Summary Protocol

Evaluating patient follow-up and complexity in cancer clinical trials. EFACCT

IRAS Reference: 218440

Background for the study

Providing cancer patients with access to the latest treatment options through clinical research is an important focus for the NHS. Due to predicted increases in cancer incidence and survival rates it is necessary to study how clinical trials are conducted within the NHS in order to identify efficient processes and practices and areas for improvement. Cancer studies are amongst the most complex in design with detailed protocols, prolonged follow-up periods and many different disciplines and teams combining to support treatments and patients. To optimise opportunities for patients to participate in trials and access new treatments there is a need to better understand how the NHS can support patients and research professionals alike. The EFACCT study will evaluate the nature of cancer clinical trial delivery in NHS hospitals to understand the implications for participants and organisations in order to identify effective solutions for patients and the NHS sites alike.

Aim of the study

The aims of the study are to explore the views of patients and research professionals who have participated in cancer clinical trials in order to identify efficiencies, impacts on resource, highlight best practices and support patient-centred models of practice. Through an in-depth review of cancer clinical trials, their designs, and the varied operational and organisational elements involved in delivering clinical research in NHS hospitals, the study intends to develop methods and models of practice to enhance trial delivery. The study is seeking to gain a comprehensive understanding of the complexity of trials, the workloads involved and patient perceptions of the impacts and benefits of participation in a cancer research study. The researchers are particularly interested in understanding the elements of studies relating to follow-up visits and trial complexity both from a patient's and a research professional's perspective. One of the main intended outcomes of the study is to create a tool to assist researchers in managing studies operationally. This tool is to be called TRACAT which stands for 'Trial Rating and Complexity Assessment Tool'.

Participants

Participants will include research professionals, experienced in delivering cancer clinical trials, and cancer patients who have previously or are currently participating in a trial. As key stakeholders involved in cancer clinical research these participants play a crucial role in identifying issues within existing processes and are invaluable in providing insight and important perspectives to support the development of future research delivery models. The study will be recruiting approximately 185 participants from 12 NHS research sites around the UK which will allow us to analyse the views of cancer trial patients and research professionals.

Study Objectives:

To main objective of the study is to define and quantify the complexity and follow-up elements involved in cancer clinical trials.

In addition to this there are secondary objectives which include;

- the development of a trial rating and complexity assessment tool (TRACAT) which will be based on study designs, types of cancer, study phases, service delivery requirements and the needs of patients
- an in-depth analysis to define different elements contributing to complexity, service pressures and barriers to efficiency in trial delivery and provide evidence of best practices used at research sites
- provide a process for trial assessment and enhanced reporting to support strategies for planning and running trials

The above objectives will be achieved by analysing measurable data on trial performance in the NHS and study documentation alongside descriptive contextual information provided by cancer trial patients and research professionals.

Research Design & Methods

Through an approach using multiple methods (mixed-methods) to understand the wide range of elements involved in research practice in the NHS, the study will combine information collected from cancer patients, research professionals and from NHS data sources. The research will incorporate a survey, questionnaires and semi-structured interviews. In addition study documents and the volume of patient follow-up visits will be measured. We will be reviewing all the different types of trials and complexities across a range of cancer trial designs and phases conducted at NHS sites. The data will be analysed to define operational models and develop the TRACAT tool aimed at supporting study evaluation, delivery and management and will be directed to enhance outcomes for cancer patients within the NHS. There are four different stages to the study (work packages). The work package involving participants is work package 3.

Work Package	**Activity Description**
Work Package 1	Documentation and Database analysis
Work Package 2	Trial Rating and Complexity Analysis Tool (TRACAT)
Work Package 3	Phase 1. Delphi Survey Study
	Phase 2. Research Professionals Questionnaires & Interviews
	Phase 3. Clinical Research Patient Questionnaires & Interviews
Work Package 4	Systematic Review

Work Package 3 (Participant Study)

Phase 1: e-Delphi Survey Study

An online survey (known as an e-Delphi) will be conducted using two expert panels (cancer clinical trial patients and research professionals). This study will aim to reach a consensus on key elements to consider in the development of the TRACAT tool and the model describing cancer clinical trials. The Delphi technique is a method used for the purpose of achieving consensus through the use of a series of questionnaires answered by a panel of participants (expert panel) who have expertise or specialist knowledge in a particular field or subject. Using the e-Delphi technique allows participants

from across the UK to participate in the study, remain anonymous and contribute to developing ideas supporting research enhancements by commenting and voting on the elements most important to them.

A series of survey questionnaires are circulated amongst participants in successive rounds, starting with open questions and then moving to questions where participants respond to items to prioritise using a 7-point scale (known as a Likert scale). This e-Delphi study will be completed online and will involve 3-4 rounds. All responses are collated and analysed by the research team and feedback is given to participants and once an agreed consensus measure has been reached the process is complete. This method is widely used in healthcare research.

Phase 2 & 3 –Questionnaire's and Interviews

Phases 2 and 3 of the participant study involves two research elements;

- Structured questionnaires - (with free text addition) – sent to cancer patients and research professionals.
- Semi-structured interviews - interviews – conducted at relevant sites in a suitable private location with cancer patients and research professionals (initial structured questionnaire will inform the interview guide).

Questionnaires will be submitted to participants which have been designed based on the e-Delphi results. The questionnaire responses will be collated and analysed. These will then in turn inform the questions to be asked in the semi-structured interviews. Phase 2 involves research professionals and Phase 3 will involve cancer patients.

Research Professionals

The study involving research professionals is being undertaken to obtain their views as key stakeholders involved in the operational delivery of cancer clinical trials, in order that the important elements contributing to trial complexity to the burden of follow-up are understood and considered. Their responses will help evaluate research to inform recommendations to be made on trial design and models to support them in their roles as well as indicating priorities for inclusion in the TRACAT tool.

Patients

The purpose of the patient research is to gain consensus and expert knowledge from cancer trial participants on the key elements to prioritise in order improve patient experiences and guide future service delivery models. The researchers are interested in a patient's perceptions of follow-up visits and the different elements of care. Through the research we are seeking to understand how participants felt about the different elements of the study they were part of and identify which areas they felt were complicated, time-consuming or were a burden or those areas which were particularly efficient and supportive. The study is being held to involve patients in describing their experiences and gain valuable knowledge of services from a patient's perspective.

Outcomes

The findings of the research aim to provide information to researchers which may inform the design of future studies and provide evidence-based knowledge to support policy makers at local and national levels based on the views of cancer patients and research professionals. As part of the

study the online tool (TRACAT) will be developed to assist research professionals in the effective management of cancer clinical trials. By creating a trial evaluation model researchers and sites will benefit from data and tools to support the planning, initiating and monitoring of studies, with a view to improving patient access to the latest treatments and effective patient-centred clinical trials designs. This tool will be evaluated by the research professionals for adoption into practice. The study results will be presented at conferences and published in peer reviewed publications as well as being made available online from the study website and via the University of Lincoln repository. Presentations will be made to the NIHR (National Institute for Health Research) and relevant NHS regulatory authorities on the research findings and recommendations made on initiatives and policies to enhance cancer clinical research in the UK.

Further Information:

Study short title (short reference)	Evaluating patient follow-up complexity in cancer clinical trials. (EFACCT).
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Sponsor/Funder	This research is being conducted as part of a PhD doctoral study by the Chief Investigator and sponsored by the University of Lincoln. The study is funded by cancer charitable funds in the name of Roman Kopyt, provided through the Lincolnshire Clinical Research Facility at United Lincolnshire Hospitals Trust.
Study Design	Multi-centre study using mixed-methods.
Study Participants	Research professionals and cancer patients.
Planned Study Period	August 2017 – June 2019
Study documentation and full protocol	Copies of all study documentation and the full protocol are available from the Chief Investigator or from the study website.