(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

REGISTRATION PART

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

We are inviting you to be registered for a clinical trial

- We are inviting you to take be registered in a clinical trial called POETIC-A for patients who have been recently diagnosed with early breast cancer.
- 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 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 tissue from your surgery will be screened, and a treatment part.
- All of the information you will need to know to make a decision about whether to participate in the **registration part** can be found in this information sheet.
- We will use a biological marker called Ki67 to select a group of women diagnosed with early breast cancer, some of whom will receive additional medical therapy in the treatment part of the study.
- In this registration part, all patients will receive, or have received, endocrine (hormone) treatment prior to an operation. We will collect a sample from your tumour removed at the time of your breast surgery.
- Depending on the results from your sample at surgery you could be eligible for the treatment part of the trial. There is a separate information sheet describing the treatment part, which you will be given after surgery if you are found to be potentially eligible.
- You can watch a short video that explains this part of the study by going to https://go.icr.ac.uk/poetica or by scanning the QR code below.

Contents

How to contact us

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 Registration Part

1 Why are we doing this study?

You have been diagnosed with early stage breast cancer that is hormone sensitive (also known as oestrogen receptor positive or ER+). The treatment plan for this type of cancer depends on a number of factors. Surgery, radiotherapy, chemotherapy and endocrine (hormone) therapy are the standard treatments. In women with hormone sensitive early breast cancer, taking endocrine therapy for a minimum of five years after surgery is very effective at reducing the risk of the cancer coming back.

However, for some women, their cancer may be less sensitive to endocrine treatment. The aim of this trial is to identify a group of women in whom standard endocrine therapies may not work so well. These women will be invited to take part in the treatment part of POETIC-A (covered by a separate Participant Information Sheet), where half of the participants will receive a newer treatment for their kind of breast cancer (in addition to standard endocrine therapy) with the hope of reducing the chance of the cancer coming back. There is no guarantee that the newer treatment will bring benefits to individual patients.

2 Why am I being invited to take part?

Your doctor has explained that you have been diagnosed with early stage breast cancer that is hormone sensitive (ER+). In this situation, doctors may use endocrine therapy with a type of drug called an aromatase inhibitor (such as letrozole or anastrozole) before you have your surgery. This provides useful information, as we can measure how sensitive your cancer is to endocrine treatment. We do this by examining a tumour sample taken during your surgery, to look for signs that it has responded to your treatment. Women invited to join the registration part of POETIC-A may have received, or currently be receiving, letrozole or anastrozole for at least 10 days just before surgery as part of standard care. If you have not already had this treatment, your doctor will prescribe it for you to take for at least 10 days immediately before surgery. Whilst the minimum treatment time is 10 days, some women will take (or have taken) letrozole or anastrozole for longer periods, up to a maximum of 6 months.

Patients can join the registration part of POETIC-A before or after their surgery. Once you have had your surgery, we would like to look at a sample taken from your cancer to measure a biological marker called Ki67. Measuring Ki67 tells us how quickly your cancer cells are growing and dividing. If the Ki67 levels dropped a lot after you received letrozole or anastrozole, we think you are likely to be sensitive to endocrine treatment, as this indicates that the growth of cancer cells has slowed. However, if the Ki67 did not drop by very much, then you are likely to be less sensitive to endocrine therapy, and this means we should explore additional treatments after surgery (in the treatment part of POETIC-A).

Therefore, the POETIC-A study is separated into two parts: the 'registration' part and the 'treatment' part. At least 8,000 women will enter the registration part.

3 What is the study treatment?

If you have not already received treatment with an endocrine therapy called an aromatase inhibitor before your surgery, your doctor will prescribe it. This will be given in tablet form and used to treat hormone sensitive (ER+) breast cancer in women who have had their menopause.

The hormone oestrogen can stimulate the growth of some breast cancers. Women who have had their menopause do not produce oestrogen from their ovaries but do still make a small amount by turning other hormones, called androgens, into oestrogen. Androgens use an enzyme in the body called

aromatase to convert them into oestrogen. Aromatase inhibitors stop aromatase so it can't convert androgens into oestrogen. This means that cancer cells cannot grow, grow slower, or die.

Your hospital can choose between two very similar aromatase inhibitors called letrozole and anastrozole. Your doctor will be able to tell you which one your hospital uses.

4 What will I need to do if I take part in the REGISTRATION part of POETIC-A?

Straight away:
If you decide to take part, you will be given this information sheet to keep and you will be asked to sign a consent form. If you did not have breast imaging (mammogram, ultrasound or MRI) around the time of your diagnosis, this will need to be done.

If you have not already done so, once you have joined the study, you will start treatment with either letrozole or anastrozole. If you have already started your treatment, you will need to carry on taking this until you have surgery.

It is important that you take the treatment every day, as directed by your doctor. Your doctor or research nurse will give you a treatment diary card that you will need to complete every day to show you have taken your letrozole or anastrozole. Once you have taken the full course of treatment, you will hand your completed treatment diary card back to the study team who may ask you further questions if you have missed any doses.

Surgery:
We will ask for some of the tumour tissue removed during your surgery to be sent to the POETIC-A laboratory for use in the study.

Post surgery therapy and Ki67 result:
After your surgery, you will continue to receive treatment (such as chemotherapy and radiotherapy if you need them) for your breast cancer as per standard practice at your hospital. The Ki67 result from your surgery sample will be provided to your doctor when it is available.

If your tumour sample shows that your Ki67 level is still 'high', your doctor or nurse will discuss the next steps with you. You will then be invited to enter the treatment part of the POETIC-A study, where we want to find out if adding a drug called abemaciclib to the standard endocrine treatment could reduce the risk of the cancer returning. You will receive a different Participant Information Sheet for this part of the study.

If your tumour sample shows that your Ki67 level is 'low', that means that we expect you to respond well to standard endocrine treatment alone. You would then not need any additional treatment as part of the POETIC-A trial; but you will be recommended to continue your endocrine treatment and complete any other treatment as directed by the local team treating you.

You can find an overview of the study, and how it fits into your care pathway at the end of Part One of this information (see page 6). You may find it useful to keep track of the study process, if you agree to take part.

In the future:
We would like to continue collecting routine information about all patients registered to the POETIC-A study, regardless of whether they join the treatment part. More information about this is given in Part 2 of this information sheet.

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

What are the possible benefits of taking part in this registration part of POETIC-A?

The main objective of the registration part is to find out if you may be suitable for the treatment part of the study. We do not know if taking part in POETIC-A will help you, but the information we gain may help us to improve treatments for patients with breast cancer in the future.

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

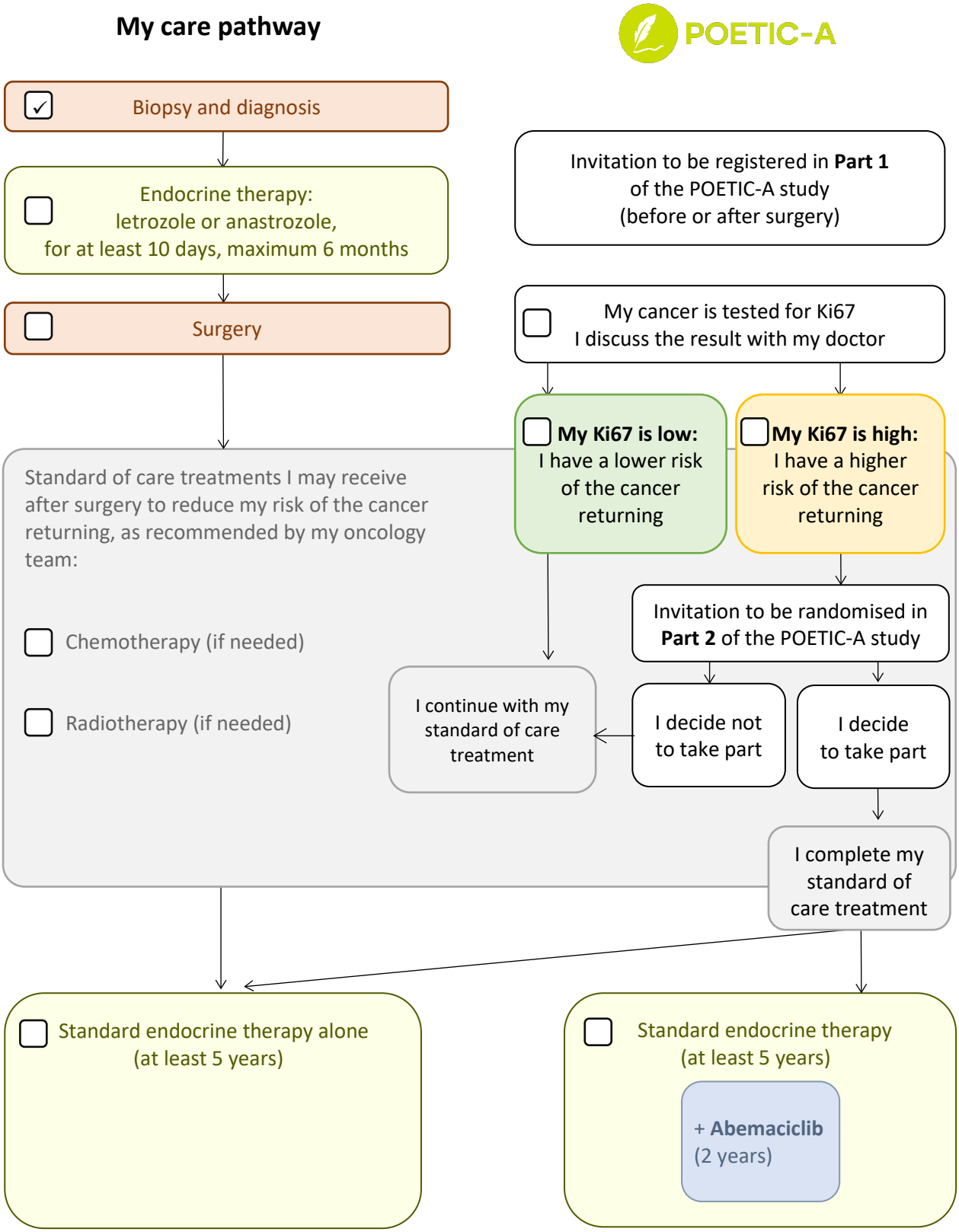
As with any drug, endocrine therapy (letrozole or anastrozole) has side effects. These are uncommon and usually mild, but no-one can predict whether you will have any of them. The main side effect is joint stiffness. Other less common side effects include tiredness, hot flushes, vaginal dryness or irritation, slight hair thinning and headache. It is important to be aware that most women with hormone sensitive breast cancer are advised to take at least five years of endocrine therapy after surgery as part of routine care. However, in this study you will also be taking endocrine therapy for at least 10 days before surgery.

If you take part in the registration part of this study, you will not need to have any additional mammograms or other tests using x-rays, compared to your care outside of the study.

This completes Part 1 of the Participant Information Sheet.

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

My care pathway



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 patients donate some of their tumour tissue at surgery.

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 samples may be labelled with your initials, date of birth, your unique 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 tumour samples will be stored securely at a laboratory at The Royal Marsden NHS Foundation Trust. Surplus tumour 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 UK or 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 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.

What will happen 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 is a publicly funded organisation and will process your information as we conduct scientific research in the public interest. This includes processing sensitive health and genetic information, which will be used with appropriate safeguards in place, as required by the General Data Protection Regulation (GDPR).

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 drug used in the treatment part of the study 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 also 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 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. This is so that the overall quality of the trial is not compromised. However, we will use the minimum personally-identifiable information possible. 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.

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 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 hospital. We recommend that you obtain a copy of your hospital's 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 [insert complaints/patient support and advisory service team as applicable] at [Trust/Health Board name] on [insert relevant contact details].
[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 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 new 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 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 not to continue, your 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 co-ordinated by The Institute of Cancer Research. The research is approved and funded by Lilly, the company who manufacture abemaciclib (the study drug in the treatment part of POETIC-A). The trial is approved and endorsed by Cancer Research UK. Your 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 (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 doctor or research nurse will be happy to answer any questions. Once you have reached your decision, please let your doctor or research nurse know. If you choose to join the POETIC-A registration 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 the Cancer Research UK's patient website (www.cancerhelp.org.uk).

Macmillan Cancer Support (www.macmillan.org.uk) 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.

Breast Cancer Now is a registered charity providing information and support to anyone affected by breast cancer: https://breastcancernow.org. Their breast care nurses are available for advice on the helpline 0808 800 6000.

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 REGISTRATION

Version 7.0, 05/07/2023

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

EudraCT: 2019-003897-24
Sponsor Number: CCR5137

Centre: _____ Clinician: _____

Patient's Hospital Number: _____ Registration ID: _____

Please initial to confirm

1. I confirm that I have read and understood the **POETIC-A Participant Information Sheet for TRIAL REGISTRATION, Version 7.0, dated 05/07/2023** and have had the opportunity to ask questions and had these answered satisfactorily.	
2. I agree to take part and be **registered into the POETIC-A Trial**. 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 agree to my name, date of birth, post code, hospital number and NHS or Community Health Index (CHI) number being sent to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU) when I join POETIC-A.	
4. I agree to ICR-CTSU using NHS and national health and registration data to keep in touch with me and follow up my health status.	
5. I understand that sections of my medical records 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.	
6. 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 UK or European Economic Area (EEA), but that I will not be identifiable from this information.	

7. I agree to my GP being informed about my participation in this study.	
8. I agree that tumour tissue taken at the time of surgery for my breast cancer can be used as part of POETIC-A. I understand that my tissue samples may be labelled with my initials, date of birth and unique trial ID number when they are sent to the POETIC-A central laboratory at The Royal Marsden NHS Foundation Trust. I agree for surplus materials to be stored indefinitely at the central laboratory or another approved storage facility in the UK.	

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

Note to hospital staff:
If consent was obtained remotely, enter details of remote consent below and countersign above once from received.

Name of person who took remote consent	Date of remote consent

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