York Foundation Trust R&D Unit
Guidance Document
R&D/G03

Site Selection and Feasibility Assessment for Trust Sponsored Studies

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This Template will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	15th July 2019	

Contents

1. Introduction

This guidance document defines the process to be used when identifying possible sites to undertake research sponsored by York Teaching Hospitals NHS Foundation Trust (YTH). It is essential that a feasibility assessment is undertaken for each proposed site to ensure they are able to conduct the research in accordance with the requirements of the protocol. Each site must have the capacity and capability to conduct the research safely and efficiently and must be able to deliver the agreed recruitment target within the specified deadlines. The responsibility for meeting recruitment and retention commitments and the accuracy of study data falls to the site, however it is the Sponsor's responsibility to ensure that, to the best of their knowledge only sites that will meet the protocol requirements are selected.

2. Scope

This document applies to all multi-site research sponsored by YTH. Completion of the site assessment is not required if YTH is a standalone, single site, nor is it required if Patient Identification Centres (PIC) centres are to be included.

3. Definition and Site Selection

Site selection is crucial for study quality and completion of a trial within budget, to time and target, and to ensure the generation of high quality data. The ability to identify, engage, and effectively work with experienced and competent sites is a key contributing factor to clinical trial success. Site qualities such as team dynamics, administrative requirements, procedures, resource availability, and experience ultimately impact both study timelines and data quality and integrity.

Site selection also has the potential to dramatically impact product timelines and study finances. Sites unable to recruit to target increase the length of the enrolment period and become an economic burden. The time and cost of training, opening and maintaining a site can be considerable and underperforming sites aren't viable. Unmet targets and unrealistic choices and expectations can be costly for both Sponsor and site, as a result of resourcing site set-up only to find that sites lack capacity and/or potential recruits. In addition, sites with insufficient experience are more likely to incur protocol violations or to have low-quality data that will require further training, on-site visits and more queries for clarification, all of which have an impact on costs and study duration. Choosing appropriate sites able to recruit an adequate number of patients while maintaining high-quality data is crucial for timely and successful completion of studies.

A feasibility assessment is designed to determine whether a proposed site is able to deliver a study protocol with or without any amendment to sponsor and study organizational processes. Feasibility is a process of thorough assessment, including risk assessment and contingency planning. Challenges

or potential issues can thus be identified as early as possible to ensure sites are able to deliver. This process informs site selection - identifying where an individual site's issues are surmountable, and where they are not. This enables precious resources to be targeted most appropriately and efficiently to enable those sites selected to deliver effectively.

Undertaking a complete feasibility assessment increases the likelihood of timely approvals, helps to limit delays, and should serve to ensure the smooth transition from Sponsor approval and opening to recruitment, through study delivery, to closure.

A comprehensive feasibility assessment should consider the following:

- Past research experience and qualifications of the investigator, the research team and supporting departments
- Interest in the research question
- A proven track record of successful participation in studies including the ability to collect high quality data
- Recruitment and retention history and strategy
- Preparation of “reserve” sites should be considered, so the study can be extended if recruitment issues arise
- Availability of a suitable patient population in the area of the disease or condition to be studied
- Identification of any possible barriers to recruitment and anticipated rate of recruitment. The Investigator should be able to demonstrate potential for recruiting the required number of suitable subjects within the agreed recruitment period.
- Assessment of site facilities (is existing equipment available and accessible? is any protocol-specific or specialized diagnostic or therapeutic equipment required? is there space to store, file, and archive study equipment? are clinical and research areas available and suitable? are all required facilities and equipment held at one site or over several sites? are patients seen at multiple sites?)
- Geographic location of site (as regards travel time and expense in setting-up, monitoring, and closing-out sites).Availability of resources (staffing, support departments including but not exclusive to pharmacy, labs and radiology, sample processing and storage, access to and type of equipment, ability to perform the required clinical assessments)
- Identification of an appropriate qualified and delegated “back-up” co-investigator in the absence of the PI so as not to affect recruitment rates, query frequency and the accuracy of study data
- R&D processes – approvals, contractual arrangements, finance arrangements and budget requirements
- Current studies - amount of studies open and in set up, any conflicting or competing studies recruiting from the same patient population and potentially introducing recruitment bias (be realistic and conservative in agreeing numbers)

- Consideration of the current standard of care for the condition to be studied
- Required training - does the site have experience of running this "type" of study? (study specific training will be delivered at site initiation)
- Adequate time remaining to conduct, oversee and complete the study according to protocol within the agreed time period

4. Process for all multi-centre studies

Investigators from sites wishing to undertake research sponsored by YTH must contact the study Trial Manager (TM) or designated individual delegated by the Chief Investigator (CI) at the earliest opportunity to discuss the process for site selection. Alternatively the CI, in conjunction with the Sponsor Representative (SR) and the TM may approach potential sites about study participation, as they may already have specific sites in mind due to successful previous working relationships and clinical knowledge. Sites may also be identified by recommendations from colleagues, via publications, professional groups or research networks. The CI has ultimate responsibility for selecting appropriate sites for a particular study although this task may be delegated to a member of the study team.

The application and Risk Assessment process includes a requirement that each site completes a Site Feasibility Assessment (SFA) in order to establish their site's suitability. SFAs will be reviewed and discussed with the Sponsor team as part of the selection process. A site without a completed SFA will not be considered for selection unless that site and facilities are already known to the CI or Sponsor. The reason and decision for not performing an SFA must be documented in the TMF. In most cases the SFA will be required.

The SFA allows sites to make a thorough and current assessment about their feasibility and enables the Trust to make an informed assessment about suitability. The outcome of the SFA will be as follows:

- Feasible – no action required
- Potentially feasible – some issues to be resolved prior to selection
- Not feasible at this time

The TM or delegated other will manage the SFA process, collating all responses from sites and liaising with the SR with regard to assessment. The SFA must include details of all support services within sites, the R&D Unit, and any additional contacts such as contracting and the clinical team. The individual completing the SFA need not be the proposed Principal Investigator (PI) but must be an individual with the appropriate organizational knowledge.

Not all sections of the SFA will be relevant to every study. In these cases it will be made clear that the protocol does not require those sections to be

completed. The sections in question will be marked as “not applicable” by the Sponsor team prior to forwarding to the individual site.

When completed the SFA must be sent to the SR or delegated other for review. The assessment will be discussed with the CI and a decision made as to whether to include the site in the study. The decision will be communicated by email from the SR to the proposed PI, and copied to the CI and site R&D Unit. If suitable to host the study, site participation is confirmed and set-up can commence. If unsuitable, the Sponsor team will explain their decision to the site.

A copy of the submitted SFA and any correspondence must be retained in the Trial Master File (TMF). A list of proposed participating sites including the PI's name and qualifications must be included in the IRAS submission to HRA/REC and MHRA as required.

The Sponsor team will then liaise with the selected site to arrange local set up and obtain local approvals. This will include agreeing contracts, providing the Local Information Pack and Investigator Site file and agreeing a mutually convenient date for the site initiation visit. Site initiation will vary depending on the type and complexity of the study and may be conducted by a site visit, by a teleconference, or by e-learning (detailed instructions or slides to the site). Site initiation must be completed prior to the site opening to recruitment and before any study related procedures are carried out.

5. Supporting documents or further reading

R&D/GT01 – Site selection feasibility checklist (Trust Sponsored Studies)

R&D/S09 – Set Up and Management of Research Studies

For all YTH Trust SOPs follow the link below:

https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/

For HRA site set up guidance:
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/nhs-site-set-up-in-england/