

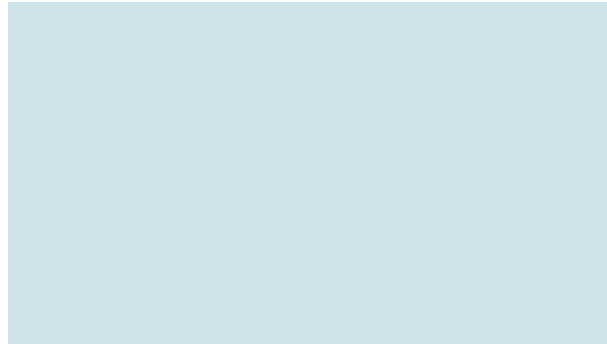


What are clinical research studies?

Clinical research studies help scientists and doctors explore whether a medical strategy, device, drug, or therapy is safe and effective for people. These studies are important because they help identify which medical approaches work best for specific illnesses in specific groups of people.

Participation in clinical research is voluntary, and participants can leave a study at any time. If you decide to join the LEGEND substudy, there is no guarantee that the study drug will improve your bladder cancer, but what researchers learn may lead to better cancer medications in the future.

For more information about the LEGEND substudy, contact:



Do you have bladder cancer that is high risk OR has not responded to therapy?

You may be able to join the LEGEND substudy, which is testing a gene therapy and a bladder rinse in people with non-muscle invasive bladder cancer (NMIBC).

LEGEND



What is the LEGEND substudy?

The LEGEND substudy is a clinical research study designed to test whether 2 study drugs (a gene therapy and a bladder rinse) can safely help the body destroy cancer cells and delay or prevent bladder removal for people with NMIBC. It is a substudy because there is also a main study, which is only testing 1 of the study drugs (the gene therapy without the bladder rinse).

What are the study drugs?

EG-70 The main investigational* study drug, EG-70, is a type of gene therapy. It includes tiny pieces of DNA, called genes, that are intended to give the immune system new instructions on how to recognize and fight cancer cells. EG-70 is a *non-viral* gene therapy, which means it does not use a modified virus to get into cells and deliver the DNA, like many other gene therapies.

Polidocanol The other investigational* study drug, polidocanol, is being tested as a bladder rinse. It is an existing drug, but this is the first time it is being used in the bladder to find out if it helps EG-70 work better.

Dosing

Study participants will receive polidocanol (the bladder rinse) directly into the bladder through a temporary tube called a catheter. Then, through the same catheter, participants will receive EG-70.

**Investigational* means the drug has not been approved by any regulatory authority to be used for the treatment of bladder cancer.

- EG-70 has not yet been approved for any condition.
- Polidocanol is approved for some medical uses, but it is investigational as a bladder rinse.

Who can join the study?

You may be able to join the LEGEND substudy if you meet the following study requirements:

- 18 years of age or older
- Diagnosed with NMIBC (bladder cancer that has not extended into the bladder muscle) that is considered high risk OR that did not respond to, or returned after, BCG therapy (Bacillus Calmette-Guerin), which is an immunotherapy drug infused in the bladder and sometimes used to treat NMIBC

Other study requirements will apply.

What can study participants expect?

If you join the LEGEND substudy, your active participation may last up to 144 weeks (about 2 years and 9 months). If you stop taking the study drugs before this, you may have up to a year of follow-up. The substudy is divided into the following periods:



Screening (up to 4 weeks)

- You will have study tests and procedures to find out if you can be in the substudy.



Study Drug (up to 144 weeks)

- You will receive at least 1 cycle, and as many as 12 cycles, of the study drugs. One cycle is 12 weeks.
- **Initial Study Drug Period** (Cycles 1 to 4): You will receive the study drugs once a week for the first 2 weeks of each cycle and once again in the fifth and sixth week of each cycle.
- **Study Drug Maintenance Period** (Cycles 5 to possibly 12): If the cancer has not come back at the end of the first 4 cycles, you will continue for Cycles 5 to 12. You will receive the study drugs once a week for the first 2 weeks of each cycle.
- You will have regular study visits for tests and procedures, including a cystoscopy, urine cytology, and/or a bladder biopsy near the end of each cycle to find out the status of the cancer and whether you can continue with the next cycle.



Follow-up (up to 1 year)

- Once you stop taking the study drugs, you will have a study visit at Week 12 of your final cycle, and you may have a follow-up visit 8 weeks later.
- You will also have follow-up visits either by phone or in person every 3 months.
- You may also have a visit 1 year after the first test showing the cancer did not come back, if applicable.