

*All highlighted fields should be updated by the participating site as required.  
(To be printed on local hospital headed paper)*



A Randomised phase II trial of Enhancement of efficacy of Atezolizumab by Radiotherapy in Metastatic urothelial cancer

## **PATIENT INFORMATION SHEET**

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## **We are inviting you to take part in a clinical trial called RE-ARM**

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- Before you decide whether to take part, it is important for you to understand why this research is being done and what it would involve for you.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide if you wish to take part.
- You are free to decide if you want to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors in any way.
- You can decide to stop taking part in the study at any time without giving a reason.
- This information is designed to be read alongside discussions with your medical team. Ask your study doctor if anything is not clear or if you would like more information.

Thank you for reading this information and considering taking part in our research.

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## **How to contact us**

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If you have any questions about this clinical trial, please talk to your medical team. Their details are given on page **x** of the information sheet.

This study is coordinated by the research centre at The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU).

# Part One: About the RE-ARM trial

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## 1 Important information

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### What is the purpose of this study?

We want to find out if giving people radiotherapy while they're taking atezolizumab improves how well atezolizumab treats their cancer.

Atezolizumab is a type of cancer treatment called an immunotherapy. It works by enhancing the body's natural immune response to cancer. It works in about one in five (20%) of people who take it for advanced urothelial cancer.

Radiotherapy uses targeted beams of high strength x-rays to kill cancer cells. There is evidence that radiotherapy can enhance the body's natural immune response to cancer, so it may make drugs such as atezolizumab more likely to work.

Atezolizumab normally starts working in the first few weeks of treatment. However, even if initially there is no change ('stable disease') or the cancer spreads further (progresses) during the first few weeks of atezolizumab treatment, it can start working later on. This is called a late response. The RE-ARM study aims to find out if giving people radiotherapy while they are taking atezolizumab will increase the number who have a late response.

### Why am I being invited to take part?

You have been invited to take part in this trial because you are taking atezolizumab for cancer of the urinary system that has spread to other places in the body (advanced urothelial cancer). One hundred and two patients from around 20 UK hospitals will be invited to participate in RE-ARM.

### Do I have to take part?

No, it is up to you to decide whether or not to take part in RE-ARM. Your participation is entirely voluntary and you will be given sufficient time to decide if you wish to participate. Whether or not you decide to participate will not affect the standard of care you receive. If you do agree to participate you will be asked to sign a consent form. You are free to decide to end your participation at any time and you do not have to give a reason.

Provided you agree, your GP will be informed about your participation in this trial.

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## 2 What treatment might I have if I decide to take part?

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Everyone who agrees to join this research study will be included in one of two treatment groups:

### **Group 1: Atezolizumab only**

If you're in this group, you will continue to receive atezolizumab in the same way as you do at the moment, once every three weeks. You can carry on until you and your medical team decide you are no longer benefiting from the treatment, or for up to two years (whichever happens sooner).

### **Group 2: Atezolizumab with radiotherapy**

If you're in this group, you'll continue to receive atezolizumab every three weeks as described above for group one. You will also have radiotherapy to an area to which your cancer has spread. You would not normally receive radiotherapy as standard treatment outside of the trial. This will take place during the first three weeks of atezolizumab given after you join the study, and will be given for five consecutive days during one week. You will have to come to hospital each day for this. The radiotherapy treatment will take about 10 minutes each day.

### **Who decides what treatment group I'll be in?**

The only way to make sure that the people in the two groups are as similar as possible is to use a process called randomisation, where a computer randomly assigns you to one of the groups. This is because we need to be sure that if one group does better than the other, it is because of the treatment and not because the patients in the two groups are different from each other in some way. Randomisation ensures that the treatments can be compared fully and fairly. If you join the trial you will have an equal chance of being in group one or group two.

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## 3 What happens during the trial?

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### **What will my taking part in the trial involve?**

You will have at least a day to decide if you would like to take part in RE-ARM after the initial discussions with your medical team. If you decide to join the study you will be asked to sign the consent form at the end of this leaflet. You may need to have some additional blood tests and a CT scan before you can join the study, if you have not had these done recently as part of your current treatment. Your medical team will explain if this is the case. Any extra tests will only be done after you have agreed to take part and signed the RE-ARM consent form.

If your test results confirm RE-ARM remains a suitable option for you, your medical team will telephone the research centre responsible for coordinating the trial. The centre will then record your details and tell your medical team which treatment group you will be in and provide a unique number called a Trial ID. Your medical team will then let you know as soon as possible which

treatment group you are in. Whichever treatment group you are in, you will be treated with the best possible care.

A summary of these initial assessments are outlined below:

Assessment	Further details
Review of your medical history	To check that you are suitable to enter the study.
Medication assessment	A list will be taken of all the medications you are taking including prescription and over-the-counter vitamins and alternative medications.
Collection of blood samples	To measure your full blood count and your liver, kidney and thyroid function.
CT scan	To record where your cancer is and its size.

### What if the tests show that the study is not suitable for me or I decide that I do not want to take part?

If the tests show that RE-ARM is not a good option for you, or you decide you do not want to participate, then your medical team will discuss with you the treatment options available outside of this study.

### What happens next if the study is suitable for me?

Once you are entered into RE-ARM you will continue to have atezolizumab. If you are allocated to group 2 you will also receive radiotherapy as described above.

Whichever group you are in, whilst you are receiving atezolizumab you will have check-ups before you have your next round of atezolizumab every three weeks. These check-ups will include a blood sample and assessment of any symptoms you may be having, with treatment as appropriate. At every other visit an additional blood sample will be taken to check how well your thyroid is working. Every nine weeks you will have a CT scan to measure the size and locations of your cancer, to assess whether the treatment is working. After a year, these scans will be performed every 12 weeks.

All of these checks are normally done for anyone receiving atezolizumab, whether or not they are taking part in a trial. They are summarised in the table below:

Assessment	Timing of assessment
Discussion with your trial doctor to document changes in your health, symptoms or medications since your last visit	At every clinic visit prior to the next cycle of atezolizumab (every 3 weeks)
Collection of blood samples to measure your full blood count and your liver and kidney function	At every clinic visit prior to the next cycle of atezolizumab (every 3 weeks)
Collection of a blood sample to measure your thyroid function	Every 6 weeks (to be taken at the same time as the other blood collection listed above)
CT scan	Every 9 weeks for the 1 <sup>st</sup> year, every 12 weeks in the 2 <sup>nd</sup> year

If you and your medical team decide you should stop having atezolizumab treatment, you will agree the best check-up schedule for you at that time. Your hospital will continue to send updates to the research centre every three months from these routine visits.

You need to consider carefully how these assessments and hospital visits will affect you and your family. As well as the assessments described above, your medical team may feel that you need additional assessments dependent upon your health. Please ask your medical team if you have any questions about the tests and procedures.

### **What are the side effects of treatment with atezolizumab?**

As with any treatment, atezolizumab can have side effects and you will have discussed these with your medical team before you started your current atezolizumab treatment.

No-one can predict before you begin treatment whether you will have any of these, or how serious they might be. Not all patients will have side effects, and they can often be treated to make them less serious or uncomfortable. There may also be risks involved in taking atezolizumab that have not been identified in the studies done so far, so please report anything that is troubling you to your medical team. Your progress will be closely monitored and your medical team will offer whatever help is available to cope with any side effects you're having. Occasionally some people need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious.

#### **Side effects which are very common (occurring in at least 1 out of 10 patients)**

- Decreased appetite
- Cough
- Shortness of breath
- Nausea
- Vomiting
- Diarrhoea
- Urinary tract infections
- Rash
- Itching
- Pain in the muscles, bones or joints including back pain
- Fever
- Fatigue
- Physical weakness or lack of energy

The majority of side effects reported in previous studies have been manageable and medical team will discuss with you what needs to be done in case you have these or any other side effects while you are taking atezolizumab.

#### **Side effects which are common (occurring in fewer than 1 out of 10 patients)**

- Decrease in platelets (thrombocytopenia) – this may increase risk of bleeding
- Hypersensitivity (allergic) reactions
- Abnormalities with thyroid function i.e. hypothyroidism/hyperthyroidism
- Low blood pressure

- Blocked nose
- Inflammation of the lining of the lungs (pneumonitis)
- Abdominal pain
- Inflammation of the lining of the colon (colitis)
- Swallowing difficulties
- Hepatitis
- Flu like symptoms including chills
- Inflammation or excess fluid in the lining around the heart (pericarditis/pericardial effusion)

**Side effects which are uncommon (occurring in fewer than 1 in 100 patients)**

- Diabetes
- Adrenal insufficiency where the adrenal glands do not produce enough steroid hormones
- Guillain-Barré syndrome
- Non-infective meningitis
- Inflammation of the pancreas
- Severe skin reaction (Stevens Johnson syndrome- causing blistering of skin)

**Side effects which are rare (occurring in fewer than 1 in 1,000 patients)**

- Inflammation of the pituitary gland (hypophytitis)
- Inflammation of the brain
- Inflammation of heart (myocarditis)
- Compression of the heart due to excess fluid in the lining around the heart (cardiac tamponade)

It is important that you tell your medical team any symptoms you are having, whether or not you think they are caused by your treatment so they can be treated as early as possible before they become severe. Your medical team will be able to advise you what to do and give you medication to help with symptoms if needed.

It is also important to note that you will not be able to receive any live vaccine whilst you are receiving atezolizumab. This is a standard decision for any patient who is receiving treatment with atezolizumab whether they are within the RE-ARM study or not.

**What are the side effects of treatment with radiotherapy?**

As with any treatment, radiotherapy can have side effects. No-one can predict before you begin treatment whether you will have any of these, or how serious they might be. Not all patients will have these side effects, and they can often be treated to make them less serious or uncomfortable. Your progress will be closely monitored and your medical team will offer whatever help is available to cope with any side effects you're having. Occasionally some people need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious.

You may experience a radiation skin reaction, a bit like sunburn, to the skin in the area where you have the radiotherapy treatment. This can be quite uncomfortable, and may require treatment with creams or painkillers. The possible side effects of radiotherapy depend on the area where you're

treated. As this will be different for everyone who takes part, depending on where their cancer has spread to, your medical team will discuss any other potential side effects with you.

It is possible that atezolizumab could worsen side effects of radiotherapy. This will be closely monitored throughout the trial by a group of independent doctors to make sure treatment is safe.

It is important that you tell your medical team about any symptoms you're having, whether or not you think they are caused by your treatment. Your medical team will be able to advise you what to do, and give you medication to help with symptoms if needed.

## **Vaccinations**

Whilst you are receiving treatment in RE-ARM you will be able to receive vaccinations providing they are not live (eg MMR/yellow fever). COVID-19 and flu vaccinations currently approved in the UK can be given whilst receiving atezolizumab. If you have any concerns about vaccinations please discuss them with your medical team.

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## **4 What are the possible advantages and disadvantages of taking part?**

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### **What are the possible benefits of taking part?**

There is no guarantee that you will benefit directly from taking part in this study. The aim of RE-ARM is to find out whether there is a benefit of giving radiotherapy in addition to atezolizumab, but we do not currently know whether this is the case. The information we get from this study may help in treating people with cancer like yours in the future.

### **What are the possible disadvantages and risks of taking part?**

#### ***Side effects***

You may have side effects from the study treatment as listed in the previous sections. There is no way of predicting if you will have any side effects, nor how severe they will be. You should contact your medical team if you think you are having any side effects, even if you are not sure that any problems you may have are related to taking the trial treatment. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious.

#### ***Additional blood tests***

You may have more blood tests if you enter the treatment study than if you were not taking part. Risks linked with blood sampling include pain from the needle being inserted, light-headedness, possible fainting and (occasionally) infection.

#### ***Radiation exposure***

If you receive radiotherapy to treat your cancer, you will be exposed to radiation that you would not have if you were treated with standard treatment outside of the trial. Radiation can cause cell damage which may, after many years or decades, cause a new cancer to develop. We believe the possible benefit of radiotherapy is likely to outweigh this risk for people with advanced urothelial cancer.

By joining the study you also may have more CT scans than you would if you did not take part. These scans expose you to ionising radiation, which can have an adverse effect on your body,



including a small increased risk of causing a cancer several years after the exposure. Again, we believe the benefits in terms of monitoring your cancer outweigh any such risk.

***Additional hospital visits and travel***

You may need to attend hospital more frequently than you would if you decided not to participate in this study. Your medical team will explain if this is the case for you. This may cause some disruption to your normal activities and home life and this should be discussed with your family and friends if it will impact on them.

***Private medical insurance***

If you have private medical insurance you should check with your insurance company before agreeing to take part in this trial to ensure that your participation will not affect your cover.

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

# PART 2

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## 1 Quality of life study

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If you decide to take part in the RE-ARM trial, we would like to ask you some questions about the way you feel, both physically and emotionally. These are called quality of life questionnaires. These will help us to understand about how the trial treatments affect you from your point of view.

### When will I be asked to complete a questionnaire?

You will be asked to fill in some short questionnaires asking about your quality of life and general health. We will ask you to fill in a questionnaire four times:

- before you find out which treatment group you are in
- after nine weeks of atezolizumab treatment within the trial
- 6 and 12 months after you started treatment on the trial

The questionnaires should take about 20 minutes to complete.

A member of your medical team will explain the questionnaires before you complete them and answer any questions that you have.

### If I want to join the RE-ARM study, do I have to complete the questionnaires?

No, completing the questionnaires is optional. If you choose to complete them at the start you can change your mind about completing future questionnaires at any time.

## 2 Tissue and blood sample donation

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We would like to collect samples of blood and cancer samples from people who join RE-ARM. These will be used to investigate how atezolizumab treatment with and without radiotherapy affects peoples cancer. If you agree to participate in the RE-ARM trial, you will be invited to take part in the sample collection sub-study.

### What samples will I be asked to donate?

If you agree to join RE-ARM you will be asked to donate the following blood samples and tumour tissue samples from your urothelial cancer:

#### Blood samples

We will ask you to provide additional blood samples at the following time points:

- Before you start your trial treatment
- At the end of your radiotherapy treatment if you are part of the group who receives radiotherapy

- After six weeks of atezolizumab
- After nine weeks of atezolizumab
- If your cancer progresses

If you agree to provide these samples, at each of the times described above we will collect 4 or 5 small tubes of blood (33 to 43 mls of blood in total which is the equivalent to approximately 2-3 tablespoons) at the same time that blood samples described in part one are taken.

### **Tissue samples**

Samples of your cancer will have been taken as part of your diagnosis. These samples are routinely stored by the hospital after they have been examined to give the diagnosis. You will not need to have any more samples taken for RE-ARM but we would like your permission to access the samples stored by your hospital.

### **What information about me will be sent with my samples?**

The samples you donate will be labelled with your trial ID number, initials and date of birth when they are sent to the central laboratory. This is to make sure that the laboratory can check they are from the right participant. After this, they will be relabelled with just your trial ID for future storage to maintain your confidentiality whilst allowing biological details to be compared to treatment findings.

### **What will happen to any samples I give?**

Any samples you agree to donate will be sent to the central laboratory at the University of Manchester and will be used in combination with other with samples from other people who have joined the study. Some samples will also be sent to The Institute of Cancer Research. Whilst some analysis of samples for RE-ARM may be done at other external research facilities, this will always be done under the supervision of the University of Manchester and The Institute of Cancer Research and no information which could identify you will be sent to external collaborators.

The samples are being collected so that we can use them to investigate genetic differences between people's cancers, to investigate why they develop cancer and to predict how they react to treatment. Therefore, your tissue samples and/or blood samples may be analysed for potential changes in DNA and RNA. (genetic changes). If we show that genetic differences do explain why some patients develop urothelial cancer or react to their treatment differently, this knowledge could help many patients in the future. The results of any such analyses will not be made available to you or your doctor. Genetic analysis would be for research purposes only and will not affect any insurance you may hold.

The samples collected in this study will be stored indefinitely. After the end of this study samples will be stored in a Human Tissue Authority licensed facility and no information that could identify you will be kept with them. It is possible that in the future other research may be carried out on the samples collected within this trial. This research may be conducted in the UK or overseas. Your personal details will not be shared with other researchers. Any future research on samples will be approved by an ethics committee before it is done.

### **If I want to be part of the RE-ARM study, do I have to donate samples?**

No, donation of samples is optional.

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## 3 Confidentiality

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### Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using your information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least five years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the UK General Data Protection Regulation (GDPR).

Your rights to access, change, or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at [www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency](http://www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency).

*[Insert appropriate name for NHS site]* will collect information from you and/or your medical records for this research study in accordance with our instructions.

*[Insert appropriate name for NHS site]* will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

### Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number will be passed to the Clinical Trials and Statistics Unit at the Institute of Cancer Research (ICR-CTSU) where the study is being coordinated. You will be given a unique trial ID number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this trial ID number to be linked to you.

From time to time, we would like to know how you are getting on. Ideally, we would like to do this for life, and we would like to use national records, which are kept on everyone's health status to find this out. One of these is held at the General Register Office (GRO). We will need to give them

enough information to identify you. This is usually your name, date of birth postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, the UK's regulatory authority (the Medicines and Healthcare Regulatory Authority, MHRA) and ethics committee approving the study, the pharmaceutical company, Roche, which manufactures the study drug and may have offices outside of the UK/EU, and third parties approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

**[Insert appropriate name for NHS site]** will keep identifiable information about you from this study for 5 years after the study has finished.

### **Will information about me be shared with other researchers?**

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you could be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Our main privacy policy can be found at <https://www.icr.ac.uk/legal/privacy>. If you have any questions about your rights under the UK GDPR or how we use your information please contact our Data Protection Officer at [dataprotectionofficer@icr.ac.uk](mailto:dataprotectionofficer@icr.ac.uk).

### **Involvement of your General Practitioner/family doctor**

Your GP will be informed about your participation in the RE-ARM trial. This is to make sure that your GP knows you are taking part in the trial in case of any side effects and/or drug interactions.

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## **4**

## **Further Information**

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### **What if something goes wrong?**

Every care will be taken during the course of this clinical trial to ensure you receive appropriate care and treatment. If you are not happy with the general care and treatment you receive, please speak

first to your doctor, who will try to resolve the problem. If you are still unhappy and wish to complain formally about the care and treatment received during the trial, you may do so under the standard NHS complaints procedure, which is available to you at your doctor's hospital.

**[Sites in England]** Concerns can also be raised by talking to your local Patient Advice and Liaison Service (PALS). You can contact the PALS team at **[insert Trust name]** on **[insert relevant contact details]**.

**[Sites in Scotland]** Concerns can also be raised by talking to the Patient Advice and Support Service (PASS). You can contact PASS via the National Citizens Advice Bureau on 0808800 9060 or through your local Citizens Advice Bureau ([www.cas.org.uk/patientadvice](http://www.cas.org.uk/patientadvice)).

**[Sites in Wales]** Concerns can also be raised by talking to the Patient Support and Advisory Service (PSAS). You can contact PSAS on 0300 0200 159 or emailing [hdhb.patientsupportservices@wales.nhs.uk](mailto:hdhb.patientsupportservices@wales.nhs.uk).

**[Sites outside England/Scotland/Wales]** Concerns can also be raised by talking to **[insert equivalent local organisation and relevant contact details]**.

**[Delete above sections as appropriate for location of trial site.]**

You will be closely monitored both during and after treatment and any side effects will be treated as appropriate. If you suffer any side effects or injury, please notify your doctor immediately so you can obtain appropriate medical attention.

In the unlikely event that you are injured by taking part, compensation may be available.

If you are harmed due to the negligence of someone treating you, then you may have grounds for legal action but you might have to pay for it. NHS Trusts are responsible for clinical negligence and other negligent harm to individuals that are under their care and covered under the NHS Indemnity Scheme.

If you suffer adverse side effects of the trial treatment or harm caused by procedures you have undergone specifically for the trial you may be able to claim compensation from The Institute of Cancer Research as sponsor of the RE-ARM trial. In deciding the level of compensation to be awarded, consideration will be given to the likelihood of side effects and any warnings that were given.

### **What if relevant new information becomes available?**

Sometimes during the course of a study, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss whether you want to, or should, continue in the study. If you decide not to carry on, your doctor will make arrangements for your continued care. If you decide to continue in the study you may be provided with an updated information sheet and be asked to sign an updated consent form.

If new information means it would be in your best interests to withdraw you from treatment in the trial, your doctor will explain the reasons for this and arrange for your continued care.

If the trial is stopped for any other reason, you will be told why and your doctor will arrange for your continued care.

### **What happens if I don't want to carry on with the trial?**

You are free to withdraw from, or reduce your level of participation within, RE-ARM at any time. You do not have to give a reason and your future treatment will not be affected by your decision. Your medical team will discuss your treatment options with you and will offer the most suitable treatment available.

If you were to reduce your participation, for example by stopping trial specific hospital visits, we would like to continue to collect information on your progress that is routinely recorded in your medical records. This is so that the overall quality of the study is not impaired and enough information is collected to answer the main aim of the trial.

If you decide you want to stop participation and do not want any more information to be sent to the research centre, trial data collected before your decision will still be processed along with other data collected as part of the clinical trial, however no new data will be added to the trial database and you may request that all retained identifiable samples are destroyed to prevent future analysis.

### **Who is funding and organising this research?**

The study was designed by investigators at the Institute of Cancer Research and is funded by Roche Products Ltd, the company who manufacture atezolizumab. The study is coordinated by the ICR-CTSU. Roche are supplying the drugs free of charge and providing additional funding to support the management of the study, but will not have any influence over trial design or analysis and will not have access to your data unless it is related to the safety of the drug. The study funding helps to cover the cost of collecting information about you for inclusion in the study plus the cost of the laboratory tests, and also helps pay for staff at the research centre. None of the researchers or doctors at the hospitals taking part will receive personal payments from this funding.

### **What will happen to the results of the study?**

Independent experts will review the progress of the research and the results will be published in a medical or scientific journal as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide how to treat metastatic urothelial cancer in the future.

### **Who has reviewed the trial?**

All research in the NHS is reviewed at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This trial has been reviewed and given a favourable opinion by the London - Surrey Borders Research Ethics Committee. Their approval means they are satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits, and that you have been given the right information to decide whether to take part. The trial has also been reviewed and approved by the Medicines and Healthcare Regulatory Authority, the Health Research Authority (HRA) and by the Committee for Clinical Research (CCR).

### **What happens now?**

Your medical team will be happy to answer any questions. Once you have decided please let your medical team know. If you choose to join the RE-ARM trial you will be asked to sign the consent form and will be given a copy to keep together with this information sheet.

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## 5 Useful contact information

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### Who can I contact for further information?

You have the right to ask questions about this study at any time and are encouraged to do so. You can call your medical team if you feel that you are developing any side effects or if you have any questions about this study or your participation in this study.

Your hospital study doctor is: xxx

Your hospital study nurse is: xxxx

Contact phone numbers: xxxx

Out of hours number: xxxx

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line; Freephone 0808 808 00 00, Monday to Friday, 9.00am to 8.00pm.

In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

You can learn more about clinical trials on the Cancer Research UK patient website ([www.cancerhelp.org.uk](http://www.cancerhelp.org.uk)).

***Thank you for your interest in our research.***



## CONSENT FORM

**RE-ARM:** A randomised phase II trial of enhancement of efficacy of atezolizumab by radiotherapy in metastatic urothelial cancer

Ethics Committee Reference: 21/LO/0150

RE-ARM trial ID:

Name of Researcher taking consent:

**Please write your initials in the box to the right of each statement if you agree, and please sign at the bottom**

	<b>Initials</b>
1. I confirm that I have read and understand the RE-ARM Patient Information Sheet Version 4.0 dated 17/08/2022. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<div></div>
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	<div></div>
3. I agree to my name, date of birth, postcode, hospital number and NHS or Community Health Index (CHI) number being sent to Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU) when I join the RE-ARM trial.	<div></div>
4. If I withdraw from the study, I consent to my doctor providing authorised researchers with basic clinical information and other relevant non-clinical information that would be routinely collected and written in my medical records.	<div></div>
5. I understand that sections of any of my medical notes may be looked at by responsible individuals from the ICR-CTSU research team, trial sponsor, regulatory authorities, the pharmaceutical company or from the NHS Trust, where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.	<div></div>
6. I consent to the Institute of Cancer Research using information held by the NHS and national databases to follow up my health status.	<div></div>
7. I agree to my GP being informed of my participation in the study.	<div></div>
8. <b>I agree to participate in RE-ARM.</b>	<div></div>

***To be printed on hospital headed paper***

**PART B – OPTIONAL SECTION**

***Please initial to indicate whether you wish to consent to the following optional items.***

- |     |                                                                                                                                                                                                                                                                                     |                                                                                         |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 9.  | I consent to taking part in the Quality of Life study and the completion of the questionnaires (optional)                                                                                                                                                                           | <div style="border: 1px solid black; width: 80px; height: 30px; margin: 0 auto;"></div> |
| 10. | I consent to donating routinely collected samples from surgery and additional blood samples as described above (optional)                                                                                                                                                           | <div style="border: 1px solid black; width: 80px; height: 30px; margin: 0 auto;"></div> |
|     | AND                                                                                                                                                                                                                                                                                 |                                                                                         |
|     | I agree that my tumour tissue samples and/or blood samples will be analysed for potential changes in DNA (gene changes). I understand that neither I nor my doctor will be informed of the results of these tests.                                                                  | <div style="border: 1px solid black; width: 80px; height: 30px; margin: 0 auto;"></div> |
| 11. | Data sharing: I grant advance authorisation for the possible future sharing of information collected about me with other organisations, including outside of the UK and European Economic Area (EEA), with the understanding that I will not be identifiable from this information. | <div style="border: 1px solid black; width: 80px; height: 60px; margin: 0 auto;"></div> |

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Name of participant

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Date

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Signature

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Name of person taking consent

---

Date

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Signature

1 copy for participant; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes