

Patient Information Sheet



Image directed redesign of bladder cancer treatment pathways

Invitation to participate

Dear Patient

We would like to invite you to take part in a non-commercial research study called BladderPath run by the University of Birmingham. We are asking you to take part in this study because you are being investigated for symptoms that are suspicious of bladder cancer. For most people, the suspicious symptom is the passing of blood in urine ('haematuria'). There are many reasons for passing blood in urine, so only around 1 in 10 people who undergo investigation will be diagnosed with bladder cancer. Three-quarters of people diagnosed with bladder cancer in this way will be diagnosed with the earliest stages of the disease where the tumour(s) is confined to the lining of the bladder. The main purpose of the study is to find out whether we can redesign the current management pathway for bladder cancer patients with a different pathway that is tailored to the stage of bladder cancer.

Our secondary purpose is to develop a urine test that can accurately diagnose bladder cancer.

We are asking everyone who is being investigated for suspected bladder cancer to take part in this study; however, it is very important to understand that the main part of this study will only be relevant to people who are found to have bladder cancer.

One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study if you wish.

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Joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you.

This information sheet is divided into three parts:

Part 1 - tells you the purpose of the study and what will happen to you if you take part in general terms

Part 2a - gives you more detailed information about the **standard** management pathway

Part 2b - gives you more detailed information about the **research study** management pathway

Part 3 - gives you more detailed information about the conduct of the study

Part 1 gives you sufficient information to make an initial decision. If you agree to enter the study, you can then read the more detailed information relating to the standard management pathway (part 2a) and/or the research study management pathway (part 2b) and the information about how the study will be run (part 3).

If you wish you can read all three sections.

Ask your study doctor or nurse if anything is not clear or if you would like more information.

Part 1

Why have I been chosen?

You have been referred to the hospital for the investigation of symptoms suspicious of bladder cancer. The first part of the study is looking at the possible development of a urine test for bladder cancer. In the future this may allow some patients to avoid invasive tests. To develop this urine test, we need urine samples both from patients with bladder cancer and from similar patients referred to the clinic who do not have bladder cancer. For this reason, we are asking everyone who has been invited to attend a clinic for the investigation of symptoms suspicious of bladder cancer to take part in this first part of the study. The second part of the study (the clinical trial assessing a new pathway) will not be relevant to approximately 9 out of 10 patients. If you do not have bladder cancer, then with your consent we would still like to retain a sample of your urine and have access to some clinical information for research purposes. In particular, we are interested in any future problems that you may develop affecting the urinary system, or other serious illnesses such as cancer. We can obtain this information, with your permission, from NHS and Public Health records. There is no need for extra follow-up visits to obtain this information.

Do I have to take part?

No, you do not have to take part in this study. Participation is entirely optional. You do not have to give a reason to decline study entry and your treatment will not be altered or affected in any way.

What will happen to me if I take part?

You will proceed to have your clinic visit as normal; however, before your bladder is inspected, we will ask you to sign a consent form that will allow us to store some of your urine so that we can use this to look for molecules that may indicate the presence of bladder cancer. Researchers at the University of Birmingham have devised a test to accurately identify bladder cancer by analysing urine. Your urine sample will be used to find out how good this urine test is for diagnosing patients with bladder cancer.

If your doctor sees an unusual growth during the flexible cystoscopy that is suspicious for bladder cancer, we will also take a small sample from the growth (termed a biopsy). Taking a biopsy in this way is not standard practice for all patients - in addition to the side effects normally associated with flexible cystoscopy, taking a biopsy may carry a small risk, as described later in this information sheet. Having a biopsy taken early helps us to decide whether you may be suitable for the main part of the study and also helps in the selection of the treatment, but a biopsy can also be taken later, at either a repeat cystoscopy or a limited transurethral resection of bladder tumour (TURBT; for further details refer to page 4). At the end of your visit, if the doctor has seen an unusual

growth suspicious for bladder cancer, we will ask you to sign a second consent form to confirm that you are willing to take part in the main study, and to allow us to collect blood samples for future research. You will then be allocated to one of two pathways randomly (like tossing a coin): Pathway 1 (standard pathway – see part 2a) or Pathway 2 (research study pathway – see part 2b).

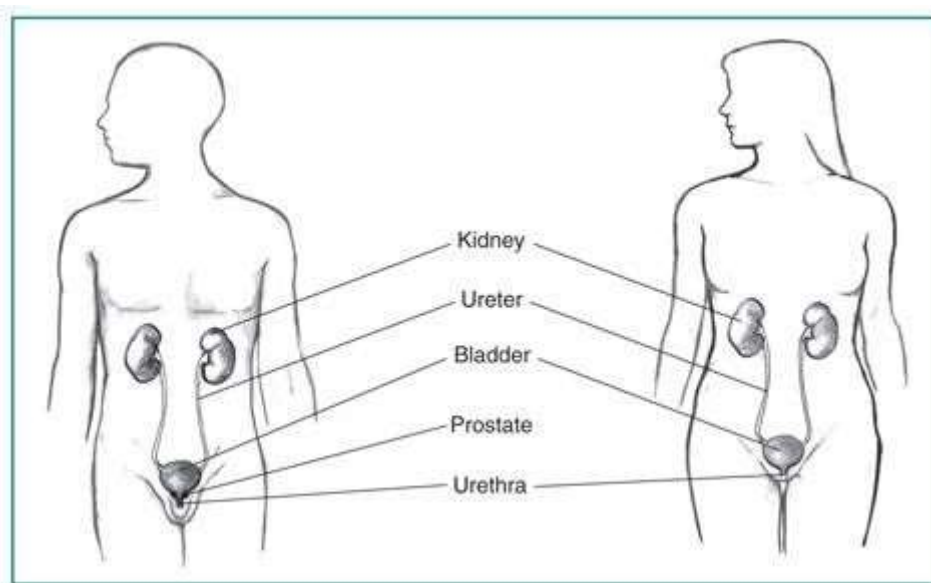
What are the alternatives for diagnosis or treatment?

If you do not wish to enter the study, your treatment will be carried out as detailed in the standard pathway (Pathway 1).

What is the purpose of the study?

The purpose of the BladderPath study is to redesign the management pathway for bladder cancer patients because the current standard pathway may delay the curative treatment for patients with the later stages of the disease, muscle-invasive bladder cancer (MIBC).

Throughout the NHS and in most major centres worldwide, the current standard method for the initial assessment of suspected bladder cancer includes a procedure called a flexible cystoscopy: using a thin flexible telescope/camera to examine the inside of the bladder under local anaesthetic. During flexible cystoscopy, if your doctor sees an unusual growth that is suspicious for bladder cancer, they may take a small sample from the growth (termed a biopsy). You will also usually have an assessment of the rest of the urinary system (the kidneys and the ureters, the tubes connecting the kidney to the bladder) carried out at the same visit by means of an ultrasound scan or possibly another X-ray or scan (this varies from hospital to hospital).



National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

Diagram 1. The male and female urinary system

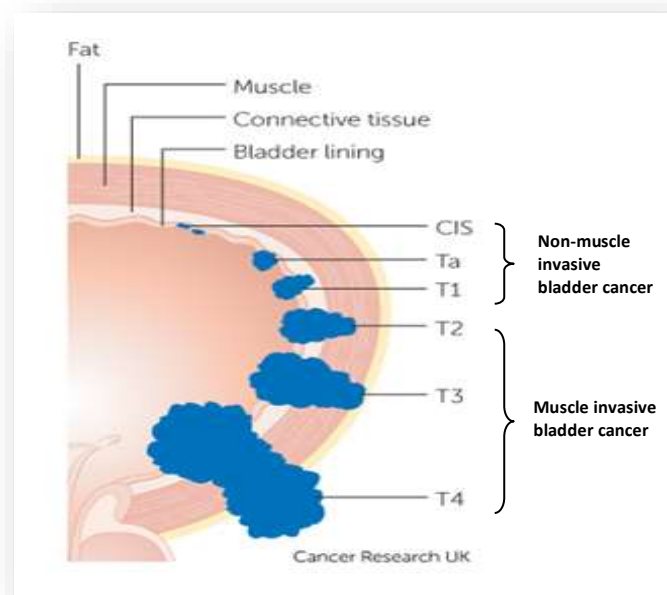


Diagram 2. Bladder cancer

For more information refer to: <https://www.cancerresearchuk.org/about-cancer/bladder-cancer/types-stages-grades/stages>

If a bladder tumour is confirmed, patients then proceed a few days or weeks later to removal of the tumour under general anaesthetic using a slightly larger, rigid telescope - this procedure is called transurethral resection of bladder tumour (TURBT). The removed tumour is assessed to decide if it is confined to the bladder lining (non-muscle invasive bladder cancer – NMIBC) or whether it invades into the bladder muscle (muscle-invasive bladder cancer – MIBC). For NMIBC, the procedure should successfully remove all tumour; nonetheless, further drug treatment directly into the bladder is usually given to reduce the risk of a tumour returning.

For MIBC, complete removal of the tumour by TURBT is not usually possible and further treatment is required. This further 'definitive' treatment may involve surgery to remove the bladder (cystectomy), chemotherapy (anti-cancer drug therapy) or radiotherapy (using high energy X-rays to kill the cancer cells). These options are not affected by taking part in the study.

A concern with the current pathway is that TURBT may delay definitive treatment for MIBC patients - in the UK the typical time from being referred by a GP to definitive treatment by a specialist is over 100 days. Therefore, it may be better to treat NMIBC and MIBC patients differently from the moment that a suspicious bladder lesion is identified by flexible cystoscopy. Doing this may mean that patients with MIBC receive their definitive treatment quicker, and patients with NMIBC may undergo TURBT quicker. The BladderPath research study will assess such a modified pathway, compared to the standard pathway.

If you are given this information sheet after your cystoscopy to take home and read, a member of the research team will phone you after a day or two to discuss the study and find out if you would like to take part.

If you choose to take part you will be asked to sign two consent forms. You can either do this at the hospital, if you have had enough time to read them and ask questions, or at home. At the hospital, your doctor or research nurse will ask you to sign the forms. At home you will be able to consent by telephone, and then to confirm your verbal consent electronically, either by:

- text message
- email, with photograph or scan of your signed consent forms with your email or text, if you are able to do that

- a recordable electronic message (such as an answerphone message), or
- by post

If not posted, you will be asked to take your signed consent forms with you to your next hospital visit, whether that is for your TURBT or MRI appointment.

You will also have been given a health questionnaire booklet with this information sheet. You will be asked to complete the booklet (described further on page 7) if you choose to take part in the study and have signed the consent forms. The booklet can be returned to the hospital at the same time as the consent forms.

When you attend the hospital you may then be asked to provide a urine sample if you agreed to this on the consent forms.

Patients entering the trial will be randomly assigned to be treated either by the current standard pathway (Diagram 3) or by the research study pathway (Diagram 4). This is called randomisation and ensures that patients in each of the pathways are similar (similar numbers of men and women, similar ages, similar symptoms, etc.) and means that, at the end of the trial, if one pathway is shown to be better than the other then that is because the pathway was better and not because the patients were different. Randomisation is done completely randomly and by a computer, this means neither the doctors nor you will select the pathway that you will follow, and there will be an equal chance of being randomised to either pathway.

We would use flexible cystoscopy with a biopsy, if possible, as an initial assessment. The very small biopsy obtainable by this procedure is sufficient to confirm the presence of cancer and also identify how aggressive the cancer cells look under the microscope. Most MIBC tumours are made up of more aggressive cells, whereas NMIBC tumour cells may be more or less aggressive. The overall appearance of the tumour may also suggest MIBC or NMIBC. Combining these factors, urologists can quite accurately predict which patients have probable NMIBC or possible MIBC before this is confirmed by the TURBT operation.

If for any reason your doctor was not able to obtain a biopsy during your flexible cystoscopy, but you are given a diagnosis of bladder cancer and wish to take part in the study, you may be asked to return for a biopsy to be taken if you are going to have an MRI rather than a TURBT. The biopsy is needed to confirm your diagnosis.

In the current standard pathway, all patients (both probable NMIBC and possible MIBC) will undergo TURBT, and the results of the TURBT will then determine how the bladder cancer is treated. In the research study pathway, patients with probable NMIBC (around two-thirds of patients) would also continue with the current standard management pathway. Those patients with possible MIBC (around one-third of patients) would proceed to have a very detailed Magnetic Resonance Imaging (MRI) scan instead of TURBT; for most patients, this MRI scan will be able to clearly identify MIBC or NMIBC. If the MRI scan diagnoses NMIBC, patients would then undergo TURBT in the standard way. If the MRI scan diagnoses MIBC, patients would proceed directly to definitive treatment without undergoing TURBT.

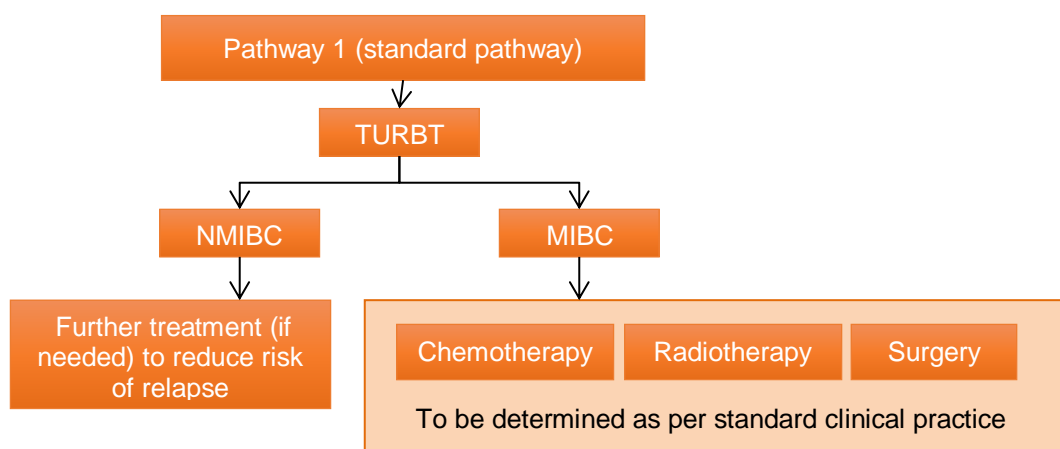


Diagram 3. Standard management pathway

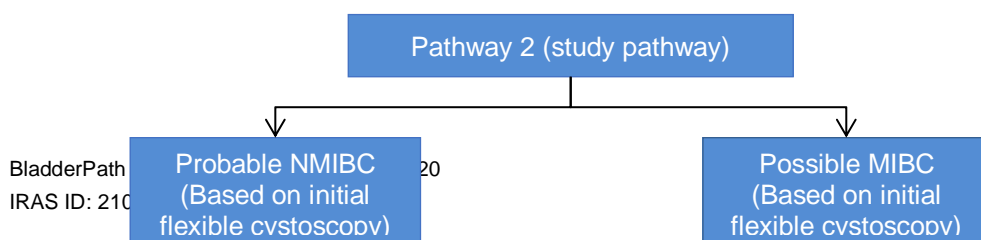


Diagram 4. Research study management pathway

What are the possible benefits of taking part?

The purpose of the study is to find out if by using an MRI scan early in the management pathway, we can identify patients with disease invading the bladder muscle (MIBC) and move directly to definitive treatment without the need for a TURBT.

If the MRI scan correctly identifies the involvement of the muscle then there are two immediate advantages:

- a) Avoiding TURBT and the subsequent risks of this operation
- b) The definitive cancer treatment could be given to you much sooner, meaning that the cancer will have less time to progress before treatment is given

There may be no immediate clinical benefit from taking part in this study. However, the information obtained from this study may result in changes in the future diagnosis, treatment, and follow-up of patients with bladder cancer.

What are the possible disadvantages and risks of taking part?

Pathway 1 (standard pathway)

No method of assessing the bladder prior to treatment is 100% accurate. There is therefore the potential for either treating too much or too little with both Pathway 1 (the current standard management pathway) and Pathway 2 (the research study pathway).

For Pathway 1, these factors are well known and are mainly that the initial TURBT underestimates the tumour stage: we know that up to one-third of patients who are thought to have NMIBC, actually turn out to have MIBC and therefore are initially undertreated, with their definitive treatment delayed. We also know that in Pathway 1, when TURBT is carried out on patients with MIBC, there is a small risk that the procedure itself may spread cancer cells elsewhere in the bladder and elsewhere in the body.

TURBT is a commonly performed procedure and the side effects are well known, for example pain and discomfort, problems passing urine. Your doctor will discuss the procedure with you including the various aspects to consider when deciding to perform a TURBT, in addition to what you should expect before and afterwards. After the procedure you may need to stay in hospital for a few days to recover, and it may take up to two weeks to recover fully. After a few months you will need to have a further cystoscopy to check how well the treatment worked.

If your cancer has grown into the muscle surrounding your bladder, or has spread outside it, your doctor may suggest other treatments after your TURBT. These include an operation to remove all or part of your bladder, radiotherapy and chemotherapy.

Pathway 2 (research study pathway)

If you are randomised into Pathway 2 and have an MRI scan, there is the possibility that the scan overestimates the tumour stage and you may be over-treated. This is the main risk of participating in this study. This is most likely to occur in cases where a NMIBC tumour is large and contains aggressive cells. Since nobody has previously carried out a study like this before, we do not know how often overtreatment will occur, but we predict that it will occur in less than 1 in 20 patients diagnosed with bladder cancer. If the scan underestimates a MIBC tumour as NMIBC, then you will have a TURBT and the tumour samples from the TURBT would show MIBC. Since this is what happens in the standard pathway anyway, you will have had one additional scan only and then will receive the correct treatment for MIBC.

It is also important to understand that undergoing MRI itself carries certain specific risks. There is an extremely small chance that you may have an adverse reaction to the MRI contrast liquid (gadolinium chelate) that will be injected into you during the scanning procedure. In addition, certain patients should not have MRI scans: if they have metal implants, certain heart pacemakers, or metal fragments from injuries (especially in the eye) and, on rare occasions, people with poor kidney function.

For some patients the MRI procedure may be uncomfortable if they suffer from claustrophobia, but most people are not bothered by this. MRI scans do not expose the body to X-ray radiation, and they are therefore safe for pregnant women. The main potential risk of the scan is that we make different treatment decisions to the ones we would have made with the standard pathway, as summarised above.

The MRI scans will initially be reviewed and reported at your local hospital, but a second review by another certified radiologist in the research team will be performed to confirm the diagnosis.

The MRI scans will be stored centrally by the research team, as well as at your hospital. Most hospitals taking part in the BladderPath study can send the MRI images electronically to an NHS computer. However, some hospitals may need to send the MRI images securely on a CD by post; these images can only be seen with special computer software. If this occurs, the CD will only contain your unique study number, date of birth and the date that the MRI was done.

With your permission, we would like to store and use your MRI scans and the associated data for further research purposes.

Biopsy

Taking a biopsy carries a small risk of additional bleeding which typically lasts no longer than 2-3 days following the procedure. You should tell your doctor if the bleeding persists.

Follow-up

There are no additional visits required as we can obtain all the clinical information needed from your routine follow-up, and your routine follow-up is unaffected by taking part in the study. We will send you 3 different health questionnaires at 3, 6, 9, 12, 18 and 24 months, and then yearly up to 5 years following your entry into the study. These questionnaires assess the side effects of the treatment you receive, and long term impact on your quality of life. We would be grateful if you could complete and return them to us, simply by posting them to the Cancer Research UK Clinical Trials Unit (Study Office) at the University of Birmingham in the pre-paid envelopes provided. In order to send out these questionnaires to you, you will be asked to give consent for us to collect your full name and home address when you are enrolled into the study.

What happens when the research study ends?

This study is testing a pathway intended to streamline the diagnosis of bladder cancer. Your subsequent treatment will proceed according to your individual needs and will not be affected by the study. When the study stops your routine bladder cancer treatment and follow-up will continue in the normal way.

Expenses and payments

You will not have to attend for extra visits as a result of taking part, and should not incur any extra expenses. We are unable to pay you for taking part in this study.

This is the end of Part 1 of the Patient Information Sheet. If you have found the information in Part 1 interesting and you would like to consider taking part in the study, please continue to read the additional information in Part 2a, Part 2b and Part 3.

Part 2a. Pathway 1 (standard pathway)

If you are allocated to Pathway 1, your treatment will proceed as per the usual standard of care:

- 1) The suspicious lesion will be removed in the operating theatre under a general anaesthetic via TURBT.
- 2) The removed lesion will be examined under the microscope by a pathologist. The pathologist will decide whether the lesion is cancerous or not. If the lesion is cancerous, the pathologist will then also try to decide whether it is an early cancer confined to the bladder lining (NMIBC) or a more advanced cancer invading into the bladder muscle or other structures (MIBC).

Non-muscle-invasive bladder cancer (NMIBC)

If the cancer is NMIBC, there are a number of options for subsequent treatment, depending on the opinion of the treating team and the extent of the disease. All of these options will be assessed by your specialists in a meeting dedicated to treatment discussions for patients newly-diagnosed with bladder cancer. The option(s) will then be discussed with you. The best option for you is selected according to the risk of the cancer coming back. The main options are:

- 1) No further treatment, apart from future inspections of the bladder;
- 2) A course of chemotherapy given directly into the bladder. This is called intravesical chemotherapy;
- 3) A course of immunotherapy with Bacillus Calmette-Guerin (BCG) given directly into the bladder;
- 4) A repeat TURBT with more biopsies to confirm the diagnosis of NMIBC.

Muscle-invasive bladder cancer (MIBC)

If the cancer is spreading (invading) into the bladder muscle, further treatment will be needed to control the disease. You may need some additional scans or other tests before a final course of treatment is decided upon. All of these options will be assessed by your specialists in a dedicated meeting for the discussion of treatment options for patients newly-diagnosed with bladder cancer. The option(s) will then be discussed with you. Possible options for further treatment include:

- 1) Surgery to remove the bladder (cystectomy). In this case, other parts of your urinary tract will be 'diverted' so that your urine collects into a special plastic bag that is attached to the outside of your tummy. This is called a 'stoma' or 'urostomy'. In some cases, it may be possible to reconstruct a new or substitute bladder from a piece of your bowel, and this is called a 'neobladder';
- 2) Chemotherapy followed by surgery (cystectomy) to remove the bladder;
- 3) Radiotherapy;
- 4) Radiotherapy combined with chemotherapy.

Your doctor or nurse can give you more information about these options and answer any questions you may have. It is important to remember that three-quarters of people diagnosed with bladder cancer do not have MIBC, so it is best to wait until you have been given the full diagnosis before considering these options.

Part 2b. Pathway 2 (research study pathway)

If you are randomised to Pathway 2, your specialists will use the findings of your initial bladder inspection (cystoscopy) along with the results of your biopsy to predict whether the lesion is possibly invading the bladder muscle (MIBC) or whether it is probably confined to the lining of the bladder (NMIBC). We have shown in previous research that this prediction is correct around nine times out of ten. If we consider that the lesion is more likely to be confined to the lining (NMIBC), you will proceed to undergo a TURBT and subsequent treatment as with the standard pathway.

If our initial assessment suggests that the tumour may be invading the bladder muscle, you will undergo a MRI scan. Other studies have shown that MRI can be very accurate in determining whether bladder cancers are actually invading the bladder muscle or not. Your specialists will then combine all of your clinical information to determine whether you have muscle-invasive (MIBC) or non-muscle invasive (NMIBC) disease. See above regarding further treatment.

Part 3: General information on the conduct of the study

What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time and your standard of care will not be affected in any way. You do not need to give a reason for your withdrawal.

How will my information be kept confidential?

All information collected about you for this study will be subject to the Data Protection Act 2018 and will be kept strictly confidential. All information will be securely stored on paper and electronically in line with the clinical trials regulations and Data Protection Act, and will only be accessible by authorised personnel.

With your permission, your research doctor will provide your full name, full address, date of birth, gender and hospital/NHS number to the Study Office when they enter you into the study, and they will notify your GP that you intend to participate in the study. They will also send a copy of your signed consent form in the post to the Study Office.

We propose to access routinely collected data from the NHS Hospital Episode Statistics (HES) to minimise the need for follow-up visits; this may include relevant data prior to the date that you gave consent to participate in the study. The Study Office may also need to access information held by Cancer Registries, Cancer Intelligence Units, General Practice databases, NHS Digital, National Cancer Registration, Public Health England and other similar data sources held by the NHS or related organisations in order to follow up on your health status. To do this, we might need to provide your full name, gender, date of birth, hospital and/or NHS number. Any information received in this way is confidential and only for the purposes of the study. Please initial the consent form to indicate you are happy for us to do this.

In the Study Office you will be identified by a unique number (called a trial number). In routine communication between your hospital and the Study Office you will only be identified by trial number, initials and date of birth. Data may be provided to the Study Office on paper or electronically.

By taking part in the study you will be agreeing to allow research staff from the Study Office to look at the study records, and this includes your medical records. It may be necessary to allow authorised personnel from government regulatory agencies, sponsors and/or NHS bodies to have access to information about you. This is to ensure that the study is being conducted to the highest possible standards.

In addition, anonymised data collected for the trial may be provided to other third parties (e.g. other academic institutions) under confidentiality agreements for ethically approved research. The initials, date of birth and pathology number of patients who donate tissue, blood and urine samples for the study will be passed on to authorised personnel at the laboratory to help them identify the tissue, blood and urine samples. All individuals who have access to your information have a duty of confidentiality to you. Under no circumstances will you be identified in any way in any report, presentation or publication arising from this study without your specific further consent in writing. If you choose to withdraw from the study, we would still like to collect relevant information about your health, as this will be invaluable to our research. If you have any objection to this please let your doctor know.

You can withdraw your consent to our processing of your data at any time. Under the provisions of the Data Protection Act 2018 you have the right to know what information the Study Office have recorded about you.

What if relevant new information becomes available?

If new information becomes available and proves one way or another that the treatment outcomes or management procedure is statistically better or worse than standard methods, then the study will be adjusted to accommodate any changes. The study will be monitored throughout by an independent Data Monitoring Committee (DMC) and a separate independent Trial Steering Committee. Confidential reports containing recruitment, protocol compliance, safety data and interim assessments of outcomes will be reviewed by the DMC, and it is their responsibility to advise the sponsor of whether there is evidence or reasons why the study should be amended or terminated.

Involvement of General Practitioner (GP)

With your permission, your GP will be informed that you are taking part in the study, and we may ask her/him to provide information on your progress. If we do need to contact your GP for any follow-up information, we will need to use your full name in our correspondence if you have agreed to provide this.

We would also like your permission to access relevant data held on databases in General Practice.

What will happen to any samples I give?

With your consent, we would like to collect and store urine samples (3 x 50 ml) and blood samples (3 x 13.5 ml), 10 ml is one level dessertspoon. These samples will be collected when you attend the first clinic visit, when you attend clinic for your definitive treatment and once during the follow-up period (coinciding with a routine clinic visit).

The blood and urine samples that will be collected as part of this research study will be transferred to a central biorepository for long-term storage. In addition, we would like to store and retain any material remaining from the tissue samples that have been taken during this study as long as they are not required for diagnosis. The samples collected will be used, first and foremost, for research as part of the BladderPath study. This research will include studies on the proteins and DNA in blood, urine and tumour tissue, which may:

- Help to more accurately distinguish MIBC from NMIBC;
- Diagnose bladder cancer earlier, or diagnose bladder cancer without the need for a camera inspection of the bladder;
- Help us to decide how we treat your disease after diagnosis.

The collection of blood, urine and tissue samples may also be very useful for research in the future that will help us to understand more about how bladder cancers behave. Such future research could be conducted by researchers in the UK or abroad, and may be carried out by academic institutions (e.g. universities) or commercial organisations (e.g. pharmaceutical companies). By giving your consent for your blood and urine samples to be collected and stored, you will be offering your samples as a gift. If, after surgery you are diagnosed as not having bladder cancer, we would still like to keep your samples for further use in approved research. The samples stored for research will be taken from samples that remain after all the information needed by doctors diagnosing and caring for you has been obtained. The blood and urine samples are stored under strict security and are given a code, so that researchers receiving the samples do not know your name or any other personal details. Researchers who wish to use the samples will only be given access to the samples after their research has been approved by an independent Research Ethics Committee (REC) who make sure that the research is in the interest of patients and is carried out ethically.

Will any genetic tests be done?

The DNA from bladder tumours can show a wide range of changes compared to your normal ('germline') DNA. In some tumours these changes can be very extensive. It is possible to detect this abnormal tumour DNA in the urine and the blood and, by comparing it with your normal ('germline') DNA; we can identify exactly what

changes those are. This is known as 'DNA sequencing', and we can do this by either looking at specific areas of DNA ('genes') that we know are related to bladder cancer, or by looking at all of your DNA. These changes may be used in the future to determine how bladder cancer patients are treated, or even to detect bladder cancer without the need for a camera inspection. We will not be looking for other genetic diseases, and we will not feedback these results to you or your clinician unless new information becomes available.

What if something goes wrong?

Studies like this one are conducted with utmost care and professionalism after thorough reviews by several groups of professionals and members of the public. Whilst mistakes can happen, the additional checks made in the study make it highly unlikely. However, any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

If you have a concern about any aspect of this study, you should contact your doctor or nurse who will do their best to answer your questions. You can also use the contact number at the end of this sheet. If you remain unhappy and wish to complain formally, you can do this through the hospital complaints procedure or relevant patient advisory group for your devolved nation. Details can be obtained from your hospital.

In the event that something does go wrong and you are harmed during the study there are no special compensation arrangements. The Cancer Research UK Clinical Trials Unit (CRCTU) does not hold insurance against claims for compensation for injury caused by participation in this study and they cannot offer any indemnity. If you are harmed and this is due to someone's negligence then you may have grounds for legal action for compensation against the University of Birmingham or the NHS Trust but you may have to pay your legal costs. NHS Trust and Non-Trust Hospitals have a duty of care to patients treated, whether or not the patient is taking part in a study, and the normal NHS complaints mechanisms will still be available to you (if appropriate).

What will happen to the results of the study?

Important results from the study will be published as they become available, which may be during the course of the study or after the study has finished, and this could possibly take several years. We intend that any results will be published in peer-reviewed medical and scientific journals and/or will be presented at scientific meetings involved with this field of research. These publications will be available upon request from your specialist doctor. You will not be identified in any report or publication. The results may also be available on the Cancer Research UK website. We will also publicise the results via the bladder cancer charities (Action Bladder Cancer UK and Fight Bladder Cancer) and their patient groups, and the CRCTU study website and social media.

Who is organising and funding the research?

This research study is being carried out by a small network of doctors across the UK. The study is sponsored by the University of Birmingham and is co-ordinated by the Cancer Research UK Clinical Trials Unit (CRCTU) at the University of Birmingham. The research is approved and funded by the National Institute for Health Research Health Technology Assessment programme (project number 14/08/60). Your doctor will not receive any payments for including you in this research study.

Who has reviewed the study?

All research in the NHS is assessed by an independent group of people called a Research Ethics Committee in order to protect your safety, rights and wellbeing and dignity. This study has been reviewed and given favourable opinion by the London Bridge Research Ethics Committee.

What happens now?

You will have some time to think about the study and make your decision. You may wish to discuss it with your family or friends. If you take part, you will receive a copy of this information sheet and a copy of the consent form to take home. If at any time you have any questions about the study you should contact your Consultant or nurse using the details below.

Further Information and Contact Details

Local Consultant Name:

Study Nurse:

Telephone:

Email/Mobile no. for consent confirmation :

Hospital contact number:

Study website: www.birmingham.ac.uk/research/activity/mds/trials/crcu/trials/Bladder-Path

You may also find it helpful to contact:

- **CancerHelp** is an information service about cancer and cancer research studies that is run by Cancer Research UK. Freephone: 0808 800 40 40; website: <http://www.cancerresearchuk.org>
- **Action Bladder Cancer UK**, website: <http://actionbladdercanceruk.org>
- **Fight Bladder Cancer**, website: <https://fightbladdercancer.co.uk>

Thank you for taking time to read this information sheet and for considering participation in this study

This study is funded by the NIHR Health Technology Assessment Programme (project number: 14/08/60)