

Clinical trial summary (S2013)

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 immunotherapy drugs, which help the body's immune system help fight cancer. One common type of immunotherapy drug is called **immune checkpoint inhibitors**. These drugs are used for many types of cancer. But they can cause serious side effects for some people.

This study will track the health of people taking immune checkpoint inhibitors and record what side effects they have. The goal is to learn who is most likely to have serious side effects and to identify signs that might predict future side effects.

This trial is set up to find out:

- How to predict who is at risk of serious side effects during their first year of taking immune checkpoint inhibitors
- How often side effects occur in people who are taking immune checkpoint inhibitors
- How treatment with immune checkpoint inhibitors can affect patients' lives



Why is this trial important?

Immune checkpoint inhibitor drugs are used to treat melanoma, kidney, lung, breast, gastrointestinal and other cancers. Sometimes, people need to stop treatment due to serious side effects. 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, age 18 or older, who are 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 complete study surveys in English, Spanish, or French

This trial is not for people who:

- Will also be getting another type of immunotherapy or targeted therapy while they receive immune checkpoint inhibitor treatment
- 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

Talk with your doctor to learn more about who can join this study.



What can I expect during the trial?

This trial is **not** testing a new treatment. You will get the standard immune checkpoint inhibitor-based treatment that you and your doctor have chosen.

You will be asked to complete surveys for the study about your physical and emotional health, the foods you eat, what medicines you take, and your medical history. You will complete the study surveys several times during your first year of treatment. You will have regular visits with your doctor during that year. Each visit will last about 1 hour. You will also be asked if you want to give blood and stool samples for the study.



How long will I be in the trial?

Your part in the study will last for about 1 year.



Are there costs? Will I get paid?

If you use your phone or tablet to complete the study surveys, you may have extra data charges from your service provider. The drugs prescribed by your doctor are a standard treatment for your cancer. Check with your health care provider and insurance provider about what costs will and won't be covered in this study. You will not be paid for joining the study.



Where can I find more information about this trial?

- Talk with your health care provider
- Call the National Cancer Institute at **1-800-4-CANCER**
- Go to www.ClinicalTrials.gov and search the national clinical trial number: **NCT04871542**
- For a list of trial locations, visit swog.org/NCI-S2013



Key information This trial is for adults 18 years or older being

Protocol number: S2013

NCT number: NCT04871542

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

Trial sponsor: SWOG Cancer Research Network

Other trial names: I-CHECKIT Trial

Publishing date: November 15, 2024

Thank you!

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