

Learn about a clinical trial for Gastrointestinal Cancers

In this brochure, you will learn about several types of cancers

that affect the **gastrointestinal tract** and a clinical trial for these diseases. In this trial, researchers are trying to find out if the investigational medicine, patritumab deruxtecan, is safe and may help slow down or stop these cancers.

You can also use this brochure to talk

with your doctor about this

trial.

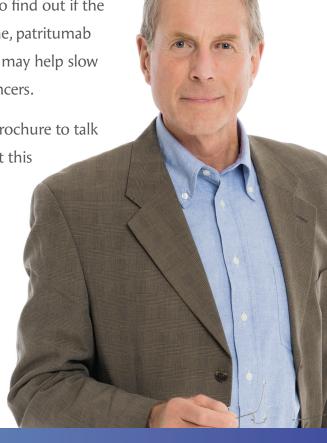


Table of contents

- What is cancer?
 - What are my treatment options?
- What is a clinical trial?
- All about this clinical trial
 - What is the goal of this trial?
 - About patritumab deruxtecan
 - Another way to think about patritumab deruxtecan
- Who can join this trial?
- If I join, how long will I be in the trial?
- What will happen during trial visits?
- What treatment will I get?
- Notes

What is cancer?

Cancer is when abnormal cells start to grow out of control. Cancer can start in any part of the body and can then spread to other areas of the body. If you are diagnosed with cancer your doctor will likely do multiple tests which may include scans and a biopsy to find out the staging (Stage 0-IV) of the cancer.

This trial is looking at multiple gastrointestinal cancers including:

- **Colorectal Cancer (CRC)** A cancer that begins in the last part of the digestive tract-colon (large intestine) and rectum.
- **Biliary Tract Cancer (BTC)** A cancer that begins in the slender tubes (bile ducts) that carry the digestive fluid, bile.
- Hepatocellular Carcinoma (HCC) A cancer that starts in the liver.



What are my treatment options?

If you have one of the gastrointestinal cancers listed in this brochure, your care team will talk about your treatment options with you and those close to you.

Your options will depend on a few things:

- Your overall health
- The stage of your cancer, which tells you if the cancer has spread and how far
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of slowing down or stopping the cancer
- How long the treatment might help extend your life
- How much the treatment might help improve your symptoms

Your care team may offer you 1 or more of these treatments:

- Local therapies treatment directed at the site of the cancer to destroy it
- **Targeted therapy** treatment that works on specific cells to stop them from growing
- **Immunotherapy** medicines that help your immune system fight the cancer
- Chemotherapy medicine to kill cancer cells or stop them from growing
- Radiation therapy treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. This would only be used to treat symptoms related to tumor growth.
- **Palliative care** also called comfort care. This is special care to help ease pain and symptoms with a focus on the person's quality of life. This does not directly treat the cancer but it helps keep you as comfortable as possible.
- Clinical trials, such as this one

Talk to your doctor to find out which treatment is right for you.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if trial drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational treatments and procedures.

All about this clinical trial

What is the goal of this clinical trial?

This trial is being done to learn:

- Whether the investigational medication is safe.
- If the investigational medicine can slow down or stop the growth of the gastrointestinal cancers included in this trial.

Patritumab deruxtecan is experimental. It has not been approved for treating cancer. Researchers don't know if this investigational medicine works to treat these gastrointestinal cancers.

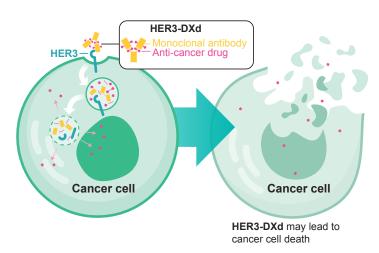
About patritumab deruxtecan:

Patritumab deruxtecan (also known as HER3-DXd) is a type of investigational targeted therapy known as an antibody drug conjugate (ADC) that may destroy cancer cells. Unlike traditional chemotherapy, ADCs have 3 parts:

- A monoclonal antibody: A protein that binds to specific receptors found on certain types of cells, including cancer cells. In this case, the specific receptor is HER3
- An anti-cancer drug: A type of drug that may lead to cancer cell death
- Linker: Connects the anti-cancer drug to the monoclonal antibody

Another way to think about patritumab deruxtecan:

- 1. HER3 receptors are involved in how cells in the body grow and survive. These receptors are more common in some cancer cells.
- 2. The monoclonal antibody in patritumab deruxtecan finds and binds to the HER3 receptor on cancer cells which brings it inside the cancer cells.
- **3.** Once inside, patritumab deruxtecan breaks down and releases an anti-cancer drug that may lead to the cancer cell death.
- **4.** The anti-cancer drug may get released from the targeted cancer cells and enter nearby cancer cells without HER3 and cause these cells to die as well.



Who can join this trial?

There are eligibility criteria that will determine if you will quality for participation.

To join this trial, you must have:

 Been diagnosed with colorectal, biliary tract cancer, or hepatocellular cancer.

Your trial staff will do tests to see if you are able to join this trial.

You and your trial doctor will discuss:

- All the requirements to join this trial
- Possible benefits, risks, and side effects of being in this trial

If I join, how long will I be in the trial?

How long you will be in the trial depends on:

- Your health
- How well you tolerate the investigational drug, patritumab deruxtecan

The trial has 3 phases:

Screening: First, the trial staff will see if you can be in the trial. This is called the Screening Phase and will last about 1 month. During this time, you will visit the site 1 or more times.

Treatment: If you can be in the trial, the next step is the Treatment Phase. You can be in the Treatment Phase as long as your cancer does not get worse and you tolerate the investigational trial drug.

♦ You will visit the trial site a total of 7 times during the first 9 weeks of treatment. After that, you will visit the trial site once every 3 weeks.

Follow-up: After you stop getting the investigational trial drug, you will enter the Follow-up Phase.

♦ You will have about 1 to 2 visits after you stop getting the investigational trial drug. You will then have follow-up visits about every 6 weeks until you have been in the trial a total of 48 weeks, and then every 12 weeks after that. The trial doctor or staff will also contact you on the phone to check on your health.

What will happen during trial visits?

You will visit the trial site on a regular schedule so that the trial doctors can see how the investigational drug is working for you.

During your trial visits, you may get:

- The investigational medicine
- Survey questions
- Blood and urine (pee) tests
- Physical exams
- Imaging scans such as CT scans and MRIs (scans that help the doctor see the cancer inside your body)

You can ask your trial doctor any questions you have about what happens during trial visits and how often they will happen.

If you are able to join the trial, your trial doctor will need to stay in contact with you even after your trial visits are over. This is very important because this clinical trial is studying how well the trial treatment works over time.

What treatments will I get?

Everyone in this trial will get the investigational drug, patritumab deruxtecan, no matter which type of cancer you have (Colorectal, Biliary Tract or Hepatocellular Cancer). You, your trial doctor, and the trial staff will know you are getting patritumab deruxtecan. Patritumab deruxtecan is given by a needle in a vein. This is called intravenous (IV) infusion. It is given every 3 weeks.

Patritumab Deruxtecan as a Standalone Treatment	
Colorectal Cancer	
Biliary Tract Cancer	
Hepatocellular Cancer	



Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

Thank you for taking the time to learn about these cancers and this clinical trial

You can use this brochure to talk with your doctor about this trial.

Your questions and notes:
You can use this space to write down notes or questions about this trial.

To learn more

To learn more about this trial, you can:

- Talk to your doctor
- Contact Merck by
 - o Visiting www.merckoncologyclinicaltrials.com
 - o Scanning this QR code:







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For more information, contact our research staff: