

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 the purpose of the study?

The main aim of this questionnaire study will be to identify the views of research professionals on the factors contributing to complexity and the burden of follow-up in the delivery of cancer clinical trials at NHS secondary care sites. The questionnaire has been designed using the responses of research professionals who participated in an initial Delphi consensus study. The purpose of this questionnaire study is to obtain the views of a wider group of professionals, experienced in the delivery of clinical research studies, on the elements of complexity and the factors contributing to the burden of follow-up in the delivery of cancer trials.

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 questionnaire 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 semi-structured questionnaire includes a list of questions allowing participants to rate items in terms of importance for inclusion in a trial rating and complexity assessment tool (TRACAT). There will also be a free-text element for participants to add further comments if they felt that the items presented did not cover all elements which should be considered for inclusion in the tool design. The outcome of the questionnaire study will also be used to inform a further stage of the study involving one-to-one interviews. Participants completing the questionnaire stage of the study may also opt to participate in an interview study.

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 allied to 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 professionals with a minimum of 18 month's experience of working within cancer clinical research in an NHS secondary care setting.
- Currently working within the field of cancer research or have participated in delivery of a cancer clinical trial within the past 18 months.
- Willing to participate in a questionnaire study.
- 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 study questionnaire either 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 be asked to do if I take part?

You will be invited to answer a series of structured questions with the option of adding your own commentary on the research topic at the end of the questionnaire. The questionnaire can be completed online. 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 structured questionnaire completed remotely and in your own time. You will not need to attend any meetings or meet with the researcher as you will be able to complete the questionnaire remotely online 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 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. 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. Quotations may be used in the study analysis to provide examples of participant views in relation to cancer clinical trial delivery but these will not be traceable to the author in order to protect anonymity. All digital files will be encrypted. Manual files will be stored in locked filing cabinets with the key held only by the Chief Investigator. 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 after which time it will be disposed of securely. All research data will be kept securely for 5 years.

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. Anonymity of participants will be maintained in any reports 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 NHS 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.

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