# Clinical trial summary

## A Study to Predict Which Patients Are at Greatest Risk for Side Effects from Immunotherapy Drugs

### What is the purpose of this clinical trial?

Many people with cancer get treated with drugs that act on their immune system. One common form of these drugs is called "immune checkpoint inhibitors." They are used for many types of cancer. But some people can have serious side effects from these drugs. This study aims to track the health of people taking these immunotherapy drugs and to record what side effects they have. The goal is to learn who is at greatest risk for serious side effects. The study team will try to learn what signs to look for to know whether a person is likely to have such side effects in the future.

**This trial is set up to find out:**

- How to predict who is at risk of developing serious side effects during their first year of taking immunotherapy drugs
- How often people taking these drugs have side effects from them
- How immunotherapy treatments can affect patients' lives

### Why is this trial important?

Immune checkpoint inhibitor drugs are used to treat melanoma, kidney, lung, and many other cancers. People who have serious side effects from them sometimes need to stop treatment. This trial aims to make it easier for doctors to know who is most likely to have serious side effects. This will help doctors and patients decide which treatment is best and who should be monitored closely.

### Who can be in this trial?

This trial is for adults 18 years or older being treated for a solid tumor cancer.

**This trial is for people who:**

- Will be getting an immune checkpoint inhibitor as standard treatment for a solid tumor cancer
- Can read and complete patient questionnaires in English, Spanish, or French about their symptoms

**This trial isn't for people who:**

- Will also be getting chemotherapy, biological therapy, or targeted therapy treatment at the same time as the immune checkpoint inhibitor
- Stopped treatment with immune checkpoint inhibitors in the past because of serious side effects
- Are still having bothersome side effects from any past cancer treatment

The study team will discuss these and any other requirements with you.

## What can I expect during the trial?

This trial is *not* testing a new treatment. You will get the standard immunotherapy treatment you and your doctor have chosen. You will also complete three questionnaires that ask about your health, your medical history, what medicines you take, and how you feel emotionally and physically. You will complete these questionnaires before starting your treatment and then up to four additional times during your first year of treatment. You will visit your doctor regularly during that year for about an hour each visit. During some of your visits, you will be asked if you want to give blood samples for the study.

## What is the time commitment?

Your participation in the study will last for one year.

## Are there costs? Will I get paid?

You may have extra data charges from your service provider if you complete study questionnaires using your phone or tablet. The drugs prescribed by your doctor are the standard treatment for your cancer. Please check with your health care provider and insurance provider to find out what costs of your treatment will – and won't – be covered. You will not be paid for joining this study.

## Where can I find more information about this trial?

- For more information about this trial, speak with your health care provider or call the National Cancer Institute at **1-800-4-CANCER**.
- Go to **www.ClinicalTrials.gov** and search using **NCT04871542**.

## Reference information

**Protocol number:** S2013

**NCT number:** NCT04871542

**Full trial title:** Immune Checkpoint Inhibitor Toxicity Risk Prediction in Solid Tumors

**Other trial names:** I-CHECKIT Trial

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** September 30, 2021

**Thank you!**

When you participate in a clinical trial,
you're moving cancer medicine and patient care forward.