

Do you or someone you know have advanced kidney cancer?

This study is for kidney cancer patients with papillary, unclassified, and translocation-associated subtypes

Learn more about the STELLAR-304 Study

Patient Information

What is a clinical research study?

A clinical research study helps to answer important questions about a medicine that is still being tested, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All medicines must be tested in clinical research studies before they can be approved to give to patients. Without people taking part in these studies, we would have no new medicines.

Some potential benefits of taking part in a clinical research study may include:

- having access to a potential new treatment that you cannot receive outside of the study
- being closely monitored by a medical team
- helping researchers to learn more about cancer to help people in the future.

Clinical research studies should include all kinds of people because certain conditions and medicines may affect people differently based on their age, sex, gender, and race/ethnicity.



Taking part in a clinical research study is an important decision. To see if you can participate or if you have any questions, please contact the study team using the information provided in this brochure.

About the STELLAR-304 Study

The STELLAR-304 Study is looking at whether a potential new (investigational) combination of medicines works for people with kidney cancer with papillary, unclassified, and translocation-associated subtypes. These subtypes of kidney cancer are also called non-clear cell renal cell carcinoma (nccRCC).

This study will compare the investigational combination that is not yet approved by health authorities, XL092 plus nivolumab, with a medicine that is already approved for renal cell carcinoma (RCC), called sunitinib. This is done to see how the investigational combination works compared with sunitinib.

Participants will be split into 2 groups at random. Twice as many participants will be selected for Group 1 as for Group 2.

- Group 1 will receive the investigational combination:
 XL092 plus nivolumab.
- Group 2 will take a medicine approved for advanced kidney cancer: sunitinib.

Why is this study important?

This study will help doctors and researchers learn more about the treatment options for nccRCC to potentially improve healthcare for people in the future.

What will this study involve?

If you decide to take part, you will be in this study for about 7 to 11 months. You may stop taking part in the study at any time. This study is made up of 3 parts.

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Study design



Pre-treatment period

- You will visit the study center to see if this study is right for you and if you want to take part.
- If you join the study, you will be assigned at random to Group 1 or Group 2.

groups
XL092 and nivolumab
sunitinib



Study treatment period

If you are in Group 1, you will:

If you are in Group 2, you will:

- receive nivolumab and XL092.
- visit the study center every 2 or 4 weeks for tests and to see how you are responding to the study medicine.
- take sunitinib.
- visit the study center once every 3 weeks for tests and to see how you are responding to the study medicine.



Follow-up and maintenance period

- After your last dose of study medicine, you will have 2 study visits with the study doctor.
- A member of the study team will contact you every 12 weeks until the study ends to check on your health.
- If you are benefiting from the study medicine, the study doctor will talk to you about the possibility of staying on the study medicine after the study ends.

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Who can take part?

People with kidney cancer may be able to take part if they:

- are 18 years of age or older.
- have a type of kidney cancer with papillary, unclassified, or translocation-associated subtypes.
- have cancer that doctors cannot remove surgically (unresectable) that is locally advanced or that is widespread (metastatic).

There are additional eligibility criteria you must meet to join the study.





What else do I need to consider?

- The study team will explain the possible benefits and risks of the study.
- You do not have to take part in the study if you do not want to.
- If you choose to take part in the study:
 - you can stop at any time
 - a team of doctors and nurses will monitor your health carefully during the study
 - you will receive all study medicines and study-related tests at no cost to you
 - you will not be paid to take part in this study but you may be paid back for reasonable travel costs during your participation.
- The study has been approved by an Institutional Review Board (IRB)/Ethics Committee (EC), which protects the rights, safety, and well-being of the participants.



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Scan the QR code to watch a video and learn more about this study

To learn more about the STELLAR-304 Study, please watch this short video (about 5 minutes) by following the instructions below:

- 1. Open the camera app on your smartphone and point it towards the QR code so that the image appears on your screen.
- 2. Click the notification that appears on your screen.
- 3. From there you will be able to access the video.

If you do not have a smartphone to scan this QR code, you can visit the website at: www.stellarkidneycancerstudy.com/video

Study participation is voluntary. By contacting us, you do not have to take part in the study.

Learn more about this study at www.clinicaltrials.gov and search for NCT05678673.

Or contact Exelixis Medical Information medinfo@exelixis.com.

You may also contact your local site: