

## 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](mailto:hMarkhamJones@lincoln.ac.uk).

#### What is a Delphi study?

A Delphi study seeks to involve a group of individuals (known as Delphi panellists) in the process of gaining consensus on a subject in which they have personal knowledge or experience. The participants or 'experts' answer questionnaires which start with open questions in the first round and then move to more structured questions in following rounds. All responses are collated and analysed by the research team and feedback is given to participants on the previous round's data submitted by the group. A statistical measure of responses is reported but individual replies always remain anonymous. Once an agreed level of consensus is reached the Delphi process is complete. This method is widely used to identify or gain consensus on healthcare priorities.

#### What is the purpose of the study?

The main aim of this Delphi study will be to identify the level of consensus amongst cancer clinical trial patients (experts) on the key elements to prioritise in order to improve patient experiences in cancer clinical trial participation. A series of questionnaires will be completed in succession allowing panellists to provide their thoughts on elements to be considered and then rank topics provided by the group using a rating scale. The scale (known as a Likert scale) will be used to rate items between 1 and 7 in terms of importance with the aim of reaching a consensus.

This research study is seeking to understand the experiences of patients who have participated in cancer clinical trials, how they felt about the experience and the elements which they felt were complex. The study is seeking specifically to look at the impact of follow-up visits and the different elements of care they experienced whilst on a cancer clinical trial conducted at an NHS hospital. 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 delivery of cancer care to trial participants.

You are eligible to take part if you;

- Aged 18 or over.
- Are willing to participate in a Delphi study using consensus methods.
- Have access to the internet.
- 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 online questionnaire and consent form and email this back to us. Further study information and consent forms can be accessed at the following website; <https://efacct.com/>

### **What will I be asked to do if I take part?**

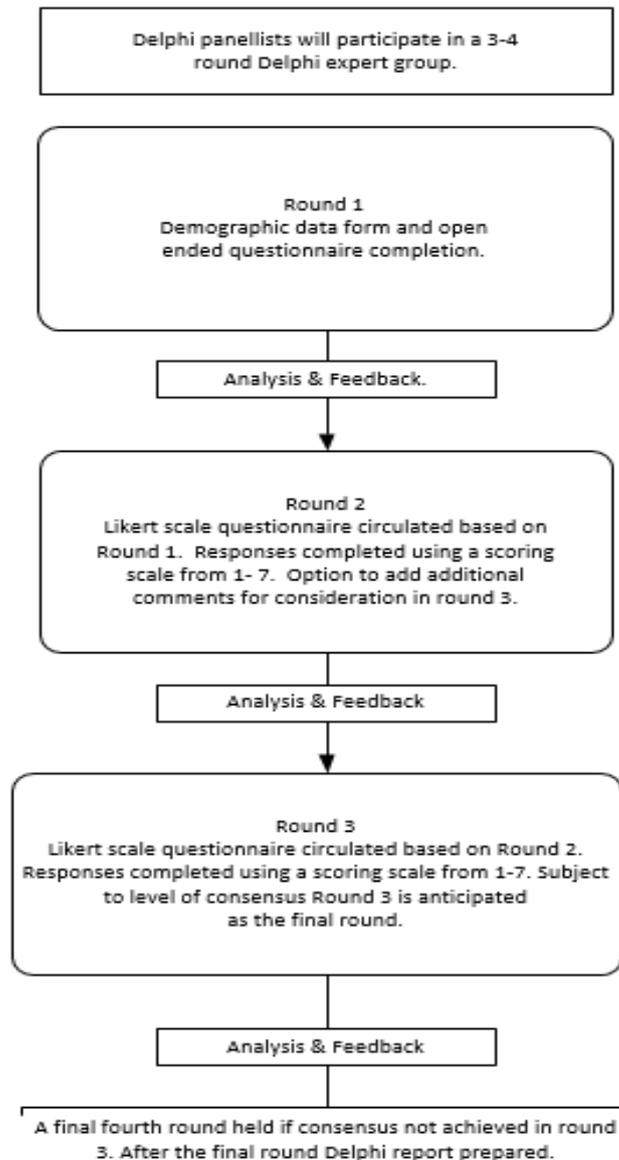
Once your consent form has been received you will be sent a link to an online questionnaire for each round of the Delphi survey at a scheduled date. The Delphi study will consist of approximately three rounds. The Delphi technique is a method used for the purpose of achieving consensus through the use of sequential questionnaires answered by a panel of participants (expert panel) who have expertise or specialist knowledge in the field of the research subject. There may be a fourth round if this is needed to achieve consensus. The anticipated length of the Delphi study is twelve weeks. Your total involvement in the study would be approximately 2–2.30 hours in total over the three month period.

In order for the study and participants to benefit from timely analysis we request that questionnaires are completed within two weeks of receipt of the link. The researcher will send out an email reminder just before the return date when the forms are needed for the data analysis for each round. You do not need to attend any meetings or meet with the researcher as you will be able to complete the questionnaires remotely online.

In the first round you will be asked to provide responses to an open-ended questionnaire. The data from all respondents in round one will be analysed and form the basis of the second questionnaire. In round two you will be asked to rank responses on a Likert scale. You will also have the option to add additional comments.

In round three you will receive analysis of the group responses and asked to rate final statements with a view to reaching consensus amongst the expert panel.

## Delphi Study Design



### 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](mailto: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. Data may be accessed by regulatory authorities as part of the research audit process.

Your personal data (email address and telephone number) will be kept until the end of the study. All research data will be kept securely for 5 years. After this time your data will be disposed of securely.

The anonymity of panel participants is an important part of the Delphi process to ensure that each panel member has the opportunity to contribute insights freely. Participants will remain anonymous to the other members of the group. Answers will be fed back to the group but the analysis will not reveal the identity of the contributors. Direct quotations may be reported in Delphi rounds or as part of the research analysis but these will not be traceable to the author.

### **What will happen if I don't carry on with the study?**

If you no longer wish to participate in the study you can withdraw at any time by contacting the Chief Investigator. No further questionnaires or study information will be sent to you. As the Delphi survey design is conducted in successive rounds the data that has already been included in initial rounds will still be used in the study analysis. All data however is anonymised once received. Your anonymity will be maintained.

### **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.

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