Feasibility and Pilot studies

These definitions have been agreed by the Efficacy and Mechanism Evaluation (EME), Public Health Research (PHR), Health Technology Assessment (HTA), Programme Grants for Applied Research and Research for Patient Benefit (RfPB) Programmes.

We expect that when pilot or feasibility studies are proposed by applicants, or specified in commissioning briefs, a clear route of progression criteria to the substantive study will be described. Listing clear progression criteria will apply whether the brief or proposal describes just the preliminary study or both together. Whether preliminary and main studies are funded together or separately may be decided on practical grounds.

Feasibility studies

Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?”. They are used to estimate important parameters that are needed to design the main study. The design of a feasibility study generally involves listing those parameters which are uncertain and describing the methods for improving their precision so that the main study will have a better chance of success. Examples of such parameters include:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size
- willingness of participants to be randomised
- willingness of clinicians to recruit participants
- number of eligible patients; carers or other appropriate participants
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a particular database; and
- time needed to collect and analyse data.

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Pilot studies

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.
Feasibility and pilot studies: which programme should I apply to?

There are a number of NIHR programmes which will fund feasibility and pilot studies. Applicants must choose the most appropriate programme in the context of the scope and aims for each programme. Some key aspects that should be taken into consideration are below:

1. **Is the programme appropriate in terms of geography and grant size?**
   RfPB funding for example, can only be accessed through NHS bodies and other providers of NHS services in England and has a maximum grant size of £350,000. Feasibility studies would normally be expected to cost less than £250,000, although well justified exceptions can be taken into account.

2. **Can a robust case be made for the plausibility of the intervention and clinical importance of any subsequent full trial?**
   If there is good proof of concept and/or efficacy data available and there is a clear plan to explore the intervention further in a large clinical trial, then HTA or EME might be considered the latter in particular if there are substantial mechanistic elements and laboratory support involved in the project. On the other hand, if the feasibility or pilot study is for a potential trial which might be viewed as more speculative, with no clear plan for a large trial in the very near future, or in which there seems a high risk that the pilot/feasibility study is likely to demonstrate that a full trial is not possible, then the smaller sums that RfPB provide might be seen as more appropriate.

Note that feasibility and pilot studies should be distinguished from Phase II trials, in which some sort of evidence for efficacy, often in a surrogate marker, is sought prior to embarking on a full Phase III trial: EME might be the most appropriate funding stream for these if there is strong scientific interest in the question, and RfPB if there is a clear potential trajectory into patient benefit.

The PGfAR and PHR Programmes also funds feasibility and pilot studies within their remits.