Routemap

Feasibility & Investigator Selection

Trial Planning Phase

Feasibility & Investigator Selection follows the Confirm Sponsor station and precedes the Contracts & Agreements station. This process occurs in parallel with Funding Secured, Trial Master File, and Trial Registration. Feasibility & Investigator Selection is good practice and is relevant to all trials. This station is part of the 'trial planning phase' group of stations.

Non-commercial trials that fail to meet their targets often result in a request for further funding or may not achieve a statistically significant result. It is important to ensure that feasibility assessment and recruitment planning are considered during the study design and planning stage of a trial. For larger trials, the sponsor should consider, during the funding process, whether a feasibility or pilot study should be undertaken. The NIHR provides Guidance on the definition of a feasibility and pilot study and advice on which NIHR programmes fund these studies.

The Association of Medical Research Charities and the NIHR Medicines for Children Research Network have produced Points to consider when assessing the feasibility of research. The US Clinical Trials Transformation Initiative (CTTI) have published a suite of Recommendations and Tools for Recruitment Planning that provide a useful framework.

MRC-NIHR Trials Methodology Research Partnership (TMRP)

The MRC-NIHR TMRP have published a range of material relating to feasibility and recruitment including:

- Guidance on maximising the impact of qualitative research in feasibility studies for RCTs was developed to help researchers consider the full range of contributions that qualitative research can make in relation to their particular trial.
- The QuinteT Recruitment Intervention (QRI) provides a flexible way of understanding recruitment difficulties and producing a plan to address them while ensuring engaged and well-informed decision making by patients. A review of qualitative research provides further insights into barriers to recruitment.
- A broad range of Tips to consider when optimising recruitment of patients to clinical trials (.PDF) has been produced by the Recruitment Working Group of the MRC-NIHR TMRP.
- This review and synthesis of qualitative research examining the perspectives of patients and health professionals provides a conceptual framework to help researchers improve recruitment to depression trials.

Investigator Selection

For multi-site trials, the careful selection and evaluation of investigator sites is critical for the successful completion of a trial within budget, timelines and to ensure the generation of high quality data. Factors that should influence investigator site selection include:

- Interest in the research question
- Experience and qualifications of the investigator
- Sufficient staff to conduct the study and their experience and qualifications
- Availability of suitable patient population:
    - Anticipated rate of patient recruitment (determined through feasibility assessments)
    - Conflicting studies (competing for the patient population and potentially introducing recruitment bias)
- Adequate time to conduct and oversee the trial
- Adequate facilities:
    - Availability of any specialised diagnostic or therapeutic equipment required by the protocol
    - Adequate space and storage conditions (including archive)
    - Available resources in NHS support departments

- Track record with similar trials previously
- Geographic location
- Contractual and budgetary negotiations and arrangements.

When undertaking site selection, the preparation of 'reserve' investigator sites (so that the trial may be extended to these sites if recruitment issues arise) should be considered as part of proactive trial planning.

Patient and Public Involvement (PPI):

Evidence of the impact of PPI on recruitment is emerging. For example, a recent systematic review published in the BMJ, found that PPI interventions modestly but significantly increase the odds of participant enrollment and that the involvement of people with lived experience of the disease condition under study was significantly associated with improved enrollment. Another study from King's College London, published in the British Journal of Psychiatry, showed that trials with higher levels of PPI were 4.12 times more likely to recruit to target. For premarket trials, a report released by The Economist Intelligence Unit (EIU) and showed that patient centric trials that reduce the burden of trial participation, take; on average, about 4 months to recruit 100 patients compared to the average of about seven months.

PPI can address questions such as:

- Will the proposed recruitment strategy work?
- How could it be made easier for a patient to participate?
- How likely are participants going to accept the study schedule/requirements?

Further reading:

- An evidence-based approach to conducting clinical trial feasibility assessments (.PDF) - Otis Johnson: Clin. Invest. (Lond.) (2015) 5(5), 491-499.
- UK Clinical Trial Gateway provides potential research participants with information about trials running in the UK, including how to locate and contact trials of interest.
- Crocker et al: BMJ2018;363:k4738.
- Ennis, L. et al. 'Impact of patient involvement in mental health research: longitudinal study' British Journal of Psychiatry (Sept 2013) doi: 10.1192/bjp.bp.112.119818.