PARTICIPANT INFORMATION SHEET

Impact of abemaciclib on patients’ roles and responsibilities

IMPACTOR study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

In this study we will be looking at quality of life in women who are starting abemaciclib (Verzenio®) treatment for breast cancer. Starting a new treatment can impact on quality of life in a number of ways. Usually, studies look at this as part of a clinical trial. Although important, research has shown that the participants in clinical trials are not always comparable to the people who might be taking the treatment in the ‘real world’. This is because clinical trials often need to control for lots of factors, such as age or having other medical conditions.

In the IMPACTOR study, we will look at the impact that abemaciclib might have for women outside of a clinical trial, and how treatment might affect their quality of life and ability to maintain or return to their normal activities, roles and responsibilities. We will do this by asking participants to complete quality of life and symptom and side effects questionnaires at several time points over six months. We will also invite some participants to take part in an interview about their experiences of treatment with abemaciclib.

It is important to understand the possible impacts of treatment to help inform patients and their health care professionals when considering different treatment options and ways to support patients and their families.

2. Who is organising and funding the research?

The research is organised by Brighton & Sussex Medical School (BSMS) and funded by Eli Lilly and Company Limited. The funders are a pharmaceutical company who have no role in the management of the study, in data collection, analysis or interpretation.

3. Why have I been chosen?

You have been chosen because you are going to start the cancer treatment abemaciclib for breast cancer. You may also be taking other medications to treat breast cancer. We hope that 150 people will take part in the study.
4. Do I have to take part?

No. Taking part is completely voluntary. You do not have to join the study. Your care and treatment will be the same whatever you decide. If you decide to take part you will be given this information sheet to keep and asked to sign a consent form.

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

If you do wish to join the study, the doctor or the researcher 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 and receive your consent to participate. You will be asked to return the consent form to the researchers who will then arrange to send the questionnaire packs to you or provide you with a link to complete them online. Please do not complete this consent form until you have spoken to the research team.

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

If you decide to take part, you will have a choice of either a) completing questionnaires for a period of 6 months, or b) completing the questionnaires and taking part in an interview about your experience of treatment and side effects.

a) Questionnaires alone

You will be asked to complete a set of questionnaires at four time points: when you join the study, and then after one, three and six months. The questionnaires ask about your general Quality of Life, symptoms and side effects of treatment, and how you are managing your day to day roles and responsibilities. The questionnaires will take about 20 minutes to complete each time.

One of the side-effects of abemaciclib can be diarrhoea. We will also ask you to complete a diarrhoea management diary weekly to record whether you have experienced any diarrhoea and if so, any measures you have taken to relieve it. The diary will take about five minutes to complete each week.

You will be able to complete the questionnaires online or on paper; it is up to you. The paper questionnaires or a web link will automatically be sent to you but at each time point you will have the opportunity to tell us if you no longer wish to participate.

b) Questionnaires and interviews

You will be asked to complete the questionnaires as described above. When we contact you for the three month questionnaires, we will also invite you to arrange a convenient time and date for the interview. If at this point you decide you no longer wish to take part in the interview, this is absolutely fine and you can carry on with the questionnaires only.

If you chose to take part in the interview, we will arrange a convenient date and time. The interview can be face to face or by telephone, based on your preference. During the
interview, we will ask you to talk about the impact, both positive and negative, on different areas of your life since starting treatment with abemaciclib. We will also talk about any side-effects you may have experienced, and any coping strategies you may use to relieve these, including help from health care professionals.

We will ask for your permission to audio-record this interview. You can ask for the recorder to be switched off at any point. After the interview, the recording will be typed out. This is done by a professional company. Our agreement with them ensures that the content of the interviews will be kept completely confidential. This company will have no access to any of your personal information and will not know your name, only your study ID number. At the end of the research the recordings will be destroyed.

The interview part of the research will only include around 50 people so even if you consent, you may not be asked for an interview. This will depend on how many people have already been interviewed when you reach the three month time point.

7. What are the possible benefits of taking part?

This study will be of no direct benefit to you, but you will be contributing to research that might benefit others in the future by helping us to better understand if treatment with abemaciclib may impact on aspects of quality of life.

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

The main disadvantage of taking part is that we would use up some of your time. It is possible that thinking about sensitive issues concerning the impact of cancer and treatments may be upsetting for some participants. Should you wish, you can take a break or stop completely. You can decide to stop participating at any point without your care or treatment being affected. It is important to note that all responses given to the questionnaires are treated anonymously. The questionnaires are marked with your unique study number, never your name. This means that researchers will not know if you are upset or distressed. Should you become upset while completing the questionnaires and wish to speak to someone, please contact the researcher Dr Helena Harder on (01273 873019) or Impactor@sussex.ac.uk who can provide you with details of local support.

9. What will happen to the results of the research study?

The results will be shared in several ways: via publication in clinical journals; at National and International conferences; and summaries on our website. If you would like to receive a summary of the study findings, please initial the box on your consent form.

10. What about confidentiality?

If you consent to take part in the research, all information collected about you during the course of the study will be kept strictly confidential. Your name, address and telephone number will be needed to contact you during the course of the study and 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 for the purposes of the study. At the end of study, your personal information will be confidentially destroyed. We will not disclose your name/address or any other information to any third parties. Only the research team at SHORE-C and the University of Sussex (the study sponsor), will have access to your personal information.

You will be given a unique study number. Your data will be stored electronically using this number, never your name. After analysis and publication of the study findings, anonymous study data will be securely archived and kept for 10 years for audit purposes. The results of the study will be published in reports and scientific journals, but it will not be possible to identify any individuals from these reports. We may include brief quotations from some interviews, but we will always change details such as names and places so nobody can be identified.

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

You are free to withdraw at any time and without giving a reason. If you do not want to take part, or you wish to withdraw from the study, this will not affect the standard of care you receive. We will be happy to discuss with you what will happen to any data that has been collected up to the point of your withdrawal from the study. You can ask to withdraw any of your data up until data analysis begins.

12. What if there is a problem?

If you have any questions about the study you should first contact the researchers using the details provided at the end of this sheet. Alternatively, if you have any concerns or complaints and wish to speak to someone outside of the research team, please contact the University of Sussex Research Governance Office at rgoffice@sussex.ac.uk or 01273 872748.

13. Harm

The Universities of Brighton and Sussex have insurance in place to cover their legal liabilities in the unlikely event harm should arise from this study.

14. Who has approved this study?

This study has received ethics approval from the North East - Tyne & Wear South Research Ethics Committee reference 20/NE/01.

Independent information

For impartial local information about the study, please contact the person who told you about this study.
SHORE-C Contact Details

If you would like any further information, please contact the research team via the SHORE-C main office 01273 873019

Thank you for taking the time to read this information sheet

General Data Protection Regulation 2018. The SHORE-C data privacy policy is available at: http://shore-c.sussex.ac.uk/dataprotection.html. To request a paper copy phone: 01273 873019