



## Clinical Research

### Clinical trial feasibility

# Analysis and evaluation

A delay in study startup and patient enrollment are major problems for cost overruns in clinical trials. A well-designed and executed feasibility study would help in ways more than one.



#### Details provided through a feasibility study

Clinical trial feasibility study should be designed and planned after thoroughly reviewing and understanding the planned trial protocol. A robust feasibility study should check the overall acceptability of the study from the scientific, regulatory and ethical perspectives. It should also note the investigator's interest in the trial, available standard of care and compatibility of the clinical trial treatments and assessments with currently available patterns of care.

It should also assess the availability of target patient population, patient database and recruitment capability of the site. Accessibility to specific equipments/tests/facilities that may be required for the given study, experienced study team and ethics committee are some other important aspects that should be evaluated in a feasibility study. Last but not the least, feasibility study should also check the competing trial scenario in the given geography and at the considered sites.

#### Different types of feasibilities

Various types of feasibilities include:

**Study feasibility:** In this study, it is assessed whether a given study can be conducted in a given geography. All factors that influence the do-ability of a trial such as regulatory challenges, ethicality of the study design, availability of patient population and required expertise are evaluated in detail. The operational challenges are also taken into consideration while evaluating the study feasibility.

**Site or investigator level feasibility:** This assesses the suitability of a given site to participate in the proposed study.

The cost of a clinical trial is influenced by several factors including startup and recruitment timelines. Appropriate selection of countries and investigational sites is the key to conducting a successful trial.

Literally, feasibility survey means a process of evaluating scientific as well as operational do-ability of a clinical study in the given geography.

Feasibility study helps in the identification of appropriate countries and investigational sites for a new clinical trial. It also provides an estimate for the per site recruitment rate and the overall enrollment period to complete the recruitment. Additionally, it aids in identifying the challenges one may face during the execution of a study and in planning strategies for risk management. All these would eventually facilitate project completion in terms of optimum timelines, patient recruitment targets and cost.

It is a general observation that companies that undertake robust feasibility survey process experience 'on target' completion and lesser delays than those who do not undertake such a thorough feasibility assessment.



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All factors at site level are taken into consideration in this feasibility assessment, such as qualification and experience of the investigator, presence of experienced study staff, availability of good infrastructure, availability of target patient pool, suitable ethics committee profile etc. It is also important to assess the attitude of the investigator during the discussion. In case there is any poor or bad experience with the given investigator, it would play a vital role in decision making for the final site selection.

### Stake holders for feasibility at the CRO end

Some Clinical Research Organisations (CROs) have dedicated team for conducting clinical trial feasibilities, while it may be the responsibility of clinical operations team in some others. Irrespective of which department handles feasibilities, it is important that the concerned teams collaborate and work close to deliver on a feasibility request. Operations team would be able to gather the operational challenges. Medical services team would be able to check if the proposed study is rational, scientifically as well as ethically. Regulatory team is responsible for identifying the regulatory challenges. Involvement of all these teams will go a long way in running a successful feasibility.

Apart from this, understanding expectations from client and regular communication with the client are also necessary.

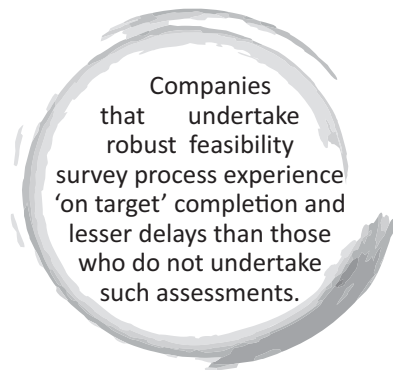
### Available tools

A well-designed feasibility questionnaire is a standard tool for undertaking clinical trial feasibility. Feasibility questionnaire should provide sufficient information about the target population to get realistic data about the site capabilities. At least the following information should be provided: eligibility criteria, study design, treatment provided to the subjects, schedule of assessment and any other specific details (eg need for hospitalisation, need for repeated blood sampling etc).

### Site selection for feasibility

Selection of investigators for obtaining inputs is a vital step to a good feasibility.

Optimum number of sites/investigators should be contacted to obtain realistic information for the planned clinical trial. For study feasibility, 3-4 good experienced investigators, with good performance in the past trials, may suffice. For site feasibility, the number of sites to be approached for feasibility would depend on the planned study (disease under consideration, client's plan regarding country selection, sample size required etc).



### Deriving the realistic recruitment estimates

As much data should be collected as possible before giving the final projections for the proposed clinical trial. The data should be compiled and analysed site wise and also across the sites. Sites that seem suitable for the planned study should be short listed; the final projection for the study should be based on the inputs received from these short listed sites rather than all the sites that responded.

It is important to keep in mind the client's expectation in terms of the number of patients for the given study and the planned country spread. It is said that the investigators are sometimes very optimistic while proposing recruitment numbers; it is the responsibility of the CRO to apply adequate filters and propose realistic estimates. Certain features of a study

can cause additional road blocks (eg repeated blood sampling, frequent visit schedule etc), which may have a significant impact on the study. The projection is complete only when we include the screen failure and dropout rate obtained in consultation with the investigators.

Further, for chronic diseases (eg: rheumatoid arthritis) the patients flow in largely from the database; hence, simple mathematical extrapolation is not advisable in such cases. Eg, if a site quotes 2 patients per site per month – it may not be correct to assume 12 patients over 6 months of recruitment period. It is desirable to ask the sites the total number of patients that the site can recruit over 6 months. More often than not, the site proposes lesser number of patients (say 8-10 patients) over 6 months.

Numbers are stated only as an example.

### Protection of confidentiality

Minimum information, which is mandatory to obtain enough facts about the site capabilities, should be shared with the site. Maintaining the confidentiality of the client's proprietary information is very critical. Clients' confidential information should not be shared with investigators without a valid Non-Disclosure Agreement (NDA). NDA may be a general NDA between the operating CRO or it may be a study-specific NDA. It is also important that the NDA used by the CRO is reviewed by the client and is acceptable to them. Some clients feel more comfortable to use their own NDA template. This process of signing an NDA with the sites needs to be customized per feasibility in consultation with the client.

### Why do the homework?

Good and effective feasibility is the backbone of any clinical study. In clinical research, the recruitment of the right patient population within the planned timelines is the most important factor in ensuring success. **MPH**

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