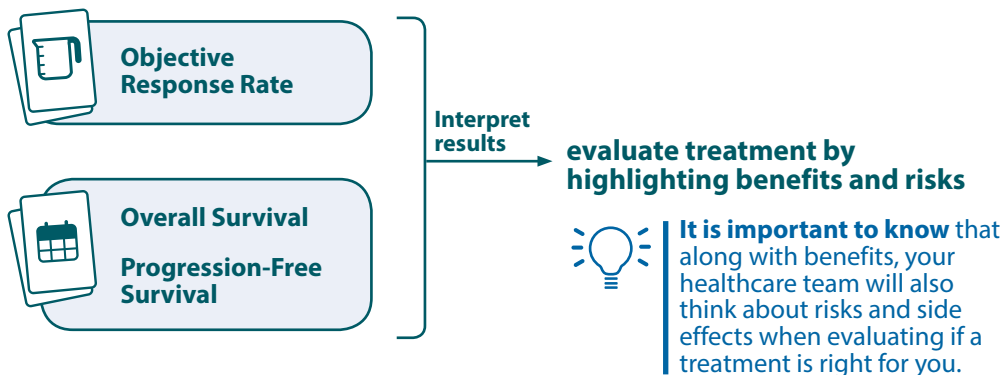
So what in the research should we look at to see if an I-O treatment is right for me?



Let's look at the details in clinical trial results, since they can reveal potential I-O benefits and risks...

How does my healthcare team use clinical trial results to evaluate treatment benefits?

Your healthcare team will examine the amount-related and time-related results together. They will interpret this information and highlight the details that will be most helpful in improving your treatment plan. These details will also reveal if you may be eligible for a clinical trial.



How does my team interpret **Objective Response Rate (ORR)** to evaluate treatments?

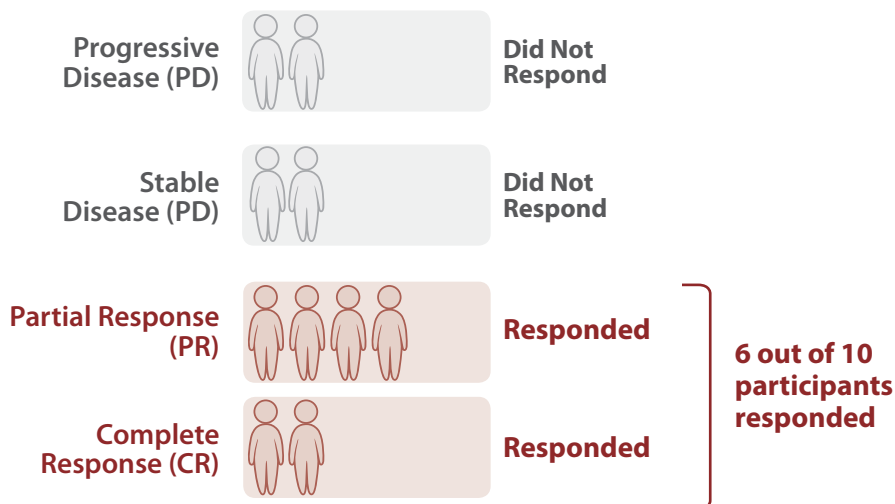
Researchers count up the number of participants who responded to treatment — the sum of all partial responders (PR) and complete responders (CR). The Objective Response Rate (ORR) is a percentage that represents all the participants who responded to treatment in the trial.

Let's walk through an example clinical trial.

Imagine there were 10 participants who received treatment:



By the end of the trial, the researchers measured the following:



In this trial a total of 6 out of 10 participants responded to treatment. So, the Objective Response Rate result is published as "ORR is 60%."

Your healthcare team will read the published ORR results and look at how many participants responded to treatment and how many did not. They will explain and discuss how the results may apply to you.



It is important to know that all participants may respond differently. The baseline amount, how long the response lasts, and how well the participant feels will also be taken into consideration.

What other response-related information will my healthcare team look at?

In addition to looking at the Objective Response Rate (ORR) results, your healthcare team will also consider the following:

- If a participant responded, how long did the response last?
- What was their quality of life like?
- Was there any change in their daily activities?



Immuno-oncology (I-O) and Response

Sometimes, it can take a while before you see a response with I-O treatments. This can be because I-O needs to help your immune system first. Then, your immune system can fight cancer.

To fully evaluate I-O's benefits and risks, it is important for your team to look at what happens after a recorded response.

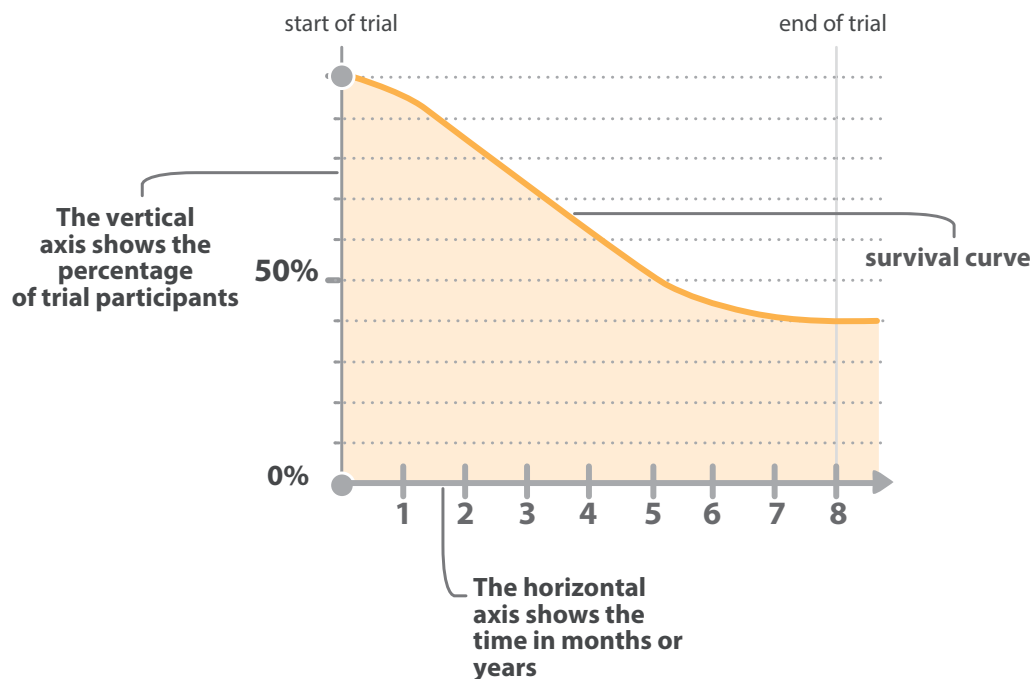


How does my team interpret Overall Survival (OS) and Progression-Free Survival (PFS) to evaluate a treatment?

Recall that Overall Survival (OS) is the length of time from the start of trial until a participant passes away. Progression-Free Survival (PFS), on the other hand is the length of time a participant lives without the cancer increasing.

To analyze everyone's OS measurements, researchers draw them as a curve on a graph. They draw another curve for PFS measurements. They publish these curves as results for your healthcare team to look at and discuss with you.

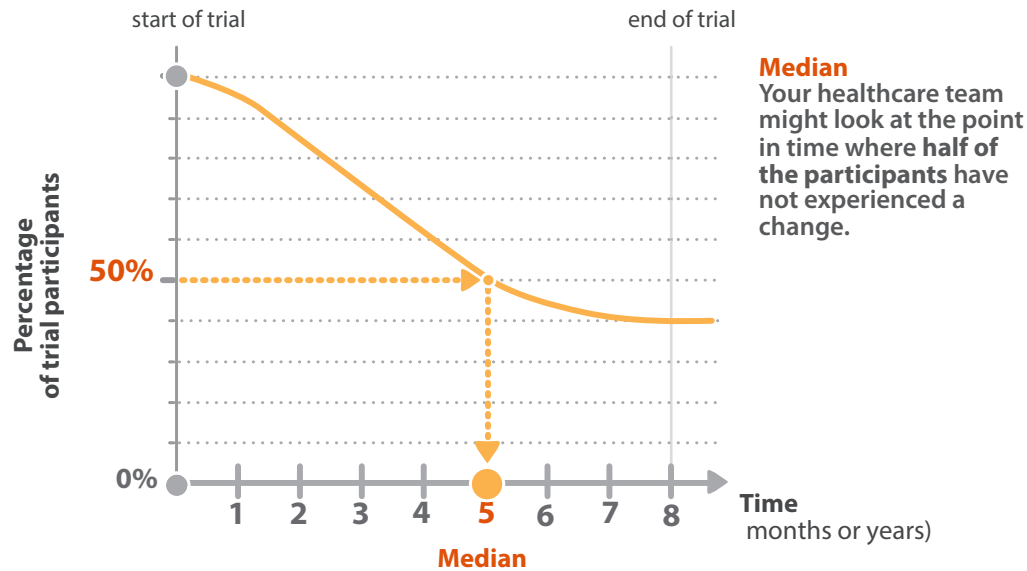
Let's look at a "survival curve" that researchers drew in an example trial. The researchers created one curve for OS and another curve for PFS. Either of the curves might look something like this:



Your healthcare team will look at the survival curves and will evaluate the curve as a whole, as well as certain time points in the trial.

What is the common way of analyzing survival curves from clinical trials?

The common way of analyzing survival curves from clinical trials is to look at the point in time where half the participants (50%) were living without experiencing a change — the median.

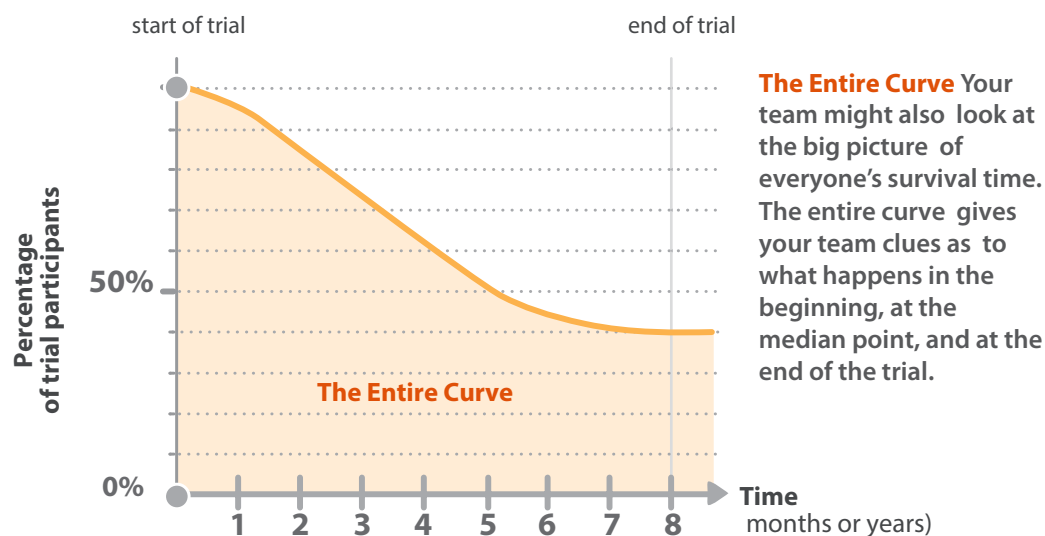
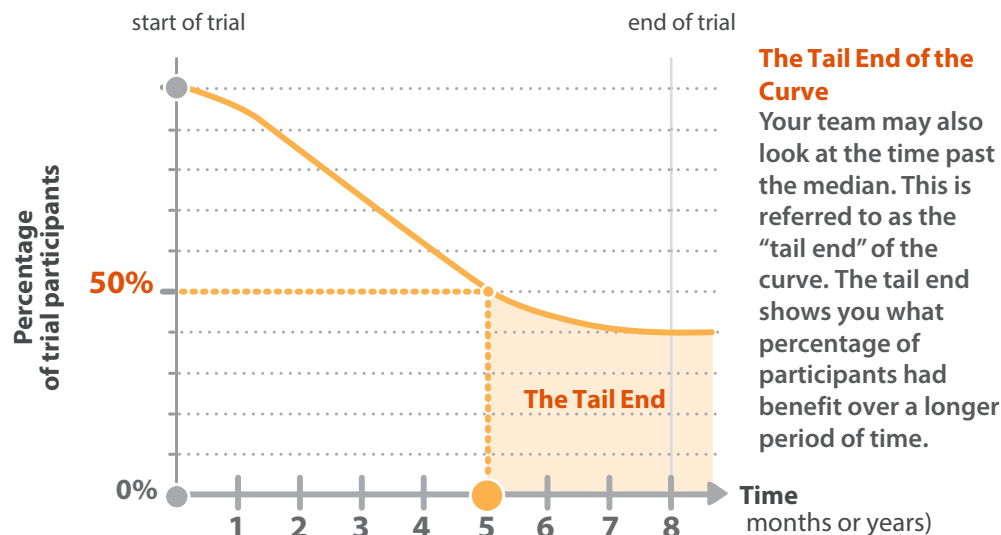


Immuno-oncology I-O) and the Survival Curve

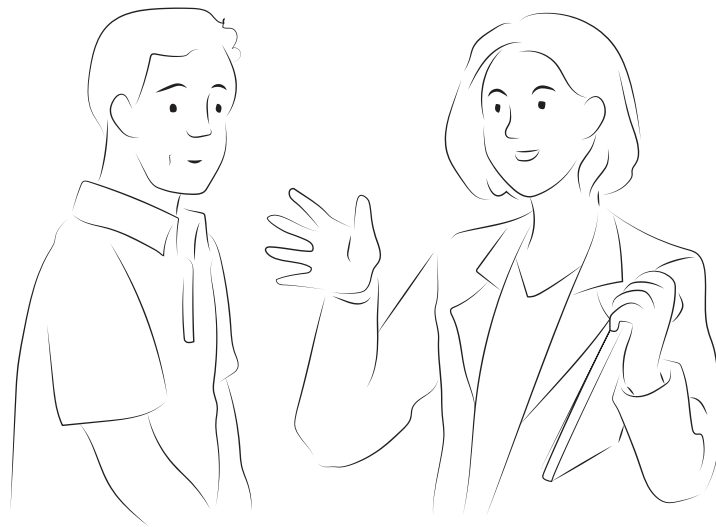
Immuno-oncology therapies work differently than other traditional treatments. They help your body's immune system fight cancer. The benefit of I-O may be seen over a longer period of time. Therefore, it is important for your healthcare team to look past the point at which half the patients have not experienced a change to what happens later on.

What other information on the survival curve can my healthcare team look at and analyze?

With newer treatment modalities, like immuno-oncology the benefit may be seen over a longer period of time. Therefore it is important for your healthcare team to look at additional aspects of the survival curves, like the tail end and the entire curve.



Your healthcare team will look at all of the clinical trial results along with the collected safety information, to make a more educated treatment decision.



This resource clarified key concepts about immuno-oncology and clinical trials to help you have a meaningful conversation with your healthcare team.

Talk to your healthcare team about how immuno-oncology may work for you, and if you may be eligible for upcoming immuno-oncology clinical trials.

Write down any notes or questions that you have about immuno-oncology and clinical trials.

Please bring your questions to your next appointment with your healthcare team.

