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

IRAS Reference: 218440

Participant Information Sheet – Research Professional

Full Study Title: Evaluating patient follow-up and complexity in cancer clinical trials: Development of an objective methodology to define and quantify trial complexity, intensity and workload to improve operational management and enhance models of trial delivery.

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 a Delphi study?

A Delphi study seeks to engage a group of individuals (known as Delphi panellists) in the process of gaining consensus on a subject pertinent to their field of expertise. The participants or 'experts' answer questionnaires, commencing with open questions and moving to structured questions in successive 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. These are reported as a statistical measure of the group response but individual responses remain anonymous. Once there is a convergence of opinion or an agreed consensus measure has been reached the process is complete. This method is widely used in healthcare predominantly to identify priorities or gain consensus.

What is the purpose of the study?

The main aim of this Delphi study will be to identify the extent of agreement and disagreement across research professionals (experts) on the factors contributing to complexity and the burden of follow-up in the delivery of cancer clinical trials. The Delphi study has been selected as a consensus method to elicit the opinions of research professionals in identifying elements of trial complexity and the factors contributing to the burden of follow-up and trial delivery in cancer clinical trials. A series of questionnaires will be circulated commencing with open questions in round one and then structured questionnaires in following rounds which use a rating scale (known as a Likert scale) allowing panellists to rate items in terms of importance with the aim of reaching a consensus.

This research study's intent is to understand the variations in complexity and follow-up and the impact of trial interventions in the delivery of cancer clinical trials at NHS secondary care sites. The complexities of trial protocol design, amendments and level of activities including follow-up can place a significant burden upon operational resources of participating sites. This research is directed at providing clear insight into the nature of cancer trials in terms of operational delivery thereby providing a platform for continual assessment, improvement of service solutions and patient outcomes. This Delphi study will help inform the development of an objective

methodology and system based tool to enable the accurate mapping and recording of factors determining the overall model intensity, workload and resource impact on trial centres. The intended outcome is to create a trial evaluation model to assist sites in study feasibility assessment, monitoring and resource planning for portfolio studies based on their design and complexity rating.

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 Research Professional working within or in collaboration with an NHS Trust and because of your knowledge of the delivery of cancer clinical trials and cancer patient care within in the United Kingdom.

You are eligible to take part if you are;

- Aged 18 or over.
- A research professional with a minimum of 18 month's experience of working within cancer clinical research in an NHS secondary care setting.
- Are currently working within the field of cancer clinical research or have participated in delivery of a cancer trial within the past 18 months.
- Are willing to participate in a Delphi study using consensus methods.
- Are a member of one of the following professions or groups;

Research professional participants.

The following roles will be approached to participate in the study; Clinical/R&D directors, Principal/Co-Investigators, R&D Managers, research nurses, officers and assistants, research pharmacists, radiographers as well as associated research professionals on site or externally. External professionals may include sponsors (commercial and non-commercial), governance bodies & network professionals (NIHR, HRA, Study Support Service, Research Design Service). All research participants should have over 18 months experience in clinical research.

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. Further study information and consent forms can be accessed at the following website; https://efacct.com/

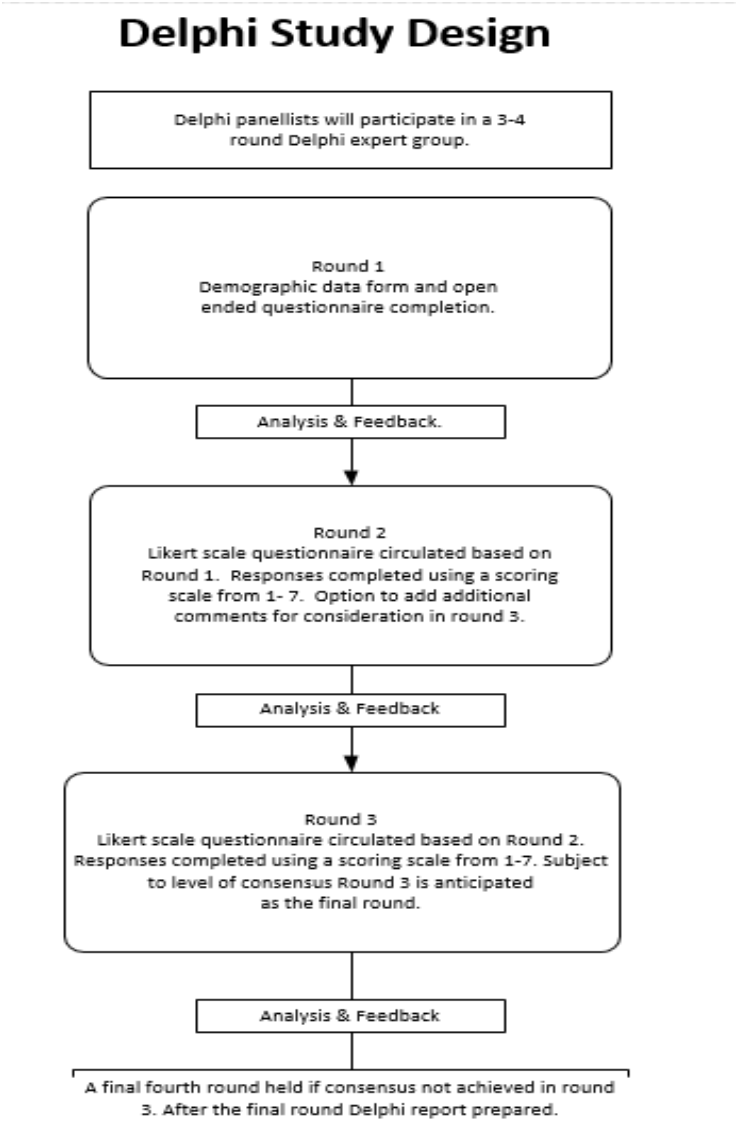
What will I be asked to do if I take part?

You will be invited to participate as a Delphi panellist which will involve answering a series of questionnaires. The anticipated number of rounds is three but the process may progress to four rounds if required to achieve consensus. Once we have received your consent form you will be sent a link to an online questionnaire for each round of the Delphi survey at a scheduled date. 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 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.

The expected timeframe for the completion of the Delphi study is 12 weeks. Each questionnaire is anticipated to take approximately 30 minutes to complete. 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 will not need to attend any meetings or meet with the researcher as you will be able to complete the questionnaires remotely online.



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 or your employer through participation in this study.

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 research professional 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 through the Chair Professor for the Faculty Research Ethics Committee: Prof. Mo Ray, School of Health and Social Care, University of Lincoln. Brayford Pool, Lincoln, Lincolnshire, LN6 7TS, Email: MRay@lincoln.ac.uk.

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

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