Site Level Feasibility Assessment Guidance

What is a feasibility assessment?
Feasibility is a process of comprehensive analysis and planning, including risk assessment and contingency planning.

Aims of a Feasibility Assessment
The aims of undertaking a feasibility assessment are to review participant recruitment and retention strategies, assess the sites facilities, review availability of resources; staffing, support departments, ethics and R&D approval processes, and contracts and budget requirements.

Requirements
The complexity and scope of the assessment should vary depending on the type of study and location of its sites.

Sites should firstly be assessed as known or unknown. It is likely that if the CI or group has already carried out a trial at a particular site, a great deal of information about this site is already available to them, (e.g. existing/previous track record of participant recruitment, previous compliance, etc.). Teams should try to access this information and hereby review the need to conduct further assessment (e.g. if concerns are present or time has elapsed).

Sites should be allowed sufficient time to complete a feasibility assessment.

As a minimum, the below should be assessed and the outcome documented:

- Site status (NHS or Non NHS)
- Site willingness to participate
- Recruitment rate & possible confounding factors in patient recruitment
- Site's ability to complete all site specific procedures
- Impact of study procedures on Standard of Care
- PI training, experience, and availability
- Investigator/Site experience in conducting similar trials
- Local approval processes
- Staff resources, including the number of PI's active trials
- Adequate facilities/equipment/resources to conduct the study properly
- Availability of potential eligible participants

Here is a list of some of the additional common questions:

- What previous clinical trial experience do as PI have?
- Were previous recruitment targets met for other similar studies?
- Do you have other competing studies?
- What is your study population?
- Size of cohort?
- How many participants may be excluded?
- What recruitment strategies do you have?

Research Costs

There are three types of cost associated with clinical studies in the NHS: "Research", "Support", and "Treatment". It is not always straightforward to allocate costs accordingly. The NIHR and other funders will ask for a detailed breakdown of all these costs. What costs will your study incur to the site?

- Research Costs: the costs of the research and development itself that end where the research ends. They relate to activities that are being undertaken to answer the research question.
- NHS Treatment Costs: the patient care costs, which would continue to be incurred if the patient care service in question continued to be provided after the research study had stopped.
- NHS Support Costs: the additional patient care costs associated with the research, which would end once the R&D study in question had stopped, even if the patient care involved continued to be provided.

Contact name of Site Contract / Costing Manager (if known)
Email Address:
Telephone number:
Additional considerations for site

Site Feasibility

Here is a checklist for sites to consider prior to agreeing to participate in a clinical trial:

- Validating Enrolment Potential
- Subject population
- Is the PI aware and willing to conduct the study?
- What track record does the PI have at meeting recruiting successfully? See http://public.ukcrn.org.uk/search/
- Has the proposed PI been a PI on a non-commercial CTIMP before?
- Has the PI undergone an MHRA inspection before?
- Are any research passports needed for lead site staff to enter the site? If so, request contact details of person who arranges at the site / local R&D office.

Participant Recruitment

- Who will be responsible for driving recruitment at the site?
- Do other departments/people need to be contacted to make them aware of the study (think of the patient pathway)? Who will do this?
- Is there anything in the protocol design or inclusion/exclusion criteria which may impact recruitment?
- How many patients are currently seen a) Per month b) Per year
- What is the anticipated screen failure rate?
- Length of recruitment
- Proposed recruitment target
- Is the start and end date appropriate for the study?

- Any similar/conflicting studies in the department?
- Review and evaluate inclusion/exclusion criteria
- Any circumstances that would affect recruitment?
- What is the expected screen failure ratio?
- Is there a patient stipend?
- Are vulnerable populations involved?
- Do you have access to special testing/monitoring required by the protocol?
- What potential problems does the PI foresee with your site with recruitment? Are they realistic?
- Can the PI meet the recruitment timelines and targets?
- Are there any seasonal issues at the site that may affect recruitment?

Health Volunteer studies

- Phase 1 studies – consider using the MHRA requirements of the site and PI: https://www.gov.uk/mhra-phase-i-accreditation-scheme#principal-investigator-in-first-in-human-fih-trials
- Is the site registered with the Over Volunteering Prevention System http://www.hra.nhs.uk/about-the-hra/our-committees/the-over-volunteering-prevention-system/
- Is the site/CTU located with an NHS Trust? What emergency provisions are available if not? Has this been risk assessed and documented?

Laboratory issues

If using local labs do they have

- Accreditation/certificates
- Training and certification for handling dry ice

- If using central labs do they have the
- Staffing for processing of samples or previous experience of central lab kit management
- Handling/training

- Sponsors will want to see evidence of Investigator and staff trained in GCP. Copies of certificates or training logs and documented on CVs.

- Does the site have access to any specialist departments and diagnostics require in the protocol, if so are they willing to be involved in clinical trials and what additional information do they need?

Pharmacy

- Which Pharmacy will be used at the site?
- Does Pharmacy have adequate storage facilities for the IMP?
- Do they have the capacity?
- Is there anything unusual about this drug/drug regime?
- Will Pharmacy have to source drugs or are these provided by Sponsor?
- Will these drugs be paid for by the Sponsor?

- Will there be out of pharmacy storage? Has this been risk assessed by the GCP Manager and Sponsor Pharmacist

Other Support Departments requirements

- Which support services/departments will you be using at the site?
- Clinical Research Facility (CRF)
- Imaging/Radiation Radiology procedures (How many scans required & frequency & the number of patients. If a lot of patients or several scans required within a very narrow timeline, please flag this as an issue to the site to discuss with Radiology as soon as possible)
- Medical Photography
- Clinical Physics/Medical Physics

Protocol Considerations

- Do you have previous experience with the site/PI?
- Does the PI have experience in the therapeutic area?
- Is the PI qualified/experienced to make the safety reporting assessments? (SAEs/SUSARs) for the relatedness of the IMP/NIMPs?
- Are the procedures consistent with the site's standards of care?
- Is study drug dosing complex (e.g. dose escalation)?
    - Are follow-up visits reasonable and are the visit windows feasible at this site?
- Randomisation consideration for the site
- Unblinding considerations for the site
- Where will patients be seen (different departments)?
- Will patients need to be sedated at any point (e.g. colonoscopies)?
- Radiology procedures (How many scans required & frequency & the number of patients. If a lot of patients or several scans required within a very narrow timeline, please flag this as an issue to the site to discuss with Radiation/imaging department at site as soon as possible)
- What are the interventions outside routine clinical care?
- Will any equipment be required for the purposes of the trial?

Staff Requirements

- Dissect the protocol and use the event schematic to evaluate all tasks involved.
- Is it feasible in light of current work load?
- Do you have qualified and 'dedicated' research staff?
- Do you have training needs?
- Review CRFs and patient questionnaires (frequently not available at feasibility stage to review). Will the participant or staff complete the questionnaires?
- Does the PI have adequate time and scheduling availability to devote to the supervision of the trial?
- Will it involve out of hours work for enrolment?
- Are their adequate sub-investigators?
- Consider ancillary or speciality staff needs

- Is there a back-up co-investigator?
- Nurse/doctor approaching patient?
- Who will be taking consent?
- If a research nurse, check they are involved in the patient's clinical care - if they are not, they cannot search patient database/notes until consent is signed by the patient
- How many studies are currently being run by the department?
- Are there any competing studies at the site?

Facility Considerations

- Is adequate clinic and office space available?
- Is any special equipment required?
- Is access to emergency equipment necessary?
- Do you have enough storage?
- Do you have archiving facility/off-site?

Supplies

- What will the sponsor supply?
- Does the site have access to all equipment needed for the protocol?
- Will the site be supplied with a device? Is it CE Marked?
- Is the device routinely used?
- Is the sponsor Loaning or gifting the device to the site? Or is it already used/delivered into the site?
- Is the device supplier registered on the DoH Master Indemnity Agreement Registry?
- http://nhsmia.bipsolutions.com/index.php
- Will electronic or remote data capture be used?
- Central lab kits, shipping, invoices
- Supplies to pharmacy for CTIMP preparation

Site facilities

- Does the department have adequate staff to conduct the study?
- Do the PI and other staff have adequate time to conduct the study?
- Does the site have Internet access/e-CRF experience?
- Does the site have the equipment available as required by the protocol and a record of equipment calibrations?
- What archiving facilities are in place?
- If other support departments are required for example? Pharmacy
- Do they have adequate storage for the study drugs?
- What staffing do they have?
- What training have they undertaken i.e. GCP

The JRMO would like to acknowledge The Institute of Clinical Research who leaflet ‘Undertaking a Feasibility Assessment for a Clinical Trial’ has been used as a basis for this guidance.