(To be printed on local hospital headed paper)

POETIC-A: Pre-Operative Endocrine Therapy for Individualised Care with Abemaciclib

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

RANDOMISATION AND TREATMENT PART

ICR The Institute of Cancer Research

CANCER RESEARCH UK

POETIC-A: Pre-Operative Endocrine Therapy for Individualised Care with Abemaciclib

We are inviting you to be randomised for a clinical trial

- We are inviting you to take part in a clinical trial called POETIC-A for women diagnosed with early breast cancer and who joined the POETIC-A registration part of the trial.
- Before you decide whether to take part, it is important that you understand why this research is being done and what it will involve.
- Please read the information in this sheet carefully. Discuss it with your friends and family if you wish. Take your time to decide.
- Please ask your study doctor or nurse if there is anything that you do not understand or anything you want to know more about.
- It is your decision whether to take part or not. If you decide not to take part this will not affect the care you receive from your doctors.

A summary of what the study involves

- The POETIC-A trial consists of two parts – a registration part where your breast tissue was screened, and a treatment part.
- All of the information you will need to know to make a decision about whether to participate in the randomisation and **treatment part** can be found in this information sheet.
- We are aiming to find out: 1) if a drug called abemaciclib given in combination with standard endocrine therapy (ET) is more effective than giving an ET alone in preventing the cancer coming back and; 2) which types of patients based on their tumour biology benefit most from abemaciclib.
- In this part of the trial participants will be allocated to receive either ET alone (routine care) or ET and abemaciclib together.
- For a short video summary of this part of the study, visit https://go.icr.ac.uk/poetica or scan the QR code.

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If you have any questions about this study, please talk to your study doctor at
Hospital Department
Hospital
Address
Address
Tel: XXXXX XXX XXX

Part One: POETIC-A Randomisation and Treatment Part

1 Important Information

What is the purpose of this study?

In women with hormone sensitive early breast cancer, taking endocrine (hormone) therapy for at least five years after surgery is very effective at reducing the risk of the cancer returning. However, for some women their cancer may eventually become resistant to these drugs. The registration part of POETIC-A has identified which women could have a higher risk of developing resistance to standard endocrine therapies. This stage of POETIC-A (randomisation and treatment) looks at this group of women and aims to:

- Confirm whether a new drug called abemaciclib given in combination with standard endocrine therapy (ET) is more effective than giving ET alone in preventing the cancer coming back
- Find out if particular groups of participants are more suitable for treatment with abemaciclib, based on their tumour biology.

Why am I being invited to take part?

You have been given this participant information sheet as you previously took part in the POETIC-A registration part of the trial. You took an aromatase inhibitor (a particular type of endocrine therapy) prior to surgery and agreed that tissue collected at the time of surgery could be measured for a biological marker called Ki67. The laboratory have confirmed that your tissue has a 'high' Ki67 measurement which could mean you are at a higher risk of developing resistance to standard treatments and your cancer coming back. Therefore, we are inviting you to take part in the POETIC-A randomisation and **treatment part** which is investigating whether adding a drug called abemaciclib to standard ET is more effective than giving ET on its own.

Do I have to take part?

No, it is up to you to decide whether or not to proceed to POETIC-A randomisation. Your participation is entirely voluntary and you will be given sufficient time to decide whether or not you wish to participate. Your decision to participate in the trial or not will not affect the standard of care you receive. If you do decide to take part in the trial you are free to withdraw at any time and do not have to give a reason.

If you do decide to take part you will be given this participant information sheet and consent form to read carefully and to sign. A copy of the signed participant information sheet and consent form will be provided to you for your records. If you do decide to take part, you are still free to withdraw from study treatment or from the study at any time.

Your GP will be informed about your participation in this study. You will receive a card, which indicates that you are participating in a clinical study.

2 What do I need to know about the medicines used in this study?

What is endocrine therapy?

You will have already received an aromatase inhibitor before surgery, and may have already re-started this or another endocrine therapy if your other treatments are complete. ET comes in tablet form and is used to treat hormone sensitive (oestrogen receptor positive) breast cancer in women who have had their menopause. ET is the standard treatment given for your type of breast cancer and is usually given for a minimum of 5 years.

What is abemaciclib and how does it work?

Abemaciclib is the drug being tested in this study and is also called Verzenios. It is made by a pharmaceutical company called Lilly. Abemaciclib works differently to chemotherapy and radiotherapy. It is a targeted treatment that works alongside endocrine therapy to stop breast cancer cells from growing and dividing. It already has a licence in the UK and European Union to reduce the risk of recurrence in some women with high risk early breast cancer. The drug has been successful in this setting, and the aim of POETIC-A is to establish whether we can identify a new group of women in whom abemaciclib can also prevent breast cancer from coming back.

Who decides which treatment group I'll be in?

Everyone who agrees to join this study will be randomly put into one of two treatment groups:

- Group 1: Standard endocrine therapy only
- Group 2: Standard endocrine therapy and abemaciclib

The only way to make sure that the people in the two groups are as similar as possible is to do this by a process called randomisation, where a computer randomly assigns you to a particular group. This is because we need to be sure that if one group does better than the other, it is because of the treatment and not because the participants in the two groups are different from each other in some way (for example, if doctors subconsciously put people they think might be more suitable in one group or another). Randomisation ensures that the treatments can be compared fully and fairly.

When we analysed the sample you donated at the time of your surgery, we will also have performed a test on the sample called an AIR-CIS test. In the future we may use this test to work out which patients gain the most from abemaciclib. However, at the moment, we will not use this to decide whether women get abemaciclib or not (as we need to check that this test is correct), and we will ensure that all women have the same chance of being offered abemaciclib or not.

Your treatment group will be selected at random by a computer by chance. Half of the participants will be in Group one and half will be in Group two. This means you could have either ET on its own or ET with abemaciclib. Whichever group you are in, you will be treated with the best possible care and will be monitored closely.

3 What happens during the trial?

What will my taking part in the trial involve?

If you agree to join the randomisation and treatment part of POETIC-A, you will be asked to sign an informed consent form and the trials unit will be notified.

You will be asked to attend a screening visit where the research team will perform a number of tests to ensure that you meet the inclusion criteria for the study. These criteria are aimed at excluding patients in whom it may be unsafe to administer abemaciclib and to reduce the risk of side effects. These tests are performed within a 21-day period before entering this next part of the trial; this is called the "screening period". This screening period may include one or more visits to the hospital to have all the necessary tests performed. Your visit to the hospital for all these tests may take several hours.

What screening assessments will be performed?

The assessments are outlined in the following table:

Assessment	Further details
Full review of your medical history	To check that you are suitable to enter the randomisation and treatment part. This will include questions about any current conditions you may have and any medicines you are taking.
Physical examination and vital signs	Including checking your height, weight, blood pressure, heart rate, respiratory rate and temperature. This may also involve another breast examination, unless you have had one recently.
Evaluation of performance status	The study doctor will assess how your disease is affecting your daily living and abilities; this is undertaken via a series of questions and observations by the study doctor.
Collection of blood samples	Approximately 2 teaspoons (10ml) of blood will be taken for routine safety checks.

What happens if I am eligible for the study?

If after the screening assessments your doctor confirms that you are eligible for the POETIC-A randomisation and treatment part, and you are still happy to take part, your doctor or nurse will contact the trials unit who will record your details and tell your doctor or nurse which treatment group you will be in. They will let you know as soon as possible after the decision has been made and arrange your first treatment visit in the next 2 weeks.

If you are **not eligible** for the study: If your screening tests results show you would not be suitable for this study, your study doctor will discuss the treatment options available outside this trial with you.

What assessments will be done during the trial?

While you are receiving trial treatment you will see one of the study doctors at regular clinic visits to monitor your progress and any side effects. There are more visits if you are allocated to Group 2: ET + abemaciclib as abemaciclib is still a relatively new drug and we want to monitor how you are more often. The table below shows the clinic visits for each group:

	Timing of clinic visits	
	Group 1: ET only	**Group 2: ET and abemaciclib**
On treatment Visits	▪ Start of treatment (Week 1 Day 1) ▪ Every month for the first 2 months (Weeks 5 and 9) ▪ Then 6 monthly up to 2 years (Weeks 25, 49, 73 and 97) ▪ With phone consultations between clinic visits (Weeks 37, 61 and 85)	▪ Start of treatment (Week 1 Day 1) ▪ Every 2 weeks for 2 months (Weeks 3, 5, 7 and 9) ▪ Then monthly for 4 months (Weeks 13, 17, 21 and 25) ▪ Then 3 monthly up to 2 years (Weeks 37, 49, 61, 73, 85 and 97)
Safety follow up visit	▪ If your doctor stopped your ET treatment because your cancer had come back within the first 2 years of treatment, you would attend a safety visit at 4 weeks after stopping treatment	▪ You will attend a safety visit when you stop abemaciclib treatment and another safety visit 4 weeks later. This could be at the end of the 2-year treatment period, or earlier if your cancer had come back during the 2-year period

Follow up visit	▪ 3, 4 and 5 years after start of treatment ▪ If your cancer has come back after the first two years of ET, you will have a visit within 14 days of your doctor confirming your relapse. After that you would not be required to attend any further follow-up visits	▪ 3, 4 and 5 years after start of treatment ▪ If your cancer has come back after the 2-year abemaciclib treatment period, you will be asked to attend a visit within 14 days of your doctor confirming your relapse. After that, you would not be required to attend any further follow up visits

During the clinic visits you will have regular assessments as outlined in the following table:

Assessment	Timing of assessment
Physical examination, if the doctor or nurse thinks it is necessary	At every clinic visit
Vital signs including checking your blood pressure, heart rate, respiratory rate and temperature	At every clinic visit (*Group 2: ET and abemaciclib only*)
Evaluation of Performance Status	At every clinic visit
Discussion with your study doctor to document changes in your health or medications since your last visit and also a review of the trial medication you have taken	At every clinic visit
Approximately 2 teaspoons (10ml) of blood will be taken for routine safety checks	At every clinic visit (*Group 2: ET and abemaciclib only*)
Mammogram or MRI scan of the breast to assess disease status	Annually as per your hospital's local practice
Research blood collection — approximately 5 teaspoons (30ml) of blood at Week 1, followed by approximately 3 teaspoons (20ml) at subsequent visits	▪ At Week 1 Day 1 ▪ Then 6-monthly ▪ At the end of your study treatment ▪ Then at 3, 4, and 5 years after start of treatment

You need to consider carefully how these assessments and hospital visits will affect you and your family. Please ask your study doctor or nurse if you have any questions about the tests and procedures.

What other study specific assessments will be done?

Blood samples will be collected for research into "circulating tumour DNA" (ctDNA) at some of your clinic visits. When cells die they release pieces of DNA into the blood stream. The DNA from cancer cells found in the blood is known as ctDNA. The results of the ctDNA blood tests will not be shared with you or your doctor. This is because the relationship between the presence of ctDNA in blood and the presence of cancer in the body has not yet been definitely established, but this is something we wish to monitor in this study. We will also ask your hospital to send us the diagnostic biopsy sample that was stored when your breast cancer was first diagnosed, for further research within the POETIC-A trial.

If you are randomised to Group 2 (ET and abemaciclib), it is important that you keep all of your empty or part-empty bottles of abemaciclib and bring them to your next hospital visit. Your doctor or nurse will ask if you have taken the medicines as prescribed since your last hospital visit and will collect the tablet bottles from you. If you have not been taking your study medicines for any reason, please tell your doctor or nurse.

How is endocrine therapy given?

You will have already taken an aromatase inhibitor (a particular type of endocrine therapy) before you had surgery but your study doctor and nurse will instruct you on which ET you will be taking (after any adjuvant treatment finishes) and how you should take it. All participants will be asked to take an ET for five years which is the same as what is usually advised in routine practice.

We will notify your GP that you are participating in the study and ask that they prescribe the ET for you as they routinely would if you were not taking part in this trial.

How is abemaciclib given and what are the side effects?

At each clinic visit we will ensure you have been given a sufficient supply of abemaciclib tablets to take home with you. Abemaciclib should be taken twice per day at least 6 hours apart, at the same time each day. You should swallow your tablets whole and not chew or crush them. Your study doctor will advise how many tablets you should take each day. Abemaciclib will be given for up to two years.

As with any treatment, abemaciclib can have side effects. No-one can predict before you begin treatment whether you will have any of these, or how serious they might be. Abemaciclib is a relatively new drug (although it is approved for use in advanced breast cancer and in some high-risk early breast cancer) and therefore the frequencies of some of the listed side effects are not certain. Side effects that have been previously reported are listed below. Not all participants will experience these side effects and medications can be given to make them less serious or uncomfortable. Your study doctor and nurse will discuss your symptoms with you at each of your clinic visits.

There may also be risks involved in taking this medication that have not been identified in the studies done so far, so please report anything that is troubling you to your study doctor. Your progress will be closely monitored and your study doctor will offer whatever help is available to cope with any side effects observed.

If you are allocated to take abemaciclib, there is a chance that you will experience loose stools (diarrhoea), which is likely to happen in the first 2 weeks of treatment. Your study doctor and nurse will give you instructions on how to manage this before it happens but if you do experience diarrhoea, it is important to treat it as soon as possible and you should contact your study team for advice. In previous clinical trials of abemaciclib the recommended measures were effective in stopping diarrhoea in most participants. A short information video on managing diarrhoea will be available for you on our study website: https://go.icr.ac.uk/poetica

People treated with abemaciclib may have a greater risk of getting an infection. It is important that you contact your study doctor immediately if you become unwell or have a fever, even if this is after-hours or at the weekend.

Side effects of abemaciclib when given with endocrine therapy	
Very common side effects (may affect more than 1 in 10 people treated with abemaciclib)	▪ Chills or fever ▪ Diarrhoea ▪ Infections ▪ Reduction in white blood cells, red blood cells, and blood platelets ▪ Dry mouth ▪ Inflammation of the mouth and lips, nausea (feeling sick), vomiting ▪ Decreased appetite ▪ Alteration in sense of taste ▪ Hair loss* ▪ Tiredness ▪ Dizziness ▪ Itching ▪ Rash ▪ Abnormalities in liver blood tests
Common side effects (may affect between 1 in 10 and 1 in 100 people treated with abemaciclib)	▪ Blood clots in veins, including in the lungs ▪ Pneumonitis/interstitial lung disease** ▪ Increased watering of the eye ▪ Muscular weakness ▪ Dry skin ▪ Pneumonia ▪ Anaemia
Uncommon side effects (may affect between 1 in 100 and 1 in 1000 people treated with abemaciclib)	▪ Neutropenia - the number of a type of white blood cells called neutrophils may decrease, which can lead to a reduced ability to fight certain infections

You will also be monitored for creatinine (a waste product made in your kidneys) in your blood. The level of creatinine increases in some patients receiving abemaciclib that does not cause symptoms.

* In previous clinical trials, approximately 1 in 10 women reported hair loss. In over 90% of those women, the hair loss was mild: such that it was not obvious from a distance but only on close inspection and did not require a wig or hair piece.

** Pneumonitis/interstitial lung disease is a serious inflammation of the lungs. You should tell your study doctor if you have shortness of breath, a cough, or a fever. In accordance with normal clinical practice you may have a CT scan or a biopsy (which may be CT-guided) to investigate your symptoms.

How long will I receive trial treatment for?

You will receive treatment with an ET for up to five years. Those allocated to also take abemaciclib will take it for up to 2 years. If your cancer were to come back during this time or you were not tolerating the trial treatments they would be stopped.

What else will happen to me during the trial?

You will be able to continue day-to-day activities as normal during the trial. You will need to attend the clinic visits as described.

You will be given a card, which will provide details about the POETIC-A trial and that you are taking an ET or an ET and abemaciclib. Please carry it with you at all times while you are taking part in this trial and show it to any other health professional you see who may not be aware of your participation in the POETIC-A trial.

What precautions should I take if I choose to participate in this trial?

You are encouraged to report anything that is troubling you to your study doctor.

Blood donation:
If you are allocated to receive an ET and abemaciclib you are not allowed to donate blood while in the study or for 3 months following your last dose of abemaciclib.

Lifestyle restrictions:
You should avoid eating grapefruit or drinking grapefruit juice if you are receiving abemaciclib as they could affect the way abemaciclib works.

Other medicines:
Your study doctor will closely monitor all the medications you are taking; you should tell your study doctor of any changes to your medications while you are participating in the study, including any prescribed by your GP, over the counter or herbal medications you are taking.

If you are allocated to receive abemaciclib there are some medicines you should avoid. These include, but are not limited to, **St John's Wort**, **clarithromycin** (an antibiotic), **phenytoin** and **carbamazepine** (used to treat seizures), **itraconazole** and **ketoconazole** (used to treat fungal infections), **digoxin** (used to treat heart disorders), **dabigatran etexilate** (used to treat atrial fibrillation).

How many other patients will be taking part in the POETIC-A Randomisation and treatment part of the trial?

Approximately 2,500 patients with hormone sensitive breast cancer will take part in this part of the study from hospitals across the UK.

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

What are the possible benefits of taking part in this randomisation and treatment part of POETIC-A?

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

What are the possible disadvantages and risks of taking part in this study?

Side effects
Abemaciclib has been used to treat breast cancer which has spread (metastatic cancer) for a number of years, but has only recently been approved for the treatment of early breast cancer. This means that not all of its side effects may be known. You may therefore experience some side effects that are not anticipated and are not listed in the previous sections. There is no way of predicting if you will experience any side effects, or how severe they will be. You should contact your study doctor if you experience any side effects, even if you are not sure that any problems you may have are related to taking the trial treatment.

Additional blood tests
You will have more blood tests if you enter the trial than if you were not taking part. Risks linked with blood sampling include pain from the needle being inserted, light-headedness, possible fainting and (rarely) infection. Where possible the blood samples collected for POETIC-A will be collected when you are having other routine blood tests.

Additional hospital visits and travel
You may need to attend hospital more frequently than you would if you decided not to participate in this study. This may cause some disruption to your normal activities and home life and this should be discussed with your family and friends if it will impact on them.

Additional radiation
If you take part in the randomisation part of this study you will have routine mammograms. Mammograms use ionising radiation to form images of your breasts. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same whether you take part in this study or not.

You may additionally have a CT scan or a CT-guided biopsy if you develop signs of pneumonitis. You would not have these procedures if you did not take part in the study. CT scans use ionising radiation to form images of your body. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chance of this happening to you should you have CT scans is about 0.05%.

5 Further information about taking part

Will my GP be involved?

Your GP will be informed about your participation in the POETIC-A trial and which treatment you were allocated to receive. This will ensure that your GP knows you are taking trial treatment in the event of any potential side effects and/or drug interactions, and knows to continue to prescribe an ET for you.

What happens when the research study stops?

You will be given an ET for 5 years and, if randomised to Group 2, abemaciclib for 2 years, or until your study doctor thinks you are no longer gaining any benefit from treatment or you are going to start on a new treatment for your cancer. The study doctor may decide that your participation in the study is no longer in your best interest and you will be withdrawn from study treatment or from the study. When you stop taking part in the study, you must go through the study withdrawal procedures that the study doctor considers necessary for your safety. Your participation in the study may also be stopped by the study sponsor, ethics committee, or the regulatory authorities. If your study treatment is stopped for any reason your study doctor will arrange your continuing care.

What alternative treatments are there?

If you do not want to take part in the study there may be other treatment options available. Study staff will discuss these alternative treatments and their associated risks and benefits with you before you decide to take part in this study.

This completes Part 1 of the Participant Information Sheet.

Please read the additional information in Part 2 before making your decision.

Part Two: General Information

6 General information about how the POETIC-A trial is conducted

What will happen to any samples I give?

We ask that all participants donate a blood sample at several time points during trial treatment. We will also collect tissue from your biopsy sample that was taken when you were first diagnosed.

Any samples you donate will be used to help us understand why people develop breast cancer and how to treat it. If we can show why some patients react to their treatment differently, this knowledge could help many patients in the future.

The group of medical professionals overseeing the POETIC-A trial will also oversee the sample collection. Your tumour tissue or blood samples may be labelled with your initials, trial ID number, date of sample collection, and pathology number when they are sent to the POETIC-A research laboratory. When they arrive at the laboratory they will be coded and personal details removed. The coding will maintain your confidentiality whilst allowing biological details to be compared to treatment findings.

The tumour and blood samples will be stored securely at a laboratory at The Royal Marsden NHS Foundation Trust. Surplus tumour and blood material will be stored indefinitely at The Royal Marsden NHS Foundation Trust laboratory or an off-site (UK based) approved storage facility. You are asked to give permission for possible future research using these samples; this may involve your samples being sent to institutions outside the European Economic Area (EEA). The confidential nature of these samples and associated data will be fully protected, and any other research using your tissue will first be reviewed and approved by an ethics committee.

Your tumour tissue samples and/or blood samples will be analysed for potential changes in DNA (gene changes). The results of these tests will not be made available to you or your doctor.

Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

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

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

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

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

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

Will my taking part in this study be kept confidential?

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

From time to time we would like to know how you are getting on. Ideally, we would like to do this for life and we would like to use national records, which are kept on everyone's health status to find this out. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the trial. Please initial the consent form to show that we have your permission to do this.

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

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

Will information about me be shared with other researchers?

Information collected about you in this study may also be shared with Lilly (the pharmaceutical company that supply abemaciclib).

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

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements

about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

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

Will my GP be involved?

Yes, your GP will be notified about your participation in the study. By signing the consent form you are agreeing to this.

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

Your participation is voluntary. If you agree to take part and then change your mind later on, you can withdraw from the study at any point without giving a reason. If you withdraw from the trial, it will not affect the standard of care you receive. Your study doctor will discuss alternative treatment with you and offer you the most suitable treatment available.

If you should withdraw fully from the study, study data collected before your withdrawal may still be processed along with other data collected as part of the clinical study. However, no new data will be added to the study database and you may request that all retained identifiable samples are destroyed to prevent future analysis.

You will be asked to return to the clinic to undergo the tests and evaluations scheduled for the safety follow-up visit. You retain the right to decide whether data from the visit can be used.

If you were to withdraw from treatment but agree for your routine hospital data to be used for the study, we would ask you to confirm this and your hospital will continue to send information on your progress to the Trials Office. This is so that the overall quality of the trial is not impaired.

What if there is a problem?

If you have any concern about any aspects of the trial you should first ask to speak with your study doctor or research nurse, who will try to resolve the problem. If you remain unhappy and wish to complain formally about any aspect of the way you have been approached or treated during the course of this trial, you may do so under the standard National Health Service (NHS) complaints procedure, which is available to you at your study doctor's hospital. We recommend that you obtain a copy of your hospitals complaints procedure or policy if you intend to make a complaint.

[Sites in England] Concerns can also be raised by talking to your local Patient Advice and Liaison Service (PALS). You can contact the PALS team at [insert Trust name] on [insert relevant contact details].
[Sites in Scotland] Concerns can also be raised by talking to the Patient Advice and Support Service (PASS). You can contact PASS via the National Citizens Advice Bureau on 0808 800 9060 or through your local Citizens Advice Bureau (www.cas.org.uk/patientadvice).
[Sites in Wales] Concerns can also be raised by talking to the Patient Support and Advisory Service (PSAS). You can contact PSAS on 0300 0200 159 or emailing hdhb.patientsupportservices@wales.nhs.uk.
[Sites in Northern Ireland] Concerns can also be raised by talking to the hospital complaints team at [insert Trust name] on [insert relevant contact details].

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

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

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

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

What if I have private medical insurance?

If you have private medical insurance please check with the company that your medical insurance policy will not be affected before agreeing to take part in this trial.

What will happen to the results of the clinical trial?

Independent experts will review the progress of the research, and the results will be published in a scientific journal as soon as there is enough information to be sure the results are reliable. The results will help to decide how to treat early breast cancer in the future. The results from this trial may also contribute to reviews of worldwide evidence about this type of cancer and its treatment. You will not be identified in any report or publication relating to this research.

What if relevant information becomes available?

Sometimes we get new information about the treatment being studied, which may affect your willingness to continue in the study. If this happens, your study doctor will tell you in a timely manner and discuss whether you should continue in the study. If you decide to continue in the study, you may be asked to sign an updated informed consent form. If you decide to discontinue, your study doctor will make arrangements for your future care.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

Who is organising and funding the research?

The research trial is being carried out by a network of doctors across the UK. The trial is coordinated by The Institute of Cancer Research. The research is approved and funded by Lilly, the company who manufacture abemaciclib. The trial is approved and endorsed by Cancer Research UK. Your study doctor will not receive any payments for including you in this research trial.

Who has reviewed the trial?

The trial has been approved by Cancer Research UK's Clinical Research Committee, Health Research Authority (HRA), the London-Chelsea Research Ethics Committee, the UK Regulatory Agency (Medicines and Healthcare products Regulatory Agency, MHRA) and the study sponsor's committee for clinical research. This participant information sheet and consent form have been reviewed by the patient review panel at The Royal Marsden NHS Foundation Trust and the Independent Cancer Patients' Voice Group.

What do I have to do now?

Your study doctor or nurse will be happy to answer any questions. Once you have reached your decision please let your study doctor or nurse know. If you choose to join the POETIC-A randomisation and treatment part you will be asked to sign a consent form and will be given a copy to keep together with this information sheet.

7 Useful contact information

You can learn more about clinical trials on Cancer Research UK's patient website (www.cancerhelp.org.uk).

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information nurse specialists on the Macmillan Support Line: Freephone 0808 808 00 00, open seven days a week, 8.00am to 8.00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns. You can also learn more about clinical trials on Cancer Research UK's patient website http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial.

For more information about the POETIC-A study and the Institute of Cancer Research, visit https://go.icr.ac.uk/poetica or scan the QR code below:

Thank you for taking the time to consider taking part in this study.

YOUR SPECIALIST IS: _____

CONTACT PHONE NUMBERS: _____

To be printed on headed paper

POETIC-A INFORMED CONSENT FORM FOR TRIAL RANDOMISATION AND TREATMENT

Version 5.0, 19 July 2022

REC Ref.: 20/LO/0196
IRAS Project ID: 271343

EudraCT: 2019-003897-24
Sponsor Number: CCR5137

Centre: _____ Clinician: _____

Patient's Hospital Number: _____ Trial ID Number: _____

Please initial to confirm

1. I confirm that I have read and understood the **POETIC-A PARTICIPANT INFORMATION SHEET FOR RANDOMISATION AND TREATMENT, Version 5.0, dated 19/07/2022** and have had the opportunity to ask questions and had these answered satisfactorily.	
2. I agree to take part and be randomised to a treatment group in the POETIC-A study once all tests confirm I am suitable to participate. 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 sections of my medical notes may be examined by representatives from the ICR-CTSU, the NHS Trust relevant to my taking part in research, the sponsor (The Institute of Cancer Research), the regulatory authorities and ethics committee approving the trial, Lilly (the pharmaceutical company that manufacture and supply the trial treatment) and third parties approved by ICR-CTSU to the extent permitted by applicable laws and regulations to make sure the information received is correct. I give permission for these individuals to have access to my records.	
4. I understand that information collected about me, including genetic details, may be shared within the sponsor organisation (The Institute of Cancer Research) or with other organisations for the purpose of health and care research which could be outside the European Economic Area (EEA), but that I will not be identifiable from this information.	
5. I agree to my GP being informed about my participation in this study.	
6. I agree to additional blood samples being taken for research as part of this study.	

7. I agree that tissue from my diagnostic biopsy can be sent to and stored at the POETIC-A central laboratory at The Royal Marsden NHS Foundation Trust.	
8. I agree that my tumour tissue samples and/or blood samples will be analysed for potential changes in DNA (gene changes). I understand that neither I nor my doctor will be informed of the results of these tests.	

Optional consent

Please initial as appropriate

	Yes	No
9. If I withdraw from the study, I consent to my doctor providing authorised researchers with basic clinical and other relevant non-clinical information that would be routinely collected and written in my medical records		
10. I consent to the possible future sharing of information collected about me with other organisations, with the understanding that I will not be identifiable from this information		
11. I consent to my data and samples being stored and used for possible future research, with the understanding that confidentiality will be protected and that ethics committee approval will be obtained before any future research is conducted, if necessary		

Name of Patient	Signature	Date
Name of Researcher	Signature	Date

1 copy for participant, 1 copy for research study file, 1 copy for participant's medical notes