

What is a clinical research study?

Clinical research studies help scientists and doctors explore whether a drug is safe and whether it works. Before a doctor can prescribe a new drug, it must go through several phases of clinical research:



Phase 1:

First study of the drug in people



Phase 2:

Study of the drug in people with the medical condition the drug is seeking to treat



Phase 3:

Study confirming how well the drug works



Phase 4:

More research after the drug is approved

The LAUREL study is a Phase 1 and Phase 2a study. The phase you join (1 or 2a) depends on when you enroll.

Clinical research studies rely on volunteers. Remember that taking part in the study is your choice. Know that the rules and ethics that doctors must follow to practice medicine also apply to clinical research studies.



For more information about the LAUREL study, visit nmibcclinicaltrial.com or contact:



When bladder cancer returns, you want to know your options.

Find out if the LAUREL study is an option for you. The study medicine may be a way to slow or stop the return and/or spread of cancer after bladder surgery to remove a tumor.





What is the LAUREL study?

The LAUREL study is a clinical research study for adults with non-muscle invasive bladder cancer (NMIBC) who need transurethral resection of bladder tumor (TURBT). The goal of the study is to find out if the study medicine is safe and does not cause too many side effects when delivered directly into the bladder. Researchers also hope to learn how the body processes the study medicine. The study medicine has been given to people in other clinical studies, and no safety issues are known so far, but more testing is needed.



Who can join the study?

The LAUREL study is for people who meet the following requirements:

- 18 years of age or older
- Diagnosed with Ta or T1 NMIBC without carcinoma in situ (CIS)
- Cancer returned after standard-of-care therapy
- Planning to have TURBT without chemotherapy

Other requirements apply. Ask your doctor if you qualify and if the LAUREL study is a good option for you.

What is the study medicine?

The study medicine is an immunotherapy, which means it is designed to stimulate the body's immune system to help slow or stop the return and/or spread of cancer. While surgery is an important part of cancer care, the healing process after surgery can make it difficult for the immune system to work as well as it should. The study medicine may be able to help the immune system do a better job targeting cancer cells. It is given as a one-time injection directly into your bladder muscle right after TURBT.

The study medicine is an investigational medicine. *Investigational* means it has not been approved by any health or regulatory agencies, and no one knows whether it will work.

What can study participants expect?

The study is divided into periods:

<p>Screening (up to 28 days)</p>	<ul style="list-style-type: none"> • Have study assessments to find out if you can be in the study
<p>TURBT and study medicine (1 day)</p>	<ul style="list-style-type: none"> • Have your TURBT procedure • Receive an injection of the study medicine • Have study assessments
<p>Follow-up (90 days or 2 years, depending on when you enroll)</p>	<ul style="list-style-type: none"> • If you enroll during Phase 1 or 2a, you will have some study visits during the 90 days after TURBT for follow-up study assessments • If you enroll during Phase 2a, you will also have study visits every 3 months for about 2 years, which is in line with typical standard-of-care follow-up