NCRI National Cancer Research Institute
Partners in cancer research
2017 NCRI Cancer Conference
5–8 November
BT Convention Centre, Liverpool, UK

A Protocol for an Evaluation Study of Patient Follow-Up and Cancer Clinical Trial Complexity: the EFACCT study.

Abstract ID: 922

Year: 2017

Session type: Proffered paper

Theme: Healthcare delivery

Helene Markham-Jones1, Prof. Christopher Bridle[1], Prof. Tanweer Ahmed[2]

[1]University of Lincoln, [2]United Lincolnshire Hospitals Trust

Abstract

Background

Clinical research delivery is crucial in advancing treatment and care options for cancer. There is a burgeoning problem internationally in delivering cancer trials due to complex protocols, stratified treatments and increasing patient populations in follow-up with extended needs. The EFACCT study will evaluate the phenomena of cancer clinical trial delivery at NHS secondary care sites identifying burdens and implications for participants and organisations.

Method

This mixed-methods study adopting grounded theory will analyse operational processes and protocols at sites delivering Phase I-IV cancer trials for commercial and non-commercial studies. Research professionals and cancer patients who have participated in clinical trials will contribute to the development of an objective methodology defining and quantifying trial complexity, intensity and workload to enhance models of trial delivery. This in-depth study involving a two-arm e-Delphi, questionnaires, semi-structured interviews as well as trial documentation, database and systematic reviews will optimise clinical trial performance data in combination with qualitative evidence to form optimal models for cancer clinical trial delivery. Data from 12 geographically dispersed sites will be synthesised and continually compared until saturation is achieved. A total UK sample of 185 participants and documentation sample of 100 studies incorporates theoretical, purposive, quota and snowball sampling techniques leveraging the benefits of health informatics and rich participant contextual data.

Results

Data analysis will include descriptive statistics, thematic content analysis, theoretical, open, axial and selective coding and constant comparison methods. Statistical summaries will use measures of central tendency and levels of dispersion.

Conclusion

The study outcomes will involve the implementation of a trial rating and complexity assessment tool (TRACAT) and an evaluative theoretical model for cancer research operational management. These elements will create new knowledge supporting future research models, strategic planning, trial implementation and evaluation alongside the provision of a mechanism to optimise recruitment and enhance patient outcomes.