Evaluating Patient Follow-up and Complexity in Cancer Clinical Trials- EFACCT

IRAS Reference: 218440

Participant Information Sheet

Study title & short reference: Evaluating patient follow-up and complexity in cancer clinical trials-EFACCT

Name of Researcher(s): Helene Markham Jones, Prof Tanweer Ahmed, Prof Chris Bridle.

We would like to invite you to take part in the EFACCT study which has been set up by the United Lincolnshire Hospitals NHS Trust and the University of Lincoln.

- Before you decide to take part it is important for you to understand why the research is being undertaken and what it will involve for you.
- Please take time to read the following information carefully, and discuss it with others if you wish.
- If anything is unclear or you would like further information please contact the study team on telephone number 01522 835481 or email hMarkhamJones@lincoln.ac.uk.

What is the purpose of the study?

The main aim of this questionnaire study will be to identify the views of cancer clinical trial patients on the key elements to prioritise in order to improve patient experiences in cancer clinical trial participation. The questionnaire has been designed using the responses of patients who participated in an earlier consensus survey study. The researchers are interested in a patient's experience of follow-up visits and the different elements of care. The purpose of this questionnaire study is to obtain the views of a wider group of patients who have previously participated in a cancer clinical trial. Through the research we are seeking to understand how participants felt about the different elements of the study they were part of and which they felt were complicated, time-consuming or were a burden or those areas which were particularly efficient and supportive.

A parallel study will be taking place which asks research professionals to comment on and rate the complexity of studies, activities and follow-up at NHS hospital sites. It is important to gain a clear insight into the nature of cancer trials in terms of operational delivery in order to develop solutions and models of care to enhance patient experiences. The intended outcome from this research is to create a trial evaluation model which will support sites in planning, setting up and monitoring studies, with a view to improve patient access to clinical trials and the latest treatments. Your insight as a patient is invaluable in being able to guide future care pathways that enhance the patient experience.

The research is being conducted as part of a PhD doctoral study sponsored by the University of Lincoln and funded by the United Lincolnshire NHS Hospital Trust through cancer charitable funds.

Why have I been invited and am I eligible?

You have been invited to participate as a patient who has previously participated in a cancer clinical trial based within an NHS Trust hospital in the United Kingdom, and because of your knowledge and experience of the receiving care as a trial participant.

You are eligible to take part if you;

- Are aged 18 or over.
- Are willing to participate in a questionnaire study.
- Have had a diagnosis of cancer and have previously participated in a clinical trial conducted at an NHS site.
- Have completed a cancer clinical trial or have attended at least one follow-up visit.

Do I have to take part?

No, participation in the trial is entirely voluntary. If you decide to participate you will be given the information sheet to keep. We will then ask you to sign a consent form to show you agreed to take part. You are free to withdraw at any time, without giving a reason.

What should I do if I want to take part?

If you would like to participate in the study all you need to do is complete the questionnaire. The questionnaire can be completed online or in a paper format. Printed questionnaires can be returned in the supplied stamped addressed envelope. By completing the questionnaire online or returning the paper form you are consenting to participate in the study. Participation is entirely voluntary. Please ensure you have understood this information sheet before submitting the questionnaire. Further study information can be accessed at the following website; https://efacct.com/

What will I have to do if I take part?

You are invited to answer a series of structured questions with the option of adding your own comments on the research topic at the end of the questionnaire. You only need to complete one questionnaire and the anticipated time to complete this will be approximately 30 minutes. The questionnaire is a self-administered form which can be completed remotely online or on a paper form. You will not need to attend any meetings or meet with the researcher as you will be able to complete the form remotely and in your own time. In order for the study and participants to benefit from timely analysis we would gratefully request that questionnaires are completed within two weeks of receipt.

Expenses and payments

Participants will not be paid and no arrangements are in place for the payment of compensation for participation within the study.

What are the possible disadvantages and risks of taking part?

There are no risks to yourself through participation in this study. Your involvement is entirely voluntary.

What are the possible benefits of taking part?

We cannot promise the study will help you directly but the information we obtain from the study will help to increase the understanding of the delivery of cancer clinical trials and the support of patients in follow-up. As a cancer clinical trial patient your insight and expertise is invaluable in identifying optimal solutions from both operational and patient perspectives.

What if there is a problem?

If you have a concern about any aspect of this study, you should contact to the research team on the details below who will do their best to answer your questions.

Chief Investigator: Helene Markham Jones. Tel: 01522 835481. Email: hMarkhamJones@lincoln.ac.uk.

If you remain unhappy and wish to complain formally you can do this by contacting the Patient Advice and Liaison Service (PALS) team at your hospital on the following contact details;

[Local PALS contact details added for participating site]

Will my taking part in the study be kept confidential?

All information collected from you during the course of the research will be kept **strictly confidential**. The study will be conducted in accordance with ethical and legal principles and the information you share with us will be handled in confidence and in accordance with the Data Protection Act 1998 and the Caldicott principles. Only authorised members of the research team at the University of Lincoln and United Lincolnshire Hospitals Trust will access the study data. The researchers have a duty of confidentiality to you as a research participant and all precautions will be taken to safeguard your information. . Personal data will be stored in linked anonymised form on a secure database on a password protected computer and will be kept for 3 months after the end of the study, after which time it will be destroyed. All digital files will be encrypted. Manual files will be stored in locked filing cabinets with the key held only by the Chief Investigator, who is the data custodian for the study. All research data will be kept securely for 5 years. After this time the data will be disposed of securely. Data may be accessed by regulatory authorities as part of the research audit process.

What will happen to the results of the research study?

The results of this study will be presented at conferences and submitted for publication in peer-reviewed journals. As the study forms part of a PhD study the results will also be published as a doctoral thesis. A summary of the results will be made available on the study's website and provided to participants. Anonymised quotations may be used in the doctoral thesis, research articles, presentations or educational meetings. Your name or any other details that may identify you will not be used in any report on the research findings and data kept secure and confidential.

Who is organising and funding the research?

This research is organised by the University of Lincoln and the United Lincolnshire Hospitals NHS Trust. The University of Lincoln is the study sponsor and the United Lincolnshire Hospitals Trust is the main funder supported by cancer charitable funds provided in the name of Roman Kopyt.

Who has reviewed the study?

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the East Midlands – Derby Research Ethics Committee. This study has also been reviewed and approved by the University of Lincoln School of Health and Social Care Ethics Committee.

Further information and contact details

Name of Researcher(s): Helene Markham Jones, Prof Tanweer Ahmed, Prof Chris Bridle.

Helene Markham Jones, MA

Chief Investigator, MPhil/PhD student in Health and Social Care Research Opportunities.

The University of Lincoln, School of Health and Social Care,
College of Social Science
University of Lincoln. Brayford Pool, Lincoln, Lincolnshire. LN6 7TS
Tel: 01522 835481 Email: hMarkhamJones@lincoln.ac.uk

Professor Tanweer Ahmed, MBA, FICR

Director of Lincolnshire Clinical Research Facility, Head of Research & Development & IP Lead.
United Lincolnshire Hospitals NHS Trust, Research and Development Department,
Lincoln County Hospital. Greetwell Road, Lincoln, Lincolnshire. LN2 5QY
Tel: 01522 573941 Email: Tanweer.Ahmed@ulh.nhs.uk

Professor Christopher Bridle CPsychol

Director of Lincoln Institute of Health, University of Lincoln.
Brayford Pool, Lincoln LN6 7TS
Tel: 01522 886004 Email: CBridle@lincoln.ac.uk