My Treatment, My Choice

A decision aid to help people decide whether to take part in a clinical trial for kidney cancer (renal cell carcinoma)

Supporting you in the shared decision-making process with your healthcare team

IKCC
International Kidney Cancer Coalition

Kidney Cancer: My Treatment, My Choice Decision Aid ©

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Action Kidney Cancer

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This workbook belongs to:

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Disclaimer
This decision aid is intended for patients to use alongside the advice of their healthcare team. It does not support any course of treatment over another. Use of this decision aid is voluntary.

Clinical Trials:
My Treatment, My Choice
Decision Aid

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Contents

Foreword 4

About this decision aid 6

Clinical trials and research 9

Should I join a clinical trial? 17

Where can I find a suitable clinical trial? 18

Deciding whether to take part in a clinical trial 19

My healthcare team 24

My clinical research team 26

My questions 29

My decision 45

My resources 51

Glossary 63

Acknowledgements 76

Foreword

Perhaps you are reading this because you are considering taking part in a clinical trial for kidney cancer yourself, or someone you care about is trying to make this decision. We understand that the medical language and the information about clinical trials can be overwhelming. One of the strongest beliefs of the International Kidney Cancer Coalition (IKCC) is that patients and their families have an essential role to play in healthcare decision-making that affects their lives.

There has never been a time with so many new discoveries in kidney cancer. Clinical trials have demonstrated the benefits of new treatments that could potentially be used to improve outcomes after surgery.

There are now more choices and patients can receive different treatments or combinations of treatments. Clinicians are getting more experienced and knowledgeable, and the choice of treatments for kidney cancer, both within the healthcare system and through participation in clinical trials, is increasing. Thanks to clinical trials, the use of robotic removal of part of the kidney, better tools to predict how well patients respond to treatment, and the role of treatment before and after surgery are all evolving rapidly. The basic biological mechanisms of kidney cancer are being untangled with the promise of biomarkers, new diagnostics, and drug targets.

We are very excited to be participating in this rapidly changing and expanding field of medicine which promises real gains in the very near future. This can only be achieved through clinical research relying on patients to take part in clinical trials for new treatments.

This decision aid was written by a collaborative team of patients, patient advocates and medical professionals who have supported thousands of kidney cancer patients worldwide.

You may find that this booklet contains a lot of medical information and new terms. If you find it difficult to read all at once, it might be helpful to read it in sections or re-read it again at another time. For more information, and to help you understand the medical terms that are used, please also read our ***My Treatment, My Choice Clinical Trial Basics*** *booklet and/or see the glossary on page 63 of this booklet.*

We hope that you find this booklet helpful and that it will support you with your decision to take part in a clinical trial in the future.

Sincerely

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About this decision aid

This decision aid is for people diagnosed with a type of kidney cancer called renal cell carcinoma (RCC), including all subtypes of RCC (for example, clear cell, papillary, chromophobe and collecting duct RCC). It is for people who would like to take part in a clinical trial to help provide more information about kidney cancer. It is also for people and their families who would like help deciding whether a clinical trial is the best option for them.

This decision aid:

- Provides information about the different types of clinical trials that may be available for you.
- Describes the possible benefits and risks of taking part in a clinical trial.
- Gives advice on how to make the best possible decision in keeping with your own values and beliefs.
- Suggests some questions you may want to ask your doctor or nurse.
- Provides lists of resources where you can find support and further information if you need it.

Access to clinical trials varies around the world. In some countries there are many clinical trials in hospitals and research centres. However, in other countries, there are very few clinical trials.

Access to treatments for kidney cancer also depends on the country where you live, your national healthcare system or your health insurance. You will need to remember this when deciding on your treatment options. For information about kidney cancer treatments, please see the other decision aids on the IKCC website (www.ikcc.org).

This decision aid describes the different types of clinical trials that may be available and how to find a clinical trial for you. It also describes the things you need to think about when deciding to take part in a clinical trial.

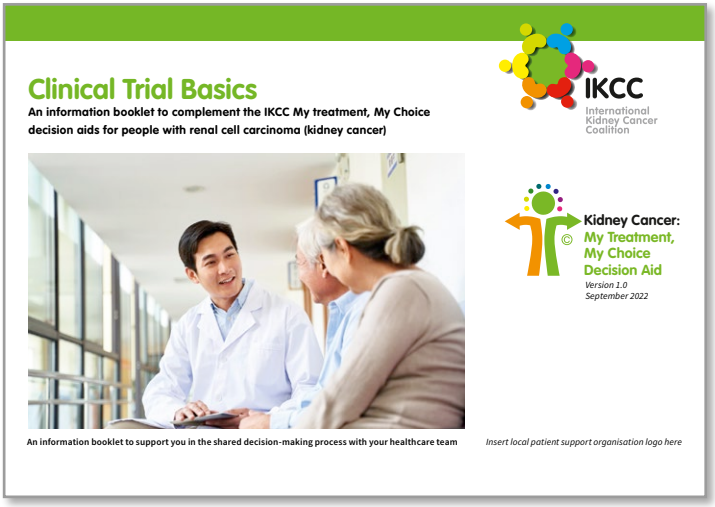
This decision aid will help you with your conversations with your doctors and nurses. It can help you decide whether to take part in a clinical trial. Some clinical trials may help you live longer and improve your life. You are the most important person involved in your own health care. Only you understand the impact of these decisions on your life.

Having kidney cancer can be overwhelming.
Learning about the disease and treatment options can help you make the best decisions about the care and treatments available to you.

You can print out this booklet and have it with you at your next appointment with your doctor or nurse.

We hope you will find this booklet useful when discussing clinical trials with your family and friends.

This booklet should be read together with the *My Treatment, My Choice Clinical Trial Basics* booklet.



Clinical trials and research

Clinical trials and research

Over the past 10 years, clinical trials and research have resulted in a lot of new treatments for kidney cancer. Clinical trials can be used to improve surgery and shorten recovery times. Clinical trials can also be used to look at new ways of removing tumours that could be more accurate and effective, for example using radiotherapy, or very high or cold temperatures to destroy tumours. Because of clinical trials, we now have combinations of medications for the treatment of advanced kidney cancer and treatments which may prevent the disease from coming back after surgery. Researchers are also looking at genes (biomarkers) to help them predict how treatments work so that treatment can be made personal to each kidney cancer patient.

What is a clinical trial?

A clinical trial is a research study that tests a new treatment or procedure to find out if it is safe, effective, and better than the existing (standard) treatments.

The treatment or procedure being tested can be a medication, or a new way of giving radiotherapy or performing surgery or something as simple as a different way of caring for patients. Sometimes the clinical trial tests a new combination of medications or treatments to see if combined treatments are better than one.

Clinical trials help improve cancer treatment. Until a cancer treatment has been through a clinical trial, there is always uncertainty about whether the new treatment will be better or worse than existing (standard) treatments. Clinical trials provide information about the treatment before it is approved for use.

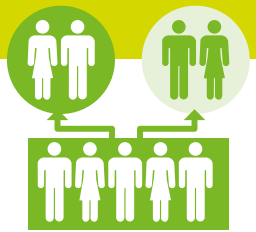
What are the two main types of clinical trial?

There are two main types of clinical trial - interventional and observational.

Interventional trials try to find out more about a treatment such as a new medicine, medical treatment, or device. In some trials all patients receive the new treatment. In other trials patients are put into different treatment groups and receive different treatments and the results are then compared.

Observational studies aim to watch what happens to patients in different situations. Observational studies do not test new treatments. The researchers watch and record what happens to the people taking part. Observational studies may look at the causes and patterns of disease. They see if there are things which could be done differently which would be better for patients. This is often done using surveys or questionnaires to record information about lifestyles and quality of life.

Clinical trials and research



There are different types of clinical trials within these two groups:

Pilot studies	Look at how the main parts of the trial will work, but on a small scale.
Feasibility studies	Carried out before the start of a clinical trial to see if it is possible to carry out the trial on a larger scale.
Observational clinical trials	The researchers simply observe and record what happens. Observational studies often use questionnaires and surveys to record information about the lifestyles, quality of life and care of the people in the studies.
Screening trials	Screening is done to try and detect cancer before it has started to cause symptoms. Screening trials are used to find tests that could diagnose cancer earlier when it can be treated more easily.
Prevention trials	Prevention trials are used to find out whether a special diet, regular exercise or a change on behaviour can prevent cancer from developing.
Translational research	Aims to ‘translate’ findings in scientific research into something that will benefit patients.

Interventional trials	Trials in which patients receive a treatment or an intervention so that researchers can evaluate the effects of the treatment or intervention on the health of the patients.
There are different interventional trials:	**Placebo-controlled trials:** Trials in which there are two (or more) groups of patients. Only one group gets the active treatment, the other group gets the placebo. A placebo is a dummy substance, but neither the patient nor researchers know which person is in which group. Everything else is the same between the two groups, so that any differences between them will be caused by the active treatment.
	Single-arm trial: Only one group of patients who are all receiving the same treatment.
	Multi-arm trial: Two or more groups of patients receiving different treatments are compared. This type of study can also be placebo-controlled which means that only one group gets the placebo. Neither the patient nor researchers know which person is in which group. Everything else is the same between the groups, so that any differences between them will be caused by the active treatment.

Investigational clinical trials	There are **4 phases** of investigational clinical trials, which are described in the table below:	
Phase 1 clinical trials	The first study of a treatment in humans	This phase of trial investigates whether the new medicine is safe in small numbers of cancer patients. Phase 1 clinical trials with cancer patients can also be used to find the right amount of medicine (the dose) that needs to be given to patients.
Phase 2 clinical trials	Investigates the safety and effectiveness off a treatment in larger numbers of people (10s-100s)	Phase 2 clinical trials try to find the right dose of the medicine to use, and how safe it is. When phase 2 clinical trials are finished, and results are available, the decision will be made whether to continue to test the medicine in the next phase. The medicine must meet the strict safety guidelines in each country.

Phase 3 clinical trials	Involve large numbers of patients (100s-1000s), usually in different countries	Phase 3 clinical trials compare the effectiveness of new medicines against existing treatments or placebo (dummy treatment). Some phase 3 clinical trials look at the new medicine in different patient groups and use different doses. Some trials combine different medicines together to see if they get better results. In phase 3 clinical trials, patients are usually randomly put into different groups to compare different treatments. Sometimes the patient does not know which treatment they will be given (a blinded clinical trial) and sometimes neither the patient nor the doctor knows which treatment the patient is being given (double blind trial). This is to prevent any influence or bias from the patient or the doctor on the results of the trial. Information from phase 3 clinical trials is used to show the benefits of a new medicine over the existing medicines.
Phase 4 clinical trials	Collect information about the use of the new treatment in everyday patient care after a license has been granted.	For example, a new medicine may be assessed in the hospital or clinic together with other effective treatments to check the results are still the same as the clinical trial results.

More information about the different types of clinical trial can be found in the ***My Treatment, My Choice Clinical Trial Basics*** booklet.

Notes:

Should I join a clinical trial?

Joining a clinical trial is a big decision. There are several things you need to think about before you decide. You might like to consider the following:

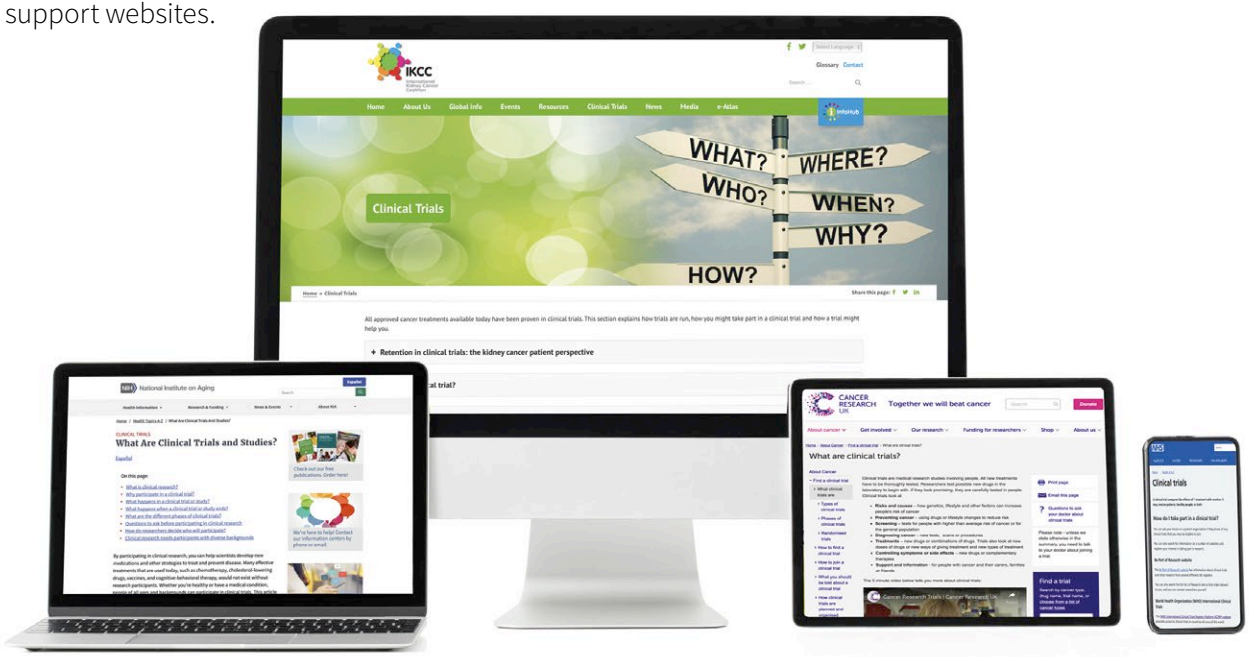
Am I eligible to join a clinical trial?

It is not always possible to join a clinical trial, even if you want to. When researchers set up clinical trials, they need to have strict standards about who can take part.
You might not be able to take part in the trial if:

- The trial is only for one type of kidney cancer.
- You have other illnesses which might affect how the treatment works and which prevent you from taking part.
- An earlier treatment could affect how you respond to the new treatment.
- You have other illnesses (e.g., diabetes or cardiac problems), which could make you more likely to have side-effects or less likely to respond to the new treatment.
- You have had another kind of cancer at some time in the past which may affect how you respond to the new treatment.
- Your country is not taking part in the trial.
- You may have tumours in a particular area of your body which will not respond to the new treatment.

Where can I find a suitable clinical trial for me?

Ask your doctor or nurse for information about clinical trials that might be right for you. Always ask about all the clinical trials that are being run in your local area – there may be several trials available in different hospitals. There are websites where you can find out more information and where you can search for a suitable clinical trial.
See *My resources on page 51* for a list of useful clinical trial and patient support websites.



Deciding whether to take part in a clinical trial

Deciding whether to take part in a clinical trial

When deciding whether to take part in a clinical trial, you should be clear about the purpose of the trial and what will happen to you. You also need to find out if the trial will benefit you for example, can you get a treatment you would not normally be able to have, or will it help other people in the future?

Observational studies

Before you decide to take part in an observational study, you need to consider the following points:

- What is the purpose of the study and how will it help you or the care and treatment of kidney cancer patients in the future?
- Look at the length of the questionnaire or survey. How long will it take you to complete?
- Is the questionnaire or survey written in a way you can easily understand?
- How many questionnaires or surveys will you need to complete and over what period?
- How will it impact on you or your family's life? How much time will you need to do it? Do you have the technology (computer, laptop, iPad) to complete the questionnaire or survey online or will you need paper copies?
- What other observations will the researchers need to carry out and how will this impact on you or your family's life?

Interventional trials

Before you decide to take part in an interventional clinical trial, you need to consider the following points:

- You will be cared for by a team of doctors and nurses with detailed knowledge about the latest treatments for kidney cancer.
- You will be monitored very closely during the trial and may benefit from additional tests and scans that would not normally be carried out.
- You may be given the opportunity to be one of the first patients to benefit from the new treatment in the clinical trial; taking part may give you access to a treatment that will work better for you.
- You may experience unexpected side effects from the new treatment.
- The new treatment may not be an effective treatment and may be less effective than currently available treatments.
- Close monitoring of the trial may result in more frequent hospital visits and more testing than would occur if you were not on the clinical trial. This could be disruptive to you and your family's life.
- You will be asked to have more tests or additional tests that are not routine clinical practice, for example, more frequent blood tests, scans, and tissue samples of your cancer (biopsies) might be taken.
- If you take part in a clinical trial, this may affect or restrict your access to other treatments if you need them in the future.

Concerns or worries

You should discuss any concerns or worries you have regarding your health and care during the clinical trial with your doctor before enrolling, and during the trial if you need to. It is very important you are told about the purpose of the clinical trial, any potential benefits, or disadvantages, and any side effects of the new treatment. You should be told how many times you are expected to visit hospital and how many tests will be carried out during the clinical trial.

You should also be told whether any expenses resulting from taking part in the trial will be paid to you, e.g., travel and accommodation expenses, time off work, or additional expenses if you need someone with you. You should ask whether expenses for family members and carers will also be covered.

Discussing clinical trials with your doctor

It might be useful to make a list of questions and to take a family member, friend, or carer with you to your discussions with your doctor about taking part in a clinical trial. They can take notes about what is discussed and ask questions that you might not think about.

Phase 3 clinical trials usually compare a new treatment with existing treatments or sometimes with a placebo or dummy treatment (see page 15). It is important to remember that in some clinical trials, treatments are randomly allocated to different groups of patients by computer and neither you nor your doctor will know which treatment you are on until the end of the trial.

Neither you nor your doctor can choose which treatment you receive. At the end of the trial, if it is revealed that you were taking the least effective treatment, you may be given the opportunity to switch to the more effective treatment if the trial allows. Your doctor will discuss this with you.

Many phase 3 clinical trials are for the first treatment of advanced kidney cancer after surgery (called first-line treatment). You need to discuss with your doctor if this will affect which treatments you can have in the future if your cancer comes back. Sometimes, taking part in a clinical trial for a first-line treatment can restrict access to other treatments in the future if you need them.

Patient information sheet and consent form

If you decide to take part in a clinical trial, you will always be asked to read a patient information sheet and sign a consent form to confirm your agreement to take part *(see My Resources on page 51)*. The patient information sheet contains all the information about the trial and the treatment being tested. Sometimes, patient information sheets can be long and complex documents, and difficult to understand. You should be able to take this document away with you and read it carefully in your own time. Your doctor or nurse can explain the patient information sheet to you so that you understand what you need to do if you decide to take part in the clinical trial.

Signing the consent form confirms that you have been fully informed about the risks and benefits of the treatment that is being looked at and what is expected of you during the trial. An example of a typical patient information sheet and consent form can be found in ***My Resources on page 51***. Once you have completed these forms you should be given copies to take away with you. They should always include a telephone number for where you can get help when you need it.

Your rights and personal information

You have the right to withdraw from a clinical trial at any time, and you do not have to give an explanation. Your care at your hospital or clinic will not be affected in any way, and you will be offered the current, existing treatment for your condition.

All the information collected during a clinical trial, including your personal details and case notes, will be kept strictly confidential according to legislation in your own country. Any tissue samples (biopsies) will be analysed and stored in a safe place and your personal information will be kept strictly confidential. The organisation responsible for analysing and reporting the results of the clinical trial can only identify your test results and details by a number and your initials.

You may be asked if your information or biopsy samples can be shared with other researchers to help research in the future. Again, your permission is needed, and all your personal information will be kept strictly confidential.

My healthcare team

You may have one main doctor, or many healthcare professionals involved with your care and treatment.

However, the most important person in your healthcare team is you! With our IKCC decision aids, you can work with your healthcare team to learn about kidney cancer, treatment options and clinical trials. Together you can make decisions that may improve your health and wellbeing.

Who are the members of my healthcare team?

Treating kidney cancer can require the skills of many different healthcare professionals. Your healthcare team might include some of the following healthcare professionals. However, not all of them will be involved in clinical trials.

In some countries, healthcare professionals work together in a multidisciplinary team (MDT). The MDT meets regularly to discuss your treatment and care. In other countries, they might work separately:

General practitioner (GP) in primary care	A family doctor who is based in the community and treats patients with minor or chronic illnesses. Can help manage your cancer symptoms, treat side effects, and assist with coordinating your care in the community.
Urologist	A surgeon who specialises in treating diseases of the kidney, bladder, and prostate (the urinary system). A uro-oncologist specialises in treating cancers of the urinary system, including kidney cancer. If required by the clinical trial the urologist can be responsible for taking biopsy samples.
Oncologist	A doctor who diagnoses and treats cancer.
Radiologist	A doctor who specialises in diagnosing disease by using x-ray scans, ultrasound, CT scans and MRI scans.

Clinical nurse specialist or cancer nurse	A specialist nurse who supports you through diagnosis and treatment. The nurse will manage your care, give you medication, and provide information about your kidney cancer.
Pathologist	A scientist or doctor who studies cells under a microscope and who diagnoses the stage, grade, and type of kidney cancer you have.
Palliative care doctor or nurse	Helps relieve symptoms, manage pain, and improve your quality of life.

Other healthcare professionals included in your healthcare team may include a dietitian, physiotherapist, psychologist, and exercise physiologist.

A member of your healthcare team might also be managing a clinical trial and may suggest you take part if they feel you are suitable for the trial. They may also recommend a clinical trial being managed by another healthcare team at a different location. Or you could ask your healthcare team if they are aware of any clinical trials you might be suitable for. This might offer you a different treatment option, which is in research and not normally available. Later in this decision aid, there are some questions you might want to ask your doctor before deciding whether to take part in a clinical trial (see page 29).

My clinical research team

The clinical research team is made up of people who work in a hospital or clinical research centre. Clinical trials are often run by pharmaceutical companies, research organisations on behalf of a pharmaceutical company, charities, or government health organisations. During the clinical trial, the hospital or clinical research centre will be monitored regularly to make sure the information collected is of a high quality.

The clinical research team will usually be led by a urologist or oncologist.

This table lists the main people involved in running a clinical trial at a hospital or specialist clinical research centre:

Principal investigator (PI)	Sometimes called the primary investigator, this person leads the clinical trial. They assist in the development of the design of the clinical trial and the detailed description of how the clinical trial will be conducted. They submit the clinical trial for approval by the hospital ethics committee (institutional review board, IRB). The PI oversees the recruitment of patients and is responsible for the clinical trial from the beginning to the end, including publishing the results. The PI is responsible for everything in the clinical trial.
Study doctors	Help monitor and care for the people who take part in the clinical trial. They arrange the treatment according to the protocol and collect information. They record how patients respond to the treatment and note any side effects to the treatment.

Research nurse	Explains the clinical trial details to patients. The research nurse also helps with giving medicines and recording side effects. The research nurse is often the main point of contact for patients in the clinical trial.
Clinical trial coordinator	A nurse or scientist who recruits suitable people into clinical trials and administers the trial. Clinical trial coordinators ensure patients understand the study and formally agree to take part. They work with the clinical research team to make sure that the clinical trial follows strict regulations.
Research pharmacist	Ensure that the medications under investigation are delivered on time and administered safely and according to instructions to the patients.

If your clinical research team is different from your healthcare team, they will send regular updates to your healthcare team about your progress in the clinical trial. They will let them have copies of blood test results and scan results, and they will also let them know if you have a side effect to the new treatment being tested in the clinical trial. In some countries, the clinical trial team might ask your healthcare team to manage and treat side effects. You could be referred to a different specialist doctor for the treatment of some side effects, such as immune-related side effects.

Notes:

My questions

My questions

The information you have learned about clinical trials has probably raised some questions. It can help to write them down in the appropriate pages of this book. By talking them through with your doctor and nurse, your questions can help you decide which options are right for you.

You need to have good communication with your doctor and nurse. The more questions you ask, the more you will understand. This will make you feel in control and confident about the decisions you make.

Talking with your doctor or nurse and the research team will also help them understand what is important to you. Tell them about your worries and what matters to you most.

The lists of questions on the following pages may help you understand kidney cancer clinical trials better. Before your appointment to discuss a clinical trial, think about the questions you may want to ask. During your appointment, write the answers in the space provided in the following table.

Talk about the possibility of taking part in a clinical trial with your family and friends and add any other questions you would like to ask which are not listed. Making notes during your appointment can be helpful, especially if you are reviewing information after your visit. Taking someone with you to appointments can be very useful, as they can take notes while you concentrate on what the doctor is saying. You may also ask your doctor for permission to record the conversation so you can listen again later.

Contact your local kidney cancer patient organisation for good up-to-date information and support. See the IKCC website (www.ikcc.org) for a list of kidney cancer patient organisations.

Questions you might like to ask your doctor

QUESTIONS ABOUT THE TRIAL	Please fill in your answers	☑
What is the purpose of the trial?		
How long will I be in the trial?		
If the treatment is successful, can I stay on it or does it stop when the trial stops?		
How many assessments/hospital visits are there and when do they take place?		
Do I need someone to be with me?		

Questions you might like to ask your doctor

QUESTIONS ABOUT THE TRIAL	Please fill in your answers	☑
What kind of tests and treatments are involved, for example, injections, infusions, blood, and urine tests, scans etc.?		
Will I need to have tissues samples taken (biopsies)? If so, how many samples are taken and when are they taken?		
How will the doctor know if the treatment is working?		
How will I be told about the trial results?		
How long do I have to make up my mind about joining this trial?		

QUESTIONS ABOUT THE TRIAL	Please fill in your answers	☑
Is there someone I can talk to who has been in the trial?		
Who can I speak with about questions I have during and after the trial?		
Who will oversee my care? Will they communicate with my own hospital?		
Where can I find out more information about clinical trials?		
Why do I need to sign an informed consent form? Do I get a copy to keep ?		

Questions you might like to ask your doctor

QUESTIONS ABOUT THE TRIAL	Please fill in your answers	☑
Where is my personal information kept during the trial? Is my personal information kept private?		
Where are biopsy samples analysed and stored during the trial? How are biopsy samples kept private? Will my biopsy samples be used in other clinical trials?		
For observational studies, how long are the questionnaires and how many do I need to complete?		
For observational studies, what other observations will be carried out?		
Will I have to stop or reduce any current activities, for example exercise, drinking alcohol, diet, work, etc.?		

QUESTIONS ABOUT RISKS AND BENEFITS	Please fill in your answers	☑
What are the possible side effects and risks of the new treatment?		
What are the possible benefits?		
How do the possible risks and benefits of this trial compare to those of the standard treatment?		
Will taking part in this trial restrict access to medication later in my treatment?		

Questions you might like to ask your doctor

QUESTIONS ABOUT YOUR RIGHTS	Please fill in your answers	☑
How will my health information be kept private? And what happens to my health information/tissue and blood samples after the trial?		
What happens if I decide to leave the trial?		
Do I have to give a reason if I decide to leave the trial?		
Will my treatment and care be affected if I decide to leave the trial?		

QUESTIONS ABOUT COSTS	Please fill in your answers	☑
Will I have to pay for any of the treatments or tests?		
Will I have to pay for travel to the hospital for trial assessments/ hospital visits, including car parking if I travel by car?		
Will I get reimbursed for time off work?		
Will my carer get reimbursed for time off work?		
If I don't have my own transport, can I get help travelling to the hospital for trial assessments/ hospital visits?		

Questions you might like to ask your doctor

QUESTIONS ABOUT DAILY LIFE	Please fill in your answers	☑
How will the trial affect my daily life?		
Can I bring a relative or friend with me to clinic visits?		
How often will I have to come to the hospital or clinic?		
If I need to go to another hospital for a biopsy, how far away will this be?		
Will I have to stay in the hospital during the clinical trial? If so, how often and for how long?		

QUESTIONS ABOUT DAILY LIFE	Please fill in your answers	☑
Will I have check-ups after the trial? If so, how often are the check-ups?		
For observational studies, how much time will be taken up with completing questionnaires?		

Questions you might like to ask your doctor

QUESTIONS ABOUT OTHER TREATMENTS	Please fill in your answers	☑
What are the other treatments for my kidney cancer, including standard treatments?		
How does the clinical trial treatment compare with the other treatments?		
If I decided to take part in this clinical trial, how will this affect my future treatment options?		

SUPPORT AND INFORMATION ABOUT CLINICAL TRIALS	Please fill in your answers	☑
Are there any support groups for my family and me?		
Do you have any printed information that I can take away with me?		
Who is my main contact if I have questions after our appointment today?		

Questions you might like to ask your doctor

MAKING A DECISION	Please fill in your answers	☑
How much time do I have to decide about taking part in the clinical trial?		
If I would like to have a second opinion before I start the clinical trial, can that be arranged?		
How many kidney cancer clinical trials do you run at this hospital/ clinical research site?		
How many clinical trials are there for my subtype of kidney cancer?		
Do I need the appropriate technology (computer, laptop, iPad) and internet connection to take part in an observational study?		

Other questions	☑

Questions you might like to ask your doctor

Other questions	☑

My decision

Summary Below is a summary of the possible benefits and disadvantages of taking part in a clinical trial:

Possible benefits	
1. May be the best or only treatment option available	Sometimes the only way for you to get access to a new medication or specific type of treatment is by taking part in a clinical trial
2. High-level care	Usually, you are seen by doctors and nurses who are experts in treating your condition. Patients who are treated in hospitals running a clinical trial have better results overall. For many patients, access to expert level care at a centre of excellence is a major benefit
3. Free medication	In most countries, the clinical trial centre will provide the costs of all medical care involved in the clinical trial (all tests, surgery, radiotherapy, and medication). If you receive medication as part of a clinical trial, you may continue that medication if the treatment proves to be effective. Be sure to ask about the costs of further treatment , or continuing with the drug, if its not routinely available that might affect your participation
4. Helping others	Participating in a clinical trial means you are making a valuable contribution to medical research and helping others who are diagnosed with kidney cancer in the future
5. Observational studies helping others	Participating in an observational study could help to improve the care and treatment of future patients and their quality of life

Possible disadvantages	
1. You may not receive the new treatment	Some clinical trials are randomised, and others are not. You may not get the new treatment. Many trials compare the new treatment with standard treatment or placebo, and patients are randomly allocated to a treatment group
2. Changing to a different healthcare team	You will be seen by expert doctors and nurses who are involved in running the clinical trial. They may not be your original healthcare team. After the trial, you can return to your original team, which might be closer to home
3. The new treatment may not work as well as the standard treatment	Despite the hopes of the researchers running the trial, the new treatment might not work as well as the standard treatment that is already available. The new treatment might not work at all for you
4. There may be more side effects	The new treatment might have fewer side effects than standard treatments, but it might also cause unpredictable or serious side effects. In some cases, these can be permanent. This is particularly relevant if you want to join a trial that is the first to test a medicine in humans (a Phase I trial)
5. More hospital or clinic visits	If you join a clinical trial, you may need more tests or more frequent appointments, as the researchers want to study the effects of the new treatment

My decision

Possible disadvantages *continued*	
6. Financial costs (if applicable)	Although you will not be paying for treatment, there may be financial costs to consider, such as the cost of travel and accommodation, or the cost of you or a carer taking time off work to go to the trial clinic. Always ask at the trial centre about any financial assistance that may be available
7. Effect on future treatment options	Taking part in a clinical trial for a first-line treatment might restrict access to medications later in your treatment. Talk to the research team to check this before agreeing to take part in the trial
8. Personal health data	Personal health data needs to be kept private and confidential. You need to consider whether you are confident that this is the case for the clinical trial you are considering
9. For observational studies, time taken to complete questionnaires and surveys and other observations	The time taken to complete questionnaires, surveys or other observations could impact on the quality of your life

Notes:

My resources

Getting additional support for taking part in a clinical trial

Cancer and its treatment can have a huge physical and emotional effect on you. It is important to look after yourself. This includes eating a well-balanced and healthy diet, not smoking, doing regular exercise, and seeking help if you feel depressed or anxious. There are professionals who can help guide and support you with these aspects of your life.

Family and friends are an invaluable source of support, whether it's helping with the shopping, coming to doctor appointments with you or simply being with you. Let your family and friends support you. Your cancer diagnosis will also affect your family and friends. It is likely that your closest family member or main carer may need help and support as well as you.

Your family and friends can also help you with deciding to take part in a clinical trial. Discussing the advantages and disadvantages of taking part in a clinical trial with family and friends can help with this decision. Close family or friends may be able to come with you to clinical trial visits and can help by taking notes while you concentrate on what the doctor is telling you.

Many people find that it's helpful sharing their experiences and knowledge with other people who have cancer and have been on a clinical trial or talking to someone trained in supporting people with kidney cancer. You may consider contacting a patient support organisation to get support and information about kidney cancer clinical trials and to help you find a suitable clinical trial and navigate your way around the healthcare system in your country.

Being a carer for a loved one with cancer can be rewarding, but it can also be tiring, stressful, and cause you a lot of worry. It is important that you look after yourself and take some time just for you. And it's important that you get some help and support too.

By the time you come to this section you should have a good understanding of clinical trials for kidney cancer and their potential benefits and disadvantages. More information about clinical trials can be found in our ***My Treatment, My Choice Clinical Trial Basics*** booklet, which can be found on our website (www.ikcc.org).

You might find it helpful to keep a personal file of important reports and documents about your kidney cancer care and treatments, including the following:

- Important medical reports and documents.
- A list of all the drugs you may be prescribed.
- Contact information for your healthcare team.
- Notes on clinical appointments and consultations.
- Questions you want to ask your healthcare team.
- A record of symptoms and side effects.

Example patient information sheet and consent form

Here is an example of the information that is often needed in a patient information sheet and consent form:

Patient Information Sheet

Clinical trial Title: The title could be the same as in the protocol or a simplified version in patient-friendly language.

Invitation paragraph: It must be clear that you are being invited to consider taking part in a clinical trial and that this is completely voluntary.

Example: We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

What is the purpose of the study? A brief outline of the main purpose of the clinical trial in patient-friendly language.

Why have I been invited? An explanation of why you have been invited to take part in the clinical trial, e.g., because you have kidney cancer and how many patients with kidney cancer are going to be involved in the clinical trial.

Do I have to take part? It should be clear that taking part is completely voluntary. You can withdraw if you change your mind at any time, without giving a reason. Withdrawal will not affect your clinical care.

What will happen to me if I decide to take part? This section details what will be involved in the clinical trial from a patient's point of view, and the order that the tests will take place. Each clinical trial visit must be described in turn.

- It must be made clear which is standard care and which is research.
- A table or flow chart might be used for complex clinical trials with many tests and visits.
- The length of time you are in the clinical trial, how often you will need to visit the hospital, and the length of each visit will be explained.
- If you will be randomly put into treatment groups, this will be explained in patient-friendly language.
- If the clinical trial needs blood or tissue samples (biopsies), they should give you an idea of the amounts to be collected
- If tissue samples are collected, it should be made clear whether these are collected for use in the clinical trial or as part of clinical care
- Any plans for long-term monitoring or follow-up should be explained.

What should I consider? The following should be explained to you:

- Conditions which may exclude you from taking part in the clinical trial
- Whether you can continue to take your regular medication
- The need for contraception
- Whether you can take part if you are in another clinical trial.

Are there any possible disadvantages or risks from taking part? You should be told of all the possible risks of taking part in the clinical trial, the possibility of these risks, and what you need to do to reduce risks. For example:

- Blood samples - the possibility of bruising and/or fainting
- Biopsies - the possibility of bruising and infection, reduced using antiseptic and trained staff
- Radiation – when used in a clinical trial, the effect of extra CT scans and x-rays in addition to standard care

- Questionnaires or interviews questions – these may cause you and your family distress, so you need to be prepared for them
- Clinical trial drug(s) – you need to be told if the drug in commonly used for kidney cancer or other conditions, or whether it is the first time it has been tested in humans
- Clinical trial drug(s) – you need to be told all the known side effects of the study drugs.

What are the possible benefits of taking part? You need to be told the possible benefits of the clinical trial drug(s) and the possibility that you might not benefit from taking the drug(s). You need to be made aware that the researchers do not know what the outcome will be, which is why the clinical trial is taking place.

Will my General Practitioner/family doctor (GP) be informed of my participation? Your GP should be told that you are taking part in a clinical trial and that this may affect you care and treatment. You GP might be asked to follow-up side effects, such as high blood pressure or depression.

Will my taking part in the clinical trial be kept confidential? The arrangements to make sure your personal information is kept safe should be explained, such as how the information is stored and the use of a code to identify patients. You should also be told whether these codes will be destroyed at the end of the study and that if your information is anonymised you might not be able to withdraw your information.

Will I be reimbursed for taking part? It should be made clear if you will be compensated for your time, for having to take the clinical trial medications, or for having to give blood or tissue samples. It should also be made clear if you and/or family members who might come with you will be reimbursed for expenses such as travel, meals, and childcare. It should not cost you anything to take part in a clinical trial. Sometimes, these expenses may be avoided by having clinical trial visits at the same time as regular clinic appointments.

What will happen to the samples I give? You should be told how any samples that you give will be used in the clinical trial, where they will be stored and analysed, and if they will be anonymous. If the clinical trial involves the analysis of DNA samples, there are limits to how it can be anonymised, because DNA is unique to each individual person. This should be explained to you. You should also be told what will happen to your samples after the clinical trial has ended, for example, will it be destroyed, stored, or used in future research (with your consent).

What will happen to my data? This section should mention that Data Protection Regulations for the country where the clinical trial is being conducted will be followed. The institute who has responsibility for keeping your personal information should be mentioned, as well as what it will be used for and how long it will be stored. Your rights to access, change, or move your personal information may be limited. This is because the researchers will need to manage your information to make sure the data collected during the clinical trial is accurate and reliable. You can ask the study team about how they use your personal information.

If your personal information will be used in another clinical trial in the future, it should be stated. It should also be stated that the information will remain anonymous. If your personal information will be shared outside your country, it should be made clear that some countries might not have the same level of data protection. You should be assured that if during the transfer of your personal information abroad, your information will remain confidential and anonymous. You should be asked to give consent for the transfer of personal information.

What will happen if I don't want to carry on with the study? It should be made clear that taking part in the clinical trial is voluntary and you can change your mind at any stage during the trial. Dropping out of the trial will not affect the care you receive from your healthcare team.

The procedure for dropping out of the clinical trial should be explained, along with any safety implications, follow-up, final visit, and any further tests. You should also be told what will happen to the samples and data collected to the time when you drop out, whether the information will be kept or removed from the clinical trial, and whether you have a choice about what happens to your personal information.

What happens at the end of the study? You will be reassured that you will not be identified from any report or publication and told what the researchers will do regarding publishing research findings, presenting findings at conferences, and letting you know the findings from the clinical trial. They should also tell you if the clinical trial is part of an educational project, such as a doctoral thesis.

What if the clinical trial finds something unexpected? Sometimes the analysis of scans, samples, or questionnaires might produce findings that are significant for you or your family (especially when genes are looked at). You should be told how this will be managed by the research and/or healthcare team. This will involve clinical verification and/or referral to your GP.

What if there is a problem? You will be given the name and contact details of who you should contact if you wish to complain or have any concerns about the way you have been treated during the clinical trial. There may not be any special compensation arrangement. However, if you are harmed during the clinical trial because of someone's negligence, you may have grounds for legal action, but you might have to pay for it.

How have patients and the public been involved in this clinical trial? You will be told how patients and the public have been involved with the planning of the clinical trial, for example by reviewing the Patient Information Sheet, by having input into the design of the study, or by being involved in setting the eligibility criteria.

Who is organising and funding the clinical trial? This section will include details about which organisations are funding the clinical trial. This could be a medical research charity, a pharmaceutical company, an academic institution, or a national healthcare service. You should also be told if your doctor is being paid for their role in the clinical trial and if there are any conflicts of interest.

Who has reviewed the study? You will be given details of the research ethics committee who has reviewed and approved the study.

Participation in future clinical trials: If you would like to take part in future clinical trials, the researchers will keep your personal details and you should be told how these details are stored. However, you are not required to take part in future clinical trial, unless you really want to take part and you give your consent for your details to be kept.

Further information and contact details: you will be given the contact details for the person you need to contact to take part in the trial. You will then be thanked for reading the patient information and considering taking part in the clinical trial.

Patient Consent Form

Clinical trial Code: ……..... Site ID Code: ……..... Participant identification number: ……..…….....

Clinical trial title: This could be the same as in the protocol or a simplified patient-friendly version

Name of Researcher: ……..……..……..……..……..……..……..…

	If you agree, please initial box
1. I confirm that I have read the information sheet dated..... (version.....) for this clinical trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
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.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, from regulatory authorities and from the national health service, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
4. (If appropriate) I agree to provide a sample(s) as part of my involvement in this clinical trial and I understand I will not gain any direct personal or financial benefit from them.	
5. (If appropriate) I agree to audio/video recording and the use of anonymised quotes in research reports and publications.	

	If you agree, please initial box
6. (If appropriate) I agree to my General Practitioner being informed of my participation in the study.	
7. (If appropriate) I understand that the information held and maintained by the Sponsor or other central healthcare bodies may be used to help contact me or provide information about my health status.	
8. (Genetic research, if appropriate,) I understand and agree that my samples will be used in research aimed at understanding the genetic influences on disease and that the results of these investigations are unlikely to have any implications for me personally.	
9. (MRI studies, if appropriate): I understand that this is a research scan that is not useful for medical diagnosis, and that scans are not routinely looked at by a doctor. If a concern is raised about a possible abnormality on my scan, I will only be informed if a doctor thinks it is medically important such that the finding has clear implications for my current or future health.	
10. I agree to take part in this clinical trial.	
11. (If appropriate) I agree to be contacted about ethically approved clinical trials for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further clinical trials.	
12. (If appropriate) I agree for my anonymised samples to be used in future research, here or abroad, which has ethics approval.	

Name of participant……Date……Signature……

Name of person taking consent……Date……Signature……

Further reading

IKCC –
Understanding clinical trials and Clinical Trials Basics

National Institute of Health (NIH) USA –
What are clinical trials and studies?

National Health Service (NHS) England – Clinical trials

Cancer Research UK – What clinical trials are

Macmillan Cancer Support –
Understanding Cancer Research Trials (Clinical Trials)

The Lancet Oncology – Cancer trials and design principles

International Conference on Harmonization (ICH) guidelines on Good Clinical Practice

Clinical trial databases

IKCC Clinical Trials Database lists most clinical trials available worldwide that are focused on kidney cancer.

ClinicalTrials.gov is a database of privately and publicly funded clinical trials conducted around the world.

EORTC Clinical Trials Database contains information about European Organisation for Research and Treatment of Cancer (EORTC) clinical trials but also clinical trials from other organisations, in which EORTC has been/is participating.

EudraCT Database (European Union Drug Regulating Authorities Clinical Trials Database) is a database for all interventional clinical trials on medicinal products authorised in the European Union (EU) or European Economic Area (EEA).

WHO International Clinical Trials Registry Platform aims to ensure that a complete view of research is accessible to all those involved in health care decision making.

Glossary

Active surveillance: A way of monitoring cancer that is slow growing or indolent, rather than treating it straight away. During this time, regular testing is undertaken to check the growth and spread of the cancer. Some patients find this treatment approach difficult to understand; however, many tumours, particularly in older people, do not cause problems for the patient, and active surveillance enables them to avoid the debilitating side effects of some cancer treatments. Also called watch and wait and watchful waiting.

Adverse event: Undesired effect that may or may not be related to treatment, such as dizziness, or a rash. A symptom caused by the treatment is a side effect. Serious adverse events in clinical trial participants are reported to the national regulatory authority.

Aetiology study: A type of study that investigates the cause of a specific disease or tries to understand why a disease gets worse or better. Aetiological studies do not have to be clinical trials. Sometimes they can involve following up participants for a long time to see who develops the disease and what factors may have caused the disease to get worse or get better.

Baseline: An initial measurement that is taken at the start of a study or just before the start of treatment. It is used for comparison over time to look for changes. For example, the size of a tumour will be measured before treatment (baseline) and then afterwards to see if the treatment had an effect.

Basket trial: A trial involving a single medicine or treatment that is studied across multiple types of cancer which all share a certain characteristic (e.g., the same mutation or biomarker).

Bias: When a particular design or analysis is likely to favour a particular outcome and would, therefore, make those results unreliable. Bias can distort the results and could lead to unsafe or ineffective treatments being licensed for use, or useful treatments being overlooked. One way to avoid bias is by using randomisation and by 'blinding' participants and their caregivers.

Blinded: Clinical trial participants do not know which treatment they are receiving. This helps prevent bias. See also 'double blind clinical trial'.

Case control study: A type of observational study that is used to identify factors that may contribute to a medical condition by comparing people with a condition/disease (the 'cases') with people who do not have the condition/ disease but are otherwise similar (the 'controls').

Case Report Form (CRF): A paper or electronic questionnaire specifically used in a clinical trial to collect data from each participating patient.

CAT scan: Computerised axial tomography scan. See definition for computerised tomography.

Centre activation: A centre can start to recruit patients into a clinical trial. This can only happen when the centre has completed all the necessary paperwork and the staff are aware of their responsibilities for the clinical trial.

Clinical equipoise: The assumption that there is not one 'better' investigational treatment (for either the control or experimental group) during the design of a randomised controlled trial (RCT). A true state of clinical equipoise exists when one has no good basis for a choice between two or more treatment options.

Clinical trial: A rigorously controlled research study that finds new ways to prevent, diagnose or treat disease. Clinical trials test new treatments and other interventions in people with cancer to make sure they are safe and effective at treating cancer. They also compare different treatments and treatment strategies. All new treatments must go through clinical trials before its benefits and risks can really be known.

Closed: Usually refers to when recruitment of new patients or volunteers into a clinical trial is stopped. Existing patients who are already in the study continue to be followed up as part of the trial. This follow-up can continue for many years if the trial has been designed to look at long-term results. When follow-up for all patients has been completed and the data collected, the trial data can be analysed and reported. Usually, no more information is collected on the patients unless specific ethics approval is granted for the researchers to do so.

Cohort: A group of people with a shared characteristic.

Cohort study: A study of a group of people who share a characteristic, such as age, condition, or stage of cancer, often used to identify the causes of diseases, and to help develop clinical trials for new treatments.

Committee for Medicinal Products for Human Use: The committee at the European Medicines Agency responsible for preparing opinions on questions concerning medicines for human use.

Common Toxicity Criteria for Adverse Events (CTCAE): A grading system use by the clinical trial team to record the severity of a side effect (adverse event) in a clinical trial.

Concomitant medication: One or more medicines taken at the same time as the trial medicine.

Consent form: A form used to record the written consent of a patient or volunteer to take part in a clinical trial.

Contract Research Organisation (CRO): A company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

Cross-over trials: Clinical trials in which two different treatments are being compared, one in each of two groups of patients. After a period, the patients cross over to have the treatment that the other group of patients received.

CT (or CAT) scan or computerised tomography: A special type of X-ray examination in which a series of X-ray pictures of your body are taken from different angles. A computer puts the pictures together to give a detailed image of the inside of your body.

Data and safety monitoring committee: A group of people not directly involved with the clinical trial who keep an eye on how things are going during the trial, and make sure everything is running safely.

Disease-free survival: Length of time after treatment during which no cancer is found. Can be reported for an individual patient or for a study population. Sometimes also called relapse-free survival

Disease progression: The course that a disease takes over time. When doctors talk about progress of disease, unfortunately they mean it has got worse.

Dose escalation study: A study that determines the best dose of a new medicine or treatment.

Double blind clinical trial: The patient, their doctor, and the researchers running the trial do not know which treatment is received by the individual patient until all data have been recorded. This helps prevent bias.

Drug brochure (investigator's brochure): A comprehensive document summarising all the information available about the medicine under investigation in a clinical trial.

Effectiveness: The degree to which something is successful at producing the desired result or effect.

Efficacy: The ability to produce the desired result or effect.

Eligibility criteria: Clearly defined criteria for who is eligible to take part in a clinical trial and who is not. These criteria are described in the inclusion and exclusion criteria of the trial.

Observational: A study that observes a group of patients over a period of time and measures certain outcomes (e.g. the causes and patterns of disease, and whether a particular factor causes cancer or not, e.g., the effect of certain exposures (e.g., tobacco smoke, long duration of HIV infection). The study does not contain any attempt to affect the outcome.

Ethical Review Board (or Research Ethics committee): A committee of healthcare professionals and lay people who review clinical trials and research studies to ensure they are conducted to appropriate ethical standards. Recruitment for a clinical trial cannot start until ethics committee approval has been granted.

Evidence base: A collection of the best available scientific research currently available about a health condition. This is used to make decisions about how best to treat and provide care for individuals with that condition, or to prevent it.

Exclusion criteria: These determine who is not eligible for a clinical trial. For example, many trials exclude women who are pregnant, or who may become pregnant, to avoid any possible danger to a baby, or people who are taking a drug that might interact with the treatment being studied (see also eligibility criteria and inclusion criteria).

Feasibility study: A small-scale study carried out before starting a much larger clinical trial to see if the larger trial can be done.

Five-year survival: A statistic indicating the percentage of people with a particular type of cancer who are living 5 years after the initial cancer diagnosis.

Good Clinical Practice (GCP): An international quality standard for the conduct of clinical trials. Randomised clinical trials are required by law to conform to GCP.

Half-life: The period it takes for half of the total amount of a substance or drug to be eliminated from the body.

Health economics: In some clinical trials the cost of all aspects of the treatments being compared is examined. This is particularly important when there is more than one effective approach to treating a condition.

Inclusion criteria: A set of criteria that clearly indicate who can join a clinical trial or research study, e.g., the condition and stage of disease they are already at, and their age. See also eligibility criteria and exclusion criteria.

Informed consent: Written permission given before surgery, clinical trials, research or other kinds of treatments and tests. The individual, or a parent or guardian, must have received all the relevant information to understand the treatment and legally agree to any risks involved.

Interim analysis: An analysis of trial data, which is undertaken before the end of the trial.

International Conference on Harmonization (ICH) Good Clinical Practice: An international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve humans. It aims to provide a common standard to help with the approval of clinical trial data by regulatory authorities.

Intervention: A measure that is introduced and evaluated through a clinical trial with the aim of improving health. It could be a treatment (e.g., drug A vs. drug B), a treatment strategy (e.g., a drug vs. a surgical technique), a different screening approach, or prevention measure.

Interventional trial: A type of clinical trial in which patients or volunteers are put into groups that receive one or more intervention or treatment so that researchers can evaluate the effects of the interventions on the health of the patients or volunteers.

Investigational drug: A substance that has been tested in a laboratory and has regulatory approval to be tested in people in clinical trials. A drug may have a license for use in one disease/condition but be considered investigational in other diseases/conditions. Also called an experimental drug.

Karnofsky index: A scale for the measurement of performance status to quantify the general wellbeing and activities of daily life of cancer patients. Patients are scored from 100 to 0, where 100 is "perfect" health, and 0 is death. Doctors occasionally assign performance scores in between standard intervals of 10. The primary purpose of the Karnofsky index was to evaluate a patient's ability to tolerate and survive treatment for cancer.

Kidney cancer: Cancer that forms in tissues of the kidneys, including renal cell carcinoma (RCC), transitional cell carcinoma (TCC) (also called renal pelvis carcinoma), and Wilms' tumour, a rare type of kidney cancer that usually develops in children under the age of 5.

Leibovich score: A scoring algorithm that can be used to predict the risk of kidney cancer reappearing after it has been resected. The scoring system is based on the stage of the primary tumour, spread to the lymph nodes, tumour size, nuclear grade, and tumour necrosis. A low score (0-2) has a low risk, whereas a high score (6-11) has a high risk of relapse.

Magnetic resonance imaging (MRI): A type of scan that uses magnetism instead of X-rays to construct a detailed picture of the inside of your body.

Multidisciplinary team (MDT): A group of health care and social care professionals who provide different services for patients in a co-ordinated way. Members of the team may vary and will depend on the patient's needs and the condition or disease being treated.

NED or No Evidence of Disease: Medical phrase to indicate that the doctors are not able to detect any sign of disease or cancer with current testing methods.

Objective response: A measurable response, usually assessed with a CT scan.

Observational study: A type of study in which individuals are observed or certain outcomes are measured. No attempt is made to affect the outcome (for example, no treatment is given). See epidemiological study.

Off-label: The legal use of a prescription drug to treat a disease or condition for which the drug has not been licensed for use.

Open label trials: A clinical trial in which participants and their doctors know which treatment (or treatment strategy) they are receiving.

Outcomes: Outcomes are measures of health, e.g., response to treatment, occurrence, or recurrence of disease, a measure of wellbeing.

Overall survival: The length of time from either date of diagnosis or start of treatment that people diagnosed with cancer (or another disease) are still alive.

Pharmacodynamics: The biological effect of medicines within the body and their mechanism of action.

Pharmacokinetics: How medicines move around the body

Partial response: A decrease in the size of a tumour or in the extent of the cancer in response to treatment. This is also called partial remission.

Patient information sheet (or materials): Leaflets or other materials, e.g., videos that provide sufficient information, in an understandable format to support patients and volunteers in making the right decision for them to take part in a clinical trial, or to for them to decline participation.

Physical examination: The process by which a doctor investigates the body of a person for signs of disease.

Pilot study: A scaled down versions of a larger clinical trial to help test whether the main parts of the clinical trial will work. The results from a pilot study can be used in the larger clinical trial.

Positron emission tomography (PET) scan: A procedure in which a small amount of radioactive glucose is injected into a vein and a scanner is used to make detailed computerised pictures of areas inside the body where the glucose is used. Because cancer cells often are very active and need more glucose than normal cells, the radioactive glucose accumulates in cancer cells and these areas are highlighted on the scan.

Placebo: A dummy treatment that is designed to be harmless and to have no effect. It looks, smells, and tastes like the treatment being tested, so that trial participants do not know if they are taking the dummy treatment or the treatment itself, i.e., they are blinded to the treatment they are taking. The effects of the active drug are compared to the effects of the placebo.

Placebo-controlled trial: A trial in which there are two (or more) groups. One group gets the active treatment, the other gets the placebo. Everything else is the same between the two groups, so that any difference in their outcome can be attributed to the active treatment.

Primary end point: The main endpoint or outcome of a clinical trial.

Principal investigator: A healthcare professional with several years research experience who is responsible for the management, conduct, and reporting of the clinical trial and for managing any collaborative relationships.

Product license: A license that allows the manufacturer to market and sell a product.

Prognosis: The likely outcome or course of a disease. The factors that affect a patient's prognosis include the type of cancer, its stage, grade, and response to treatment but also patient characteristics, for example their age.

Prognostic factor: A situation or condition, or a characteristic of a patient, which can be used to estimate the chance of recovery from a disease, or the chance of the disease recurring (coming back).

Progression: Increase in the size of a tumour or spread of cancer in the body.

Progression-free survival (PFS): The length of time a patient lives without their cancer getting worse (progressing). PFS is a measurement used in clinical trials to help determine whether a new treatment is effective.

Progressive disease: Cancer that is growing, spreading, or getting worse.

Protocol: The plan for a research study or clinical trial. Protocols need to be approved by an ethics committee before the study begins to recruit participants. They provide information on the question being addressed by the study, the treatments under investigation, the eligibility criteria, and the visit schedule and type of tests for trial participants.

Quality of life: As well as measuring the physical effects of a treatment (for example changes to blood pressure), some trials try to assess the impact of treatments on people's quality of life. For example, a 'quality of life' study might ask about; mood and general sense of wellbeing, fatigue, sleep patterns, and ability to carry out daily activities.

Randomisation: Used in randomised controlled trials. It is decided at random which treatment or treatment strategy a trial participant will receive. This ensures that each participant has the same chance of receiving the treatments or strategies being compared and avoids one treatment being given to someone because they are, for example, elderly or very sick. Randomisation ensures that the groups of people being compared in a trial are as similar as possible, except for the treatment they receive. This in turn ensures that differences seen between these groups after they have started their treatment are likely to be due to the treatments being compared.

Randomised controlled trial (RCT): A clinical trial in which the participants are assigned by chance to different treatment groups; neither the researchers nor the participants can choose which group they are in. Randomisation allows a fair comparison between trial groups to be made.

RECIST (Response Evaluation Criteria in Solid Tumours): A standard way to measure how well a cancer patient responds to treatment. It is based on whether tumors shrink, stay the same, or get bigger. There must be at least one tumuor that can be measured on x-rays, CT scans, or MRI scans.

Recurrence: Cancer that has returned after a period during which the cancer could not be detected. The cancer may come back to the same place as the original (primary) tumour, or to another place in the body.

Regression: A decrease in the size of a tumour or the extent of cancer in the body.

Regulatory body: A government organisation that establishes national standards for medicines and ensure that these standards are adhered to. Regulatory bodies also grant product licenses for new medicines.

Relapse: The return of the signs and symptoms of cancer after a period of improvement.

Relative survival: A specific measurement of survival. For cancer, the rate is calculated by adjusting the survival rate to remove all causes of death except cancer. The rate is determined at specific time intervals, such as 2 years and 5 years after diagnosis.

Remission: If a cancer is in remission, there is no sign of it on scans or during an examination. Doctors use the word 'remission' instead of cure when talking about cancer because they cannot be sure that there are no cancer cells at all in the body.

Research Ethics committee (or Ethical Review Board): See Ethical Review Board.

Response: An improvement in disease related to treatment.

Response rate: The percentage of patients whose cancer shrinks or disappears after treatment (responds to treatment).

Screening: A way of finding out if people have a higher chance of having a health problem, so that early treatment can be offered, or information given to help them make informed decisions.

Secondary end point: Clinical endpoints or outcomes from clinical trials in addition to the primary end point.

Shared decision-making: A process that ensures individuals are supported to make decisions that are right for them. It is a collaborative process through which a clinician supports a patient to reach a decision about their treatment. The conversation brings together the clinician's expertise, such as treatment options, evidence, risks and benefits, and the patient's preferences, personal circumstances, goals, values, and beliefs.

Side effects: Side effects are other effects on the body that may be related to the treatment. For example, a drug used to treat lung cancer may also cause a skin rash. Side effects can be caused by something else other than the clinical trial treatment. These are recorded separately.

Stable disease: Cancer that isn't changing, i.e., the tumour(s) is not growing, and no new tumours have developed.

Standard care: Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.

Stage/staging: A system used to describe the size of a tumour and the extent of spread of the cancer throughout the body.

Survival rate: The percentage of people in a study or treatment group who are alive for a given period after diagnosis. This is commonly expressed as 1- or 5-year survival rates.

Symptom: An indication that a person has a condition or disease. Examples of symptoms include headache, fever, fatigue, nausea, vomiting, and pain.
Systemic: Affecting the entire body. Also used to describe the supply of medicines through the circulatory system (blood) to the entire body.

Systemic treatment/therapy: A treatment that is delivered to the entire body through the circulatory system (blood). Most cancer drugs are systemic treatments.

TNM staging: A system for staging cancer based on the size of the tumour (T), lymph node involvement (N) and metastases (M). Also called AJCC staging.

Toxicity: The extent to which something can cause a side effect or be harmful.

Trade name: The name of a drug under which it is licensed and sold. Also called the brand name.

Translational research: Research aimed at translating results from basic science into results that directly benefit humans.

Trial/treatment arm: One of the groups to which trial participants are assigned to in a randomised controlled trial. The group of people receiving the current standard care are usually referred to as the control arm.
Trial phases: Clinical trials are conducted in phases from phase 1 through phase 4. Phase 1 trials aim to test safety and usually involve a small number of people. Phase 2 trials aim to evaluate effectiveness, and usually involve a larger number of people. Phase 3 trials aim to compare two or more treatments or treatment strategies and monitor side effects. Results from phase 3 trials are used to license treatments for use by patients. Phase 4 trials are post-marketing studies and collect further information on use of treatments in clinical practice.

Tumour: A swelling, or lesion formed by an abnormal growth of cells. Tumour is not synonymous with cancer and a tumour can be benign (not cancerous) or malignant (cancerous).

Tumour burden/load: The number of cancer cells, the size of a tumour, or the amount of cancer in the body.

Ultrasound scan: A real-time, moving test that uses sound waves to detect and differentiate between tumours and cysts. A small probe producing sound waves is rubbed over the area of interest and the sound wave echoes are detected by the probe and turned into a picture of the organs and structures inside your body by a computer.

X-ray: A type of electromagnetic radiation used to make images. The image is recorded on a film, called a radiograph. The parts of your body appear light or dark due to the different rates that your tissues absorb the X-rays. Calcium in bones absorbs X-rays the most, so bones look white on the radiograph. Fat and other soft tissues absorb less and look grey. Air absorbs least, so lungs look black.

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The IKCC *My Treatment, My Choice* decision aid series was conceived by and written in collaboration with kidney cancer patients for the benefit of patients worldwide.

The IKCC is an independent international network of patient organisations that focus exclusively, or include a specific focus on, kidney cancer. It is legally incorporated as a Foundation in the Netherlands. The organisation was born from a very strong desire among various national kidney cancer patient groups to network, cooperate and share materials, knowledge, and experiences.

As part of the *My treatment, My Choice* series of decision aids, this clinical trial decision aid has been developed by the IKCC working in partnership with the Action Kidney Cancer, a kidney cancer charity based in the UK.

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