

PARTICIPANT INFORMATION SHEET

Perceptions and Experiences of Abemaciclib and Endocrine Therapy (PEATY)

We are inviting you to take part in a research study. This sheet explains what is involved. Before deciding if you want to join, please take the time to read the information and talk to others if you wish.

1. What is the purpose of the study?

Our research team at Sussex Health Outcomes Research & Education in Cancer (SHORE-C) will be looking at the experiences of people who are starting abemaciclib (Verzenio®) and hormone therapy for breast cancer. We wish to learn more about the things that people expect to happen and their actual experiences during treatment, especially how they manage any possible side effects. Understanding such things will help us to develop information materials to support people.

2. Who is organising and funding the research?

The research is organised by SHORE-C and Brighton & Sussex Medical School, and sponsored by the University of Sussex (reference 084 FAL/298216). The study is funded by Eli Lilly and Company Limited. The funders are a pharmaceutical company who have no role in the management of the study, data collection, analysis or interpretation.

3. Why have I been chosen?

You are invited to join this study because you are taking part in the POETIC-A trial and are randomised to receive treatment with abemaciclib and hormone therapy for breast cancer. We hope that at least 30 people will take part.

4. Do I have to take part?

No. It is up to you to decide whether you want to join in the research. Your decision will not affect the care and treatment you receive in any way.

5. What happens next if I agree to take part?

If you do wish to join the study, the hospital doctor or nurse who gave you this information sheet will ask you for your contact details so that a researcher from SHORE-C can telephone you. The researcher will answer any further questions you may have.

6. What will happen to me if I decide to take part?

You will first be asked to sign a paper or online study consent form. Then we will ask you to be interviewed by one of our researchers at three different times: when you join the study, 4 weeks later, and then 8 weeks later.

In the first interview, before or shortly after you started your treatment, we will ask about your expectations of abemaciclib and hormone therapy and the information that you received about this treatment.

In the interviews at 4 and 8 weeks we will talk about the impact that the treatment has had on different areas of your daily life, both positive and negative. We will also ask about any side effects you may have experienced and what steps you have taken to manage these, including help from your doctors or nurses.

The purpose of the interviews is to find out about your views and experiences of the treatment, so there are no right or wrong answers. If there are any questions that you do not want to answer, just tell the researcher and they will move on to the next topic.

All interviews will be by telephone or video call (with Zoom or Microsoft Teams), whichever way you prefer. The interview will be arranged at a date and time that is convenient for you and last around 30-45 minutes. We will also ask your permission to audio-record the interviews on an external recording device. You can ask for the recording device to be switched off at any point. The audio recordings are optional. If you do not wish your interview to be recorded, we will take notes during the interview.

The researchers who conduct the interviews are not oncologists. They are not able to answer any questions you may have about your treatment in the POETIC-A trial. However, if you do have any medically related problems, they would suggest that you contact your clinical team.

The research activities in this study will not affect your participation in the POETIC-A trial in any way, and study visits will remain as normal. If for any reason you have to withdraw from the POETIC-A trial, we will offer you a final interview for the PEATY study.

7. What are the possible benefits of taking part?

This study might not be of direct benefit to you, but the research findings might benefit others in the future. The results will help us to understand more about how treatment with abemaciclib and hormone therapy affects people. This will be used to provide the best information and support for others starting this treatment in the future.

8. What are the possible disadvantages or risks of taking part?

The main disadvantage of taking part is that we would be taking up some of your time and we are unable to pay you for this. It is also possible that thinking and talking about sensitive issues such as cancer and treatments may be upsetting for some people. However, our researchers are all well-trained and experienced in this type of interviewing and will be very sensitive to your feelings. You can decide to stop the interview at any point if you find it difficult or upsetting.

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

You can stop being part of the PEATY study at any time without giving a reason, but we will keep the information about you that we already have. Withdrawal will not affect your clinical care, or your participation in the POETIC-A trial.

10. Will my details be kept confidential?

Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. You will be given a code number and your data will be stored electronically using this number only. Once we have finished the study, we will keep some of your anonymous data, including any interview notes, so we can check the results, if needed. This data will be stored securely and kept for 10 years. The study results will be published in reports and scientific journals. We will write our reports in a way that no-one can work out that you took part in the study. We may include brief quotations if you have given consent for this, but we will always change personal details such as names and places to ensure that nobody can be identified.

In this research study we will use personal information from you such as your name, address and telephone number. We will only use this information to contact you during the study and later on if you have requested a summary of the study findings. This information will be stored securely and will only be kept for as long as required. Your personal information will be confidentially destroyed at the end of the study. We will not disclose personal information or other study data to third parties. Only SHORE-C and the University of Sussex (the study sponsor) will have access to this information.

The audio recordings of the interviews will be typed up (transcribed) by a professional company. We have a confidentiality agreement with this company which will ensure that the content of the interviews will be kept completely confidential at all times. This company will have no access to any of your personal information and will not know your name, only your code number. The research team will read the interview transcripts and will remove any information, such as names of other people or places, which could identify you. Once transcribed, the audio recordings will be destroyed. The anonymised interview transcripts will be stored securely with other study data, such as interview notes, and kept for 10 years.

All information that is collected during the study will be held and processed according to the Data Protection Act 2018. The University of Sussex's Privacy Notice is available at <http://www.sussex.ac.uk/ogs/policies/information/dpa/privacynotice>. The SHORE-C data privacy policy is available at <http://shore-c.sussex.ac.uk/dataprotection.html>. To request a paper copy please phone 01273 873019.

If you have a problem about how the researchers have handled your personal information, you should contact the SHORE-C research team. If you are not satisfied after that, you can contact the University of Sussex Data Protection Officer. The research team will give you the contact details.

11. What if there is a problem?

If you have any concerns or complaints you can contact the lead researcher (h.harder@sussex.ac.uk) or the chief investigator (l.j.fallowfield@sussex.ac.uk), who will do their best to answer your questions.

If you wish to speak to someone outside of the research team, please contact the study sponsor, the University of Sussex: researchsponsorship@sussex.ac.uk or 01273 872748.

You might also wish to contact your clinical team or the NHS Patient Advice Liaison Service (PALS) for advice.

12. Insurance

The University of Sussex has insurance in place to cover their legal liabilities.

13. What will happen to the study results?

We will present the findings in a study report and in medical journals, at conferences and as a summary on the SHORE-C website. The study team will make sure that you know about the study findings by sending you a brief summary if you requested one.

14. Who has approved this study?

This study has received ethical approval from the London-Chelsea Research Ethics Committee.

15. Further information and contact details

If at any time you have questions about the study or would like further information, please contact SHORE-C on 01273 873019 or by email adminshore-c@sussex.ac.uk.

You can also contact the person who told you about this study.

Thank you for taking the time to read this information sheet