AN AGREEMENT TO BE IN A RESEARCH STUDY
INFORMED CONSENT INFORMATION

Sponsor:	A pharmaceutical company
Protocol Number and Title:	Protocol 2604-0033 version 6.0; ZYTIA RRA-13726 MCO-ABIR-147 Stated treatment preferences of men with a history of prostate cancer regarding possible future treatments
Scientific Advisor:	Andrew Lloyd, DPhill
Project Managers:	Lina Eliasson, PhD and Hayley de Freitas, MSc
Address of Study Site	ICON Clinical Research Seacourt Tower, West Way Oxford OX2 0JJ, United Kingdom
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INTRODUCTION

You are being asked to complete a survey either online or on paper and to take part in either a face-to-face interview or a telephone interview. Before you decide to take part in this study, you should read this informed consent information, which explains the study. Please ask as many questions as needed so that you can decide if you want to be in the study. Please contact **Hayley de Freitas (hayley.defreitas@iconplc.com)** should you have any questions so that you can decide if you want to be in the study.

This study has been developed and funded by a pharmaceutical company, which is a manufacturer of medicines. ICON Clinical Research has been commissioned by the pharmaceutical company to conduct this research study.

PURPOSE OF THE STUDY

You have been asked to participate in this research study which is being conducted to understand patients' preferences for the different attributes of the treatment options available for metastatic castrate resistant prostate cancer (mCRPC), also referred to as treatment characteristics or treatment aspects. For the study, we have created [30] different hypothetical treatment profiles, which do not reflect actual medicines or products.

The study is being run by ICON Clinical Research, a research consultancy working for a pharmaceutical company (a manufacturer of medicines).

WHAT WILL HAPPEN DURING THE STUDY

If you are interested in taking part in the study please complete this informed consent form. If you decide to participate, you will continue to the survey. The face-to-face interview or the telephone interview will be done after you have completed the survey. A researcher will call you to arrange the interview at a date and time that is convenient for you (if this has not already been done).

You have been asked to complete the survey document before the interview takes place. At the start of the survey you will be asked to provide some basic information about yourself, followed by some questions about your history of prostate cancer and treatments you have undergone.

The face-to-face or telephone interview will be conducted by a trained interviewer who is a member of the study team.

During the interview you will need to have access to the internet and a computer screen so that you can have the online survey in front of you during the interview. This will help you remember the specific questions and your experience with the survey. If you completed a paper survey, you will need to have this in front of you.

The interview will be audio-recorded and the interviewer will let you know when the recording is about to begin. At the start of the interview you will also be asked to confirm verbally your consent to take part in this study.

The interview will involve questions about how well you understood the survey questions and the instructions, and the relevance of these issues. The study is interested in understanding whether this survey is easy to understand and accurate for people who are have experienced prostate cancer and had treatment for this. Your feedback will be used to improve the survey for the second part of the study.

The answers you provide in the study will not be linked to your name or other information that would enable you to be identified.

Please note that if an adverse event or side effect is identified during the interview, which is linked to a medicine manufactured by the study sponsor, this will be reported to the study sponsor. We (ICON) will only report details of the adverse event or side effect, as well as your study ID number, age and sex. We will not report any of your personal information, such as name or contact details, to the study sponsor.

LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS EXPECTED TO TAKE PART IN THE STUDY

Approximately 6-8 men, aged 18 years or older, with prostate cancer in the UK, Germany and France will take part in an interview to help develop the survey. The survey may take up to 45 minutes to complete, followed by a ***[telephone interview which may take up to 65 minutes / face-to-face interview which may take up to 75 minutes]***.

UNKNOWN/UNFORSEEABLE RISKS

There are no known risks to participating in this study. However, there may be some unknown or infrequent and unforeseeable risks associated with this study. You will be informed in a timely manner, both verbally and in writing of any new information, findings or changes to the way the research will be performed that might influence your willingness to continue your participation in this study.

POSSIBLE BENEFITS OF THE STUDY

There is no direct medical benefit to you as a result of taking part in this study. However, information learned from the study may help people affected by prostate cancer in the future.

PAYMENT FOR BEING IN THE STUDY

£37.50 for the survey and £54.17 for the interview (total £91.67), when you have completed the survey and telephone interview // £37.50 for the survey and £62.50 for the interview (total £100.00), when you have completed the survey and face-to-face interview. You will receive payment within 1-3 weeks after completing the interview.

ALTERNATIVES TO PARTICIPATION

You can choose not to participate in this study.

RELEASE OF RESULTS AND PRIVACY

Records of you being in this study will be kept private. **If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.** Information related to your personal details, such as name and telephone number, will only be seen by staff involved with recruitment. The following people will have access to the survey data collected:

- ICON Clinical Research(Study coordinators)
- The pharmaceutical company (Study sponsor)
- FEKI (ethics review body)

The use of the results obtained will be governed by the UK Data Protection Act. The sponsoring pharmaceutical company will have no access to individual responses or be able to identify individuals who agree to participate.

LEGAL RIGHTS

You do not lose any legal rights by agreeing or declining to participate in this study.

WHOM TO CONTACT

You may contact the Project Managers at ICON Clinical Research
By telephone on: (available Monday-Friday 09:00-17:30 UK time)
Hayley de Freitas + (44) (0)1865 320144

By email on:
hayley.defreitas@iconplc.com

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

You may contact FEKI if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

If you would like additional information about your rights, research in general, you may visit www.feki.com.

FEKI has approved this study and this informed consent form. FEKI is a group of scientific and non-scientific people who review, and approve or disapprove research involving people across Europe, including UK, by following EU guidelines and the World Medical Association's recommendations.

If you have any questions or concerns about your health please contact your personal doctor.

LEAVING THE STUDY

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. You have the right to leave this study at any time. If you do not want to be in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

If you wish to leave this study, please contact **Hayley de Freitas at ICON Clinical Research (Hayley de Freitas + (44) (0)1865 320144 hayley.defreitas@iconplc.com).**

If you withdraw from the study, no new data about you will be collected for study purposes. No data that has already been collected for study purposes will be shared with the study sponsor or used in the study results.

Your part in this study may be stopped at any time without your permission. The following people can stop your participation and/or the study itself:

- The Pharmaceutical Company (Study sponsor)
- FEKI (ethical review body)

If you do not follow the study procedures you may be taken out of the study.

AGREEMENT TO BE IN THE STUDY

Please check you agree with the points below:

This study has been explained to me in a language I understand	☐
I understand that I have the right to withdraw at any time	☐
I understand that if an adverse event is identified this will be sent by ICON Clinical Research to the study sponsor	☐

Select 'Yes' below if you agree to participate in the study. By selecting this option you DO NOT waive any of your legal rights.

Yes, I agree to participate in the study	☐
No, I do not agree to participate in the study	☐

Please click the 'Click to Print This Page' button to print or save a copy of this screen for your own records[1]

FOR FEKI USE ONLY

[1] PDF copy of FEKI approved informed consent information displays for printing/saving