Commercial Studies – Feasibility, Site Selection and Communications

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Feasibility

- The Trust is approached by commercial companies seeking expressions of interest to participate in their studies via a number of different routes. PIs can be approached directly by a company or CRO (Contract Research Organisation, such as IQVIA or Parexel), via colleagues, via R&D requests that have come to the generic R&D email address, contact can be made via the Industry Team in the JRO, or we can receive a request for expressions of interest via the Clinical Research Network (CRN).
- Information provided at this stage can range from basic, blinded study details, to a full protocol.
- In order to release full study details, companies will often request that a CDA (Confidential Disclosure Agreement) be signed. For commercial studies, these should be forwarded to nuth.trustindustry@nhs.net for review and signature. CDAs should not be signed by the PI or by members of the study team.
- Feasibility/Expression of Interest (EOI) requests can be in the form of online questionnaires or word/pdf forms with varying levels of detail requested, including information on clinical experience and patient populations, as well as team capacity and available infrastructure. Members of the clinical team should provide information pertaining to the condition/patient population/study recruitment, and support with completing additional detail is available from the Industry Team at nuth.trustindustry@nhs.net if required.
- Study feasibility requests that come from the CRN are categorised in one of two ways. Site Identification is where a company has requested assistance from the CRN in identifying potentially interested sites. Site Intelligence requests are where the company knows which sites they want to work with, and have requested verification of site interest from the LCRN to support portfolio adoption.
- If participation in a study is declined, it is good practice to respond and provide reasons (e.g. competing study, lack of patient population etc.). Please always copy in nuth.trustindustry@nhs.net to responses either expressing interest in a study, or declining participation.
- Even if interest has been expressed in a study via the CRN, sponsors/CROs usually require their own, more in depth, feasibility form to be completed.

- Expressing interest does not commit us to participation in a study at this stage, however information should be provided in good faith and as accurately as possible.
- Support with any aspect of commercial study feasibility can be sought from nuth.trustindustry@nhs.net
- Sometimes, we do not hear from commercial sponsors/CROs following expression of interest in a study. This can be because we haven't been selected by sponsor to progress with discussion, or the study is delayed/has been withdrawn, or the UK as a whole has not been selected to participate (if it's a global study). The Industry team are happy to follow up on specific EOIs on behalf of study teams if requested.

Site Selection

- Following expression of interest, sponsors/CROs will carry out the process of site selection. This will usually involve a visit by the sponsor/CRO representative to site to discuss the protocol in more detail, assess the site infrastructure and suitability, and learn about our R&D processes.
- Site Selection Visits (often known as Pre Site Visits, or Site Qualification Visits) should be attended by the PI, the Research Team Lead or lead study nurse, and the study coordinator. For CTIMPs (Clinical Trials of Investigational Medicinal Products), they should also involve a visit to, or discussion with, a member of the Clinical Trials Pharmacy team at the relevant site.
- The Industry Team are keen to support Site Selection Visits - please invite them to any commercial site selection visits you become aware of.
- Site Selection Visits are an opportunity to assess the protocol, study timelines, etc., in greater detail, as well as ask any questions that may impact on delivery, and as such, these visits should be a two way discussion.
- Following the visit, the sponsor/CRO should contact the site to confirm selection or otherwise.
- Upon selection, it is important that if internal discussions regarding the study logistics or unforeseen circumstances have resulted in a decision not to pursue the study, or that the sponsor timelines cannot be met, or that commencement of set up will be delayed, this is clearly communicated to sponsor or CRO, and copied to the Industry Team. Please note, however, that Site Selection Visits should not be booked unless the team has capacity to deliver the study.
- If we have decided to participate in the study, following selection, the coordinator setting up the study should introduce themselves by to the sponsor/CRO contact at this stage, along with a request for the documentation required to commence local set up.
- An introduction to the pharmacy contact should be made at this stage.
- It is good practice to send sponsor/CRO our NuTH Guidance for Industry document(found here) A suggested template email to sponsors/CROs to commence study set up is included here

Communications Guide

The following points are general principles and good practice around communications with sponsors and CROs for commercial studies.

- Please avoid sending emails with internal trails of discussion to external companies – please ensure that all communication is appropriate to be sent externally before sending.
- Please ensure that communications to sponsor are clear, polite, and that any actions required are highlighted.
- Please communicate timeframes and next steps effectively. It is appropriate to let sponsors know proposed dates of returning costs once reviewed, for instance, as well as proposed dates for submission to R&D.
- Please be up front with sponsor about any potential delays so as to manage their expectations effectively. Sponsors prefer to know the reality of situations/delays in order to manage set-up.
- Please avoid stating that costs are fully agreed prior to review by R&D finance – please instead state that they are provisionally agreed by the team, request that sponsor inserts them into the contract, and state that this is subject to sign off by R&D finance as part of the overall R&D review.
- It is very important that the costs that the team have agreed with sponsor in the costing template are transcribed exactly into the financial appendix of the contract by sponsor. It should be conveyed to sponsor that any discrepancies between the figures in the costing template and the figures in the contract will delay R&D finance sign off.
- Whilst the timelines for R&D review are nominally 12 calendar days, please don't state that R&D have 12 days in which to "approve" a study; it should be made clear that the 12 calendar days are for the Expert Panel to revert with any queries or concerns, having reviewed the study, and that anything raised within this time requires resolution prior to contract signature and confirmation of capacity and capability.
- Please check, prior to booking dates for SIV (Site Initiation Visit), whether sponsor requires fully or partially executed contracts in order to run the SIV. Some sponsors are happy to run SIVs as "training visits" and initiate the site once contracts are in place. Others require signed contracts prior to SIV. If issues are picked up as part of the R&D review that delay contract signature this may impact upon the ability to run the SIV as planned. Formal site initiation should not take place until everything is in place in order to begin recruitment.
- Please escalate issues where appropriate. If in doubt, the Industry team are happy to assist where able/required.
- If you've not heard back from someone following a request for information, or costs, please follow up within a reasonable timeframe rather than waiting for a response.

- Please be mindful of R&D submission and expected contract signature dates when planning study recruitment targets and dates. Delays in confirmation of capacity and capability may impact upon timeframes in which patients can be recruited.