A study aimed at improving the conduct and efficiency of trials by developing a standardised set of site performance metrics and a systematic approach to reporting

Project Outline

The rationale of this project is to develop a standardised set of site performance metrics and a systematic approach to reporting that will result in:

• information that is clear and easy to interpret for individuals of all levels of experience who are responsible for the management and oversight of clinical trials.

• the timely identification and resolution of potential problems, so minimizing their impact and improving the performance and efficient delivery of the trial.

Aim

The aim is to improve the conduct and efficiency of trials by agreeing a standardised set of performance metrics for the monitoring and reporting of site performance in trials, and developing a standardised tool for presenting the metrics to trial mangers, Trial Management Groups (TMG) and Trial Steering Committees (TSC).

Objectives

The objectives are to:

• reach consensus about metrics that are important and should be monitored routinely in ongoing multicentre trials.

• establish a set of initial baseline benchmark indicators for each performance metric for the purpose of trending and predicting potential issues.

• develop a standardised systematic method for reporting and presenting these metrics to trial mangers, TMGs and TSCs.

Design

Mixed method study using focus groups of stakeholders, a Delphi survey, and final consensus workshop.

Research Plan

We will take a comprehensive, mixed methods approach to develop the key performance metrics, benchmark indicators that will trigger action and standardised reporting for monitoring site performance in ongoing trials. This will be achieved through developing a Delphi survey to determine key performance metrics, informed by focus groups of stakeholders (see stakeholders listed below) and literature searching, conducting the Delphi survey, and agreeing the final key metrics at a consensus workshop.

Initially, small focus groups of stakeholders will establish a comprehensive list of performance metrics and parameters that are or could be measured routinely in trials. In parallel, we will start to design a Delphi survey, using data from literature searches and, eventually, the focus groups to develop a comprehensive list of performance metric and parameters to be considered for inclusion in the Delphi survey and workshop.

This survey will be sent to Trial Managers and CTU directors, as they share similar levels of understanding and experience of conducting trials and a key part of their roles is to ensure the efficient delivery of multicentre trials. They will be invited to participate through the UK TMN and UKCRC CTU Network. Three Delphi rounds will be used to steer the groups to consensus, refining the list of performance metrics. We will also document the reasons for their decisions.

Finally, data from the Delphi survey will be presented to stakeholders in a priority setting expert workshop, providing participants with the opportunity to express their views, hear different perspectives and think more widely about monitoring of site performance. We will seek consensus on: (1) the top key performance metrics, expected to be around 8-12 in number (2) benchmark indicators for each key metric that will trigger action to improve site performance.

Finally, we will develop a simple tool (probably within Excel) for the presentation of key metrics to Trial Managers, Trial Management Groups and Trial Steering Committees in a standardised format.

Timelines

We expect to commence the work as soon as possible and complete and deliver outputs by October 2017.

Months 1-3: small focus groups of stakeholders, literature searches and design of Delphi survey

Month 4: incorporate outputs from focus groups into Delphi survey

Months 5-8: disseminate Delphi survey, conduct all three rounds and collate results

Months 9: consensus meeting of stakeholders to agree key metrics

Months 10-12: develop standardised reports based on key performance metrics and write up results of the project.

Outputs

The outputs will be a standardised, agreed upon, set of quantifiable key clinical trial performance metrics and benchmark threshold triggers for remedial action. These metrics could be used in trial management to monitor and assess the status of clinical trial's sites and the impact of performance improvement efforts. In addition, this would provide a simple tool, probably within a Microsoft Excel spreadsheet, to produce a standardised report for trial monitoring, simplifying data comparison and interpretation by oversight committees. The report will utilise a traffic light based methods (or similar), plus visual indicator of directional trends to provide temporal context and highlight changes.

The value of this work is that these data would improve research management activities by providing an 'early warning system', alerting trial managers and oversight committees to potential problems, which could be addressed before a trial is adversely affected. This would also standardize performance targets across sites and trials. Further, the introduction of a standardized reporting system could save time and minimize the risk of data misinterpretation.

Additional funding will be sought to further evaluate the key performance metrics and reporting tool through collaboration with the MRC HTMR Network and Trial Forge initiative.