

ForPatients

by Roche

Small Cell Lung Cancer Cancer Non-Small Cell Lung Cancer (NSCLC) Urothelial Carcinoma Hepatocellular Carcinoma (HCC)

A study to look at how well the drug called atezolizumab works (and how safe atezolizumab is) to treat different types of cancer in the real world, outside of controlled clinical trials

A Study Investigating the Outcomes and Safety of Atezolizumab Under Real-World Conditions in Patients Treated in Routine Clinical Practice

Trial Status

Active, not recruiting

Trial Runs In

32 Countries

Trial Identifier

NCT03782207 MO40653

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This is a non-interventional, multi-country, multi-centre, multiple cohort prospective study, with retrospective collection of prior medical/treatment history data from medical records, designed to assess the real-world outcomes and safety of atezolizumab for indications in the existing label in the real world setting of routine clinical practice.

Hoffmann-La Roche

Sponsor

N/A

Phase

NCT03782207 MO40653

Trial Identifiers

Eligibility Criteria:

Gender

All

Age

≥ 18 Years

Healthy Volunteers

No

How does the IMreal study work?

This is an 'observational' study collecting real-world data. This means that all treatment decisions will be made by your regular doctors and all of the data will be collected from your medical records.

This study is recruiting patients with different types of cancer to test how different cancers respond to therapy with atezolizumab. Currently the study is looking for patients with

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urothelial cancer, often called bladder cancer, lung cancer and a type of liver cancer called hepatocellular carcinoma (HCC).

Any patients with urothelial cancer must have been treated with chemotherapy before joining the study.

Patients with lung cancer will join one of four different groups based on their specific type of lung cancer:

- Patients with a specific type of lung cancer called non-small cell lung cancer (NSCLC) that has previously been treated with chemotherapy
- Patients with a special subset of NSCLC called non-squamous NSCLC that has not been treated before
- Patients with NSCLC (with high levels of a protein called PD-L1) that has not been treated before
- Patients with a type of lung cancer called small cell lung cancer (SCLC), that has not been treated before

Any patients with HCC must have unresectable disease (that cannot be completely removed with surgery), locally advanced or metastatic disease (that has spread to other parts of the body). They should not have received any previous systemic treatment (a kind of treatment that travels through the blood and can reach and affect cells all over the body) for their disease before.

The purpose of this study is to see how treatment with atezolizumab works in real life when doctors decide that it is the best treatment option for their patients. Another aim is to see how safe atezolizumab is in real life. This will help doctors to know how better to use atezolizumab to treat their patients.

How do I take part in this study?

To be able to take part in this study, you must have been diagnosed with urothelial cancer, lung cancer (either NSCLC or SCLC) or HCC that has spread to other parts of the body. Your doctor must have decided that atezolizumab is the most suitable treatment for your cancer. You must not have previously been treated with atezolizumab.

If you think this study may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to join this study, he/she will give you all the information you need to make your decision about taking part.

If you would like to join the study, you will need to agree to your data being collected from your medical records. The data that will be collected will be kept in your medical records whether or not you choose to join the study.

What treatment will I be given if I join this study?

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In order to join the study, you and your doctor must have decided that atezolizumab is the best treatment for your cancer. Therefore, you will be given atezolizumab whether or not you decide to take part in the study. The dose and length of treatment will be decided by your doctor and the guidelines for your area, and will not be affected by whether or not you decide to join the study. Your doctor will give you atezolizumab on its own or together with other medications, depending on clinical guidelines.

How often will I be seen in follow-up appointments, and for how long?

You will be given treatment in exactly the same way as you would be if you did not join the trial. This means that you will be given atezolizumab for as long as your doctor thinks it can help you and you will not have any extra hospital or clinic visits. You or your doctor are free to decide to stop this treatment at any time. After stopping treatment, you will still be seen regularly by your doctor as part of your regular care.

What happens if I am unable to take part in this study?

If this study is not suitable for you, you will not be able to take part. However, this will not affect the treatment that you are given by your doctor. You will not lose access to any of your regular care.

For more information about this study see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT03782207>

Trial-identifier: NCT03782207