

# Clinical trial summary (S2107)

## Adding the Drug Nivolumab to Usual Treatment for Colorectal Cancer That Has a *BRAF* Gene Change



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

This study will test treatment for colorectal cancer that has a certain change in the *BRAF* gene. This gene change in cancer cells can cause them to grow and spread faster. Finding the *BRAF* gene change gives doctors more information about how to treat your cancer. If initial treatment doesn't work, people with this type of colorectal cancer may receive further treatment with a combination of 2 drugs, encorafenib and cetuximab. Researchers want to learn if this treatment can be improved by combining it with the study drug nivolumab.

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

- If adding the study drug to usual treatment lets people stay on treatment longer before their cancer gets worse
- How patients with this type of colorectal cancer respond to treatment with the study drug compared to treatment without the study drug
- How safe it is for patients to receive the study drug with usual treatment



### Why is this trial important?

Nivolumab is an immunotherapy drug that may help your immune system attack the cancer. The drug is approved by the Food and Drug Administration (FDA) to treat certain types of colorectal cancer. Adding it to the usual treatment for colorectal cancer that has a *BRAF* gene change may work better than the usual treatment alone.



### Who can be in this trial?

This trial is for adults, age 18 and older, with colorectal cancer that has a *BRAF* gene change.

#### This trial is for people who:

- Have cancer that cannot be removed with surgery or has spread to other places in the body
- Have had chemotherapy treatment for their cancer
- Have cancer that lab testing shows is microsatellite stable (MSS)

#### This trial is not for people who:

- Have received certain targeted therapy or immunotherapy drugs for their cancer
- Have inflammatory bowel disease or autoimmune disease
- Have heart problems or poor liver, kidney, or bone marrow function
- Have HIV or an active hepatitis C virus infection
- Are pregnant

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



## What treatments would I get?

A computer will randomly assign you to one of 2 study groups.

**Group 1:** Usual treatment with the drugs encorafenib and cetuximab

**Group 2:** Usual treatment with the drugs encorafenib and cetuximab, plus the study drug nivolumab

More people will be assigned to Group 2 than Group 1. You will have a 2 in 3 chance of being in Group 2. You will have a 1 in 3 chance of being in Group 1. Your doctor will not have control over which group you will be assigned to. This helps make sure the study results are fair and reliable.



## How long will I be in the trial?

You will be in the study for 3 years. Your study doctor will closely watch you for side effects and watch how your cancer responds to the treatment. You may continue treatment until it stops working or you have side effects that are too severe. You may choose to stop treatment for any reason at any time.

If you stop getting treatment, you will have follow-up visits with the study team until 3 years after you started the study.



## Are there costs? Will I get paid?

The study drug, nivolumab, is provided free to you. You will not be paid for joining the study. Check with your health care provider and insurance provider to find out what costs will and won't be covered in this 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](http://www.ClinicalTrials.gov) and search the national clinical trial number: **NCT05308446**



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

**Protocol number:** S2107

**NCT number:** NCT05308446

**Full trial title:** Randomized Phase II Trial of Encorafenib and Cetuximab with or without Nivolumab (NSC #748726) for Patients with Previously Treated, Microsatellite Stable,

BRAFV600E Metastatic and/or Unresectable Colorectal Cancer

**Trial sponsor:** SWOG Cancer Research Network

**Publishing date:** June 7, 2022

**Thank you!**

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