



**NHS**  
*National Institute for  
Health Research*

# Points to consider when assessing the feasibility of research

Prepared by the:  
Association of Medical Research Charities  
(AMRC) and  
NIHR Medicines for Children Research Network  
(MCRN)

**amrc**  
ASSOCIATION OF MEDICAL RESEARCH CHARITIES



*The Medicines for Children Research Network is part of the NIHR Clinical Research Network,  
which supports research to make patients, and the NHS, better.*

## **1. Introduction**

Many clinical studies fail to recruit sufficient numbers of participants, which wastes valuable resources and time and can delay treatments becoming available to patients. Incomplete recruitment to studies leads to significant opportunity costs. Rigorous assessment of feasibility for studies being put forward for funding is one way of increasing the likelihood that the studies run in the NHS are well designed and likely to deliver to time and to target. Equally, a record of running successful studies that answer the key research question is a strong metric of success for funders.

This document contains some pointers for funders who review clinical research studies to assist in the grant review process. In this document, we define feasibility assessments as paper or IT-based exercises to gather information from staff, families or data systems on clinical relevance, participant numbers, logistics at sites and other factors, in contrast to clinically-based feasibility studies, pilot studies and large-scale trials etc.

This document was prepared by the NIHR Medicines for Children Research Network (MCRN) and the Association of Medical Research Charities (AMRC). Given MCRN's involvement, the document includes pointers for research involving children, but other points also apply to research in other age groups. The MCRN with the NIHR Paediatrics (Non-Medicines) Specialty Group and other NIHR Clinical Research Networks (CRNs) are pleased to support feasibility assessments and can offer assistance to researchers and funders from early design stages right through to the completion of studies.

## **2. The importance of feasibility assessments**

Feasibility assessments are used to determine whether a research study is likely to be delivered successfully, taking into account the practical aspects of managing the project. The most obvious question to be asked is: can sufficient numbers of patients be recruited within a timeframe that is consistent with the available funding? However feasibility assessments are not just about numbers, and can be used to assess the relevance and intensity of the study for participants and the study team.

A robust feasibility assessment will help identify possible problems with recruitment and may highlight logistical challenges that may face sites involved with the study. Feasibility assessments also identify aspects of research that need detailed planning. This allows contingency planning, including the identification of worst case scenarios.

Ideally, feasibility assessments involving potential investigator sites should be conducted at an early stage to help inform all aspects of the study design. However, assessments may need to be repeated because clinical practice can change over the timescale needed to generate a good grant application for a clinical interventional study. An example is a study looking at treatment for sepsis that was undermined during development by the introduction of a vaccination programme, which led to a dramatic reduction in patients with the form of sepsis under investigation.

It is instructive to consider how commercial sponsors approach these problems. Commercial sponsors often have considerably more money to invest than public funders and the opportunity costs for public funders of unsuccessful research may be significantly greater than for commercial sponsors. Nevertheless, commercial sponsors often take great care over feasibility work. Commercial sponsors conduct detailed feasibility assessments for sites wishing to take part in their studies. Sites are selected only if they can demonstrate that they can recruit sufficient numbers of participants.

While it might not be possible to accurately predict recruitment targets (e.g. infectious disease cases, consent rates etc.) all possible efforts should be undertaken to assess feasibility. Validated estimates should be used whenever possible. Funders should use feasibility assessments to set targets.

Feasibility assessments cost time and money, but this may be a wise investment prior to committing much larger sums. Well designed assessments give added value, particularly in conditions and populations that have been underserved by research in the past. Feasibility assessments can identify unnecessary variations in access to care or the nature of care delivered.

### **3. Engaging with the National Institute for Health Research (NIHR)**

The NIHR provides many opportunities for researchers to conduct their research in the NHS. Grant applicants are encouraged to engage with NIHR groups to maximise their chances of delivering a successful project. Inclusion on the NIHR CRN portfolio is essential to gain access to support during study set up and implementation. Some aspects of support relating to study development can be accessed prior to inclusion/adoption to the NIHR portfolio. The MCRN assists with study development and delivery, including feasibility assessments and is pleased to work with the Association of Medical Research Charities (AMRC) partners and other funders. The MCRN includes the following infrastructure/groups to support studies:

- MCRN Coordinating Centre – a central point of contact that provides access to MCRN infrastructure and support
- Clinical Study Groups (CSGs) – specialty teams of experienced investigators, nurses, pharmacists and parents/carers that provide expertise on study design and development (both for medicines and non-medicines studies). Input from children can also be obtained
- Clinical Trials Units (CTUs) – dedicated paediatric trials units support all aspects of study design and management, ensuring that protocols are child and family friendly
- Local Research Networks (LRNs) and Comprehensive LRNs (CLRNs) – provide support for study conduct across England

Please email [info@mcrn.org.uk](mailto:info@mcrn.org.uk) to discuss how MCRN can help. Support for non-medicines studies is also available via the NIHR Paediatrics Specialty Group (please email [paediatrics@nihr.ac.uk](mailto:paediatrics@nihr.ac.uk)).

Other NIHR support includes:

- NIHR Research Design Service - provide expertise in developing grant applications
- Research Passport – for NHS and non NHS staff working across NHS organisations
- Central System for Gaining NHS Permission (CSP) – single point of entry for gaining NHS permissions
- Training – Good Clinical Practice (GCP) and other training is available

### **4. Key questions**

During the grant review process, it may be useful to consider asking detailed questions below about the practical aspects of the study. Experience has shown that studies that run into difficulties often have problems that could have been spotted in advance. A detailed feasibility assessment conducted early on in the development of the project can answer many of the questions. Data used in costings should be based on a clear specification of the project and its tasks. Ideally, the specifications and costings should be based on explicit data and should be validated by people not in the research team.

#### ***Clinical relevance***

1. Does the study have the support/interest of the relevant clinical community, as well as any patient support groups/charities?
2. For interventional studies, is the study compatible with current UK practice: is there sufficient consistency in practice across sites (e.g. is the control/comparator, treatment schedule etc. appropriate)?
3. Does the Chief Investigator have adequate expertise, experience and time to lead the study? Evidence of linkage with NIHR infrastructure would help. Expertise in the subject area is NOT in itself evidence of sufficient expertise to deliver a clinical study.

#### ***Participant numbers***

1. What evidence is there that sufficient participants can be recruited at the proposed sites? The number of people who attend a particular clinic or other setting with the condition of interest may by itself be insufficient evidence. It may be helpful to see detailed audit figures if available confirming that there are sufficient participants who meet the inclusion criteria for the proposed project.
2. Do local, regional or national patient databases exist to facilitate the identification and recruitment of participants?
3. What percentage of eligible participants is likely to enrol to the study? Many interventional studies will recruit at approximately 30-50% of all eligible patients. Higher figures can be

achieved for serious conditions soon after diagnosis or first treatment. Lower figures can be expected once a condition is established. It is possible to recruit to studies that have no direct benefit to the participants (including neonates), but these studies may recruit 5-10% of eligible patients (or less) and require the investigators to set aside time to find patients and families who are willing to participate. Are there factors that make refusal more likely (e.g. more visits than normal care, additional interventional procedures required etc.)?

4. In which clinical setting are eligible participants usually seen; primary, secondary, tertiary care or mental health services, and do recruiting sites have easy access to participants from these settings (i.e. are participants seen by recruiting sites or will they be referred)?
5. Will participants also need to be recruited from outside the NHS (e.g. schools, SureStart, direct advertising) and if so, what strategies and resources will be needed to achieve this? Have representatives from these organisations been explicitly included in the study team?
6. Are there any on-going or planned studies that could conflict with the study and limit recruitment at sites?
7. How will investigator sites be selected, will they be/have they been chosen based on robust feasibility? If sites have not been pre-selected, is the study likely to be of interest to sufficient numbers of investigators?
8. Has a pilot of the study taken place and would it be appropriate for this to be carried out before embarking on a larger project?

### **Logistics at site**

1. How many sites need to be involved? Will participants receive all relevant care at the recruiting sites or will continuing and shared care sites be involved? Have all care sites been included in the feasibility studies?
2. How many proposed sites have access to support via a local MCRN/CLRN team and/or is this study best supported within a Clinical Research Facility (especially relevant when frequent sampling or measurements are required, e.g. pharmacokinetic studies)?
3. If the study protocol deviates significantly from normal practice, are investigator sites able to accommodate this in terms of:
  - a. Clinical time – can the investigator/clinical team accommodate study visits and procedures?
  - b. Facilities – is there sufficient space available to run the study?
  - c. Equipment – do sites have the equipment needed e.g. fridges, freezers, non standard equipment?
  - d. Pharmacy support – can the department manage study drugs as required?
  - e. Laboratory support – can the department handle the samples, provide any out of hours cover needed etc?
  - f. Radiology support – is there capacity for additional imaging?
  - g. Excess treatment costs – these should be negotiated through current NHS care funding, but this issue can be a significant block for studies
  - h. Assessment of study outcomes
4. Has the study team scoped the requirements for training? Training can be generic or trial-specific. Some, but not all, people contributing to studies need to complete generic training in GCP. All staff involved in studies need to have training about their roles. Which staff at the proposed investigator sites (i.e. the clinical and research team supporting the study and any others involved such as labs or pharmacy) require training in GCP, study procedures etc.? If they do require training, is there agreement that they can be released to carry this out and is enough training available locally? How will training be resourced? Is high staff turnover anticipated during the study period?
5. Do sites have child-friendly facilities, e.g. play areas, play specialists?
6. Do sites have family-friendly facilities, e.g. crèche if long visits are needed?
7. Do sites have experience of children's studies? Can assessments, blood sampling, etc. be managed appropriately by experienced staff? Can support be provided by MCRN/CLRNs?

## **5. Conclusions**

Many clinical studies fail to recruit sufficient numbers of participants, which can prevent outcomes from being assessed, wastes valuable resources and time, and can delay the provision of treatments to patients. Conducting feasibility assessments can help to ensure that studies are well designed and likely to deliver to time and to target. Feasibility assessments do not guarantee successful studies and cost time and money, but can increase the chance of success and can be a wise investment prior to committing much larger sums.

The MCRN and Paediatrics (Non-Medicines) Specialty Group are committed to maximise the efficiency and impact of children's research in the UK and advocate the conduct of feasibility assessments where possible. The Network and Specialty Group are pleased to help AMRC partners and other funders collect feasibility data in support of their processes to fund studies to address key research questions.