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Review Article

Site selection criteria and process in clinical trial

Ruby Bhullar Garcha[1], Anjana Bhatia[2]

1. James Lind Institute, Hyderabad, India

2. Head of Deptt. Of Botany, HMV Jalandhar, India

Corresponding author: Dr. Anjana Bhatia, HMV Jalandhar,Punjab. India

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ABSTRACT

Site selection is crucial to create high quality data, for recruitment, retention, overall trial and timely completion. In order, to prevent excessive expenditure right study site, trained investigators and site coordination team are key factors in determining timely completion of study. The study site comes across few criteria and following those increases the value of sponsor's time and money, helps to qualify and participate in the study though their relative importance may vary according to the type/phase of the trial, the trial objective(s), available funds/resources and so forth. Site qualities that impact study timeline, data quality and integrity are team dynamics, administrative requirements, procedures, resource availability and experience as key factors of clinical trial success. Site selection process is a noble time to ask questions about the study, delivery of the investigational product, the inclusion and exclusion criteria, the timelines and ones desire for engagement to maintain commitment to clinical excellence. External factors cannot be ignored such as regulatory climate and competitive landscape that effect study outcome and vastly affect a site's ability to deliver over the course of a trial.

Keywords: Site selection, Clinical trial, study site

INTRODUCTION

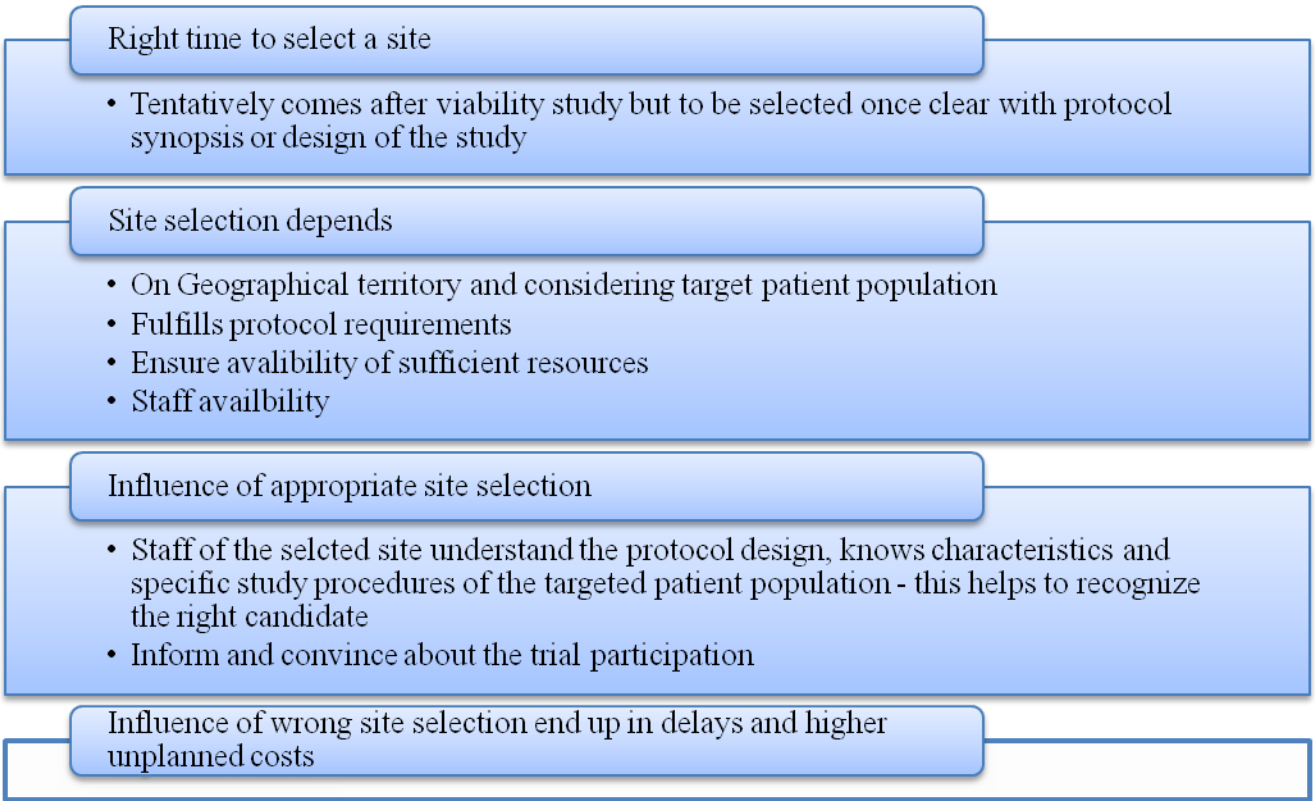
Success of the clinical research is significantly reliant on the effective site selection. Site refers to the hospital, laboratory or health care setting where the research will be conducted. A proactive planning and identification of the appropriate site selection criteria can be helpful in ensuring success of the clinical trial [1]. There are various factors that influence the site planning. Recognizing those elements will contribute in discussion of the site selection criteria and procedure for clinical research. The successful site performance can be equated with the potential for delivering qualified subjects along with evaluation of data which have a significant impact on the research outcomes [2]. This paper will focus on analyzing the appropriate site selection criteria along with its procedure.

SITE SELECTION:

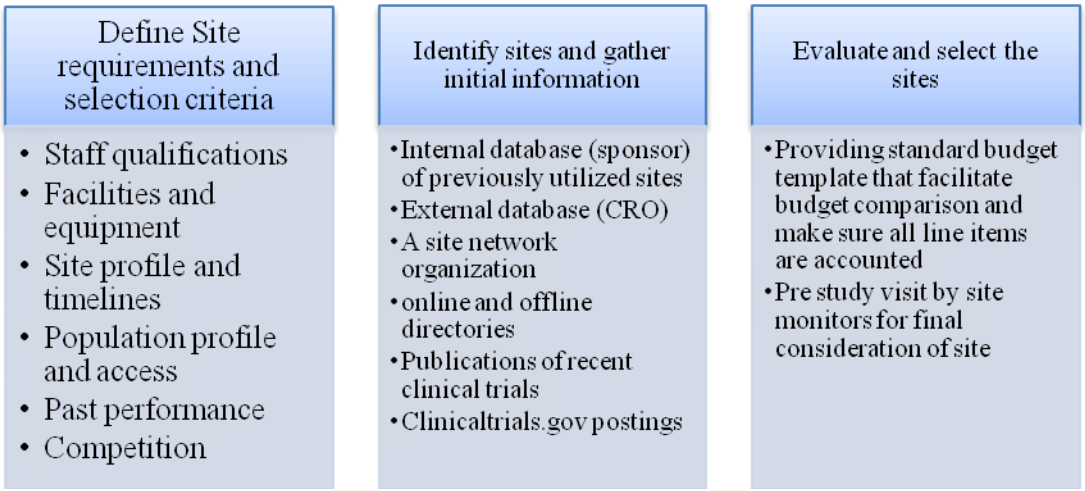
First of all, it must be noted that there is no ideal site for the clinical research. The researcher needs to outline the required qualities for that specific research. It is important to match the requirements or need of that particular clinical study with the characteristics of the study. One of the most important factors is the experience and qualification of the researcher along with the research staffs for selection of a site. Technical experts must be appointed for in identifying the technical requirements and facilities. Therefore, the researcher must focus on the site experience i.e. the area of clinical research and the therapeutic area [2]. Another important factor that needs to be analyzed is the staffing, workload, resources along with the time commitment of that particular site. The next important thing which needs to be taken into consideration is the interest and enthusiasm of the site for conducting the clinical research. It is essential to analyze the skills along with the potential of the personnel for this study.

Staff turnover rates must be considered as high staff turnover rate may lead to problem for the clinical study [3]. The functional responsibilities of the site personnel must be analyzed in before selecting the site. The patient population must be studied and need to be compared with the requirement of the clinical study [4]. One of the important selection criteria is the technical feasibility and availability of the required equipments. The researcher is responsible for ensuring that the site meets the subject diversity requirements. If the staffs of the site are found to be friendly and customer oriented, it will be favorable for the study. Subject friendly facilities are essential for conducting the clinical study. Financial constraints of a clinical trial or research must be considered at the time of site selection. Hence, the clinical study budget must be fair and reasonable [5]. The policies and procedures of the ethical review committee must be reviewed. Moreover, the legal procedures of that institution must be analyzed as it is essential to comply with those rules. Operational procedures along with training process at the site must be evaluated as it is one of the most important site selection criteria for clinical research. Audit and GCP compliance history must be reviewed by the site selection committee [6]. Another significant criterion is the flexibility of the clinic hours of that hospital. Moreover, the security system and storage facilities of the site need to be scrutinized to ensure appropriate system for the clinical research. These are the principle factors that need to be analyzed at the time of site selection of a clinical research. It is important to match the research requirements with the characteristics of the site on the basis of the discussed factors [7]. Therefore, the sites will be rated as per matching the research criteria and the site having higher level of competency in terms of the above stated factors, final decision will be taken [8].

Point to consider for right results from **right site selection** for the success of a clinical trial as [9]:



Steps for an Optimal Site selection [10]:



SITE SELECTION IN COVID-19:

The novel COVID-19 has explicitly and severely impacted the ability of the site to work that leads to new approach with virtual visits, using tele medicines all the way through protocol amendments [11].

Negative Impact on sites [11]:

- Delay in patient enrolment and recruitment
- Trial delays and cancellation

Recently a survey conducted on April 23,2020 Medidata reveals about 69% of respondents state COVID-19 has affected an ability to conduct ongoing trials whereas 78% believes it has impacted their ability to initiate new trials [11]. Thus, **top four concerns** expressed by them were [11]:

- Ability to enroll patients
- Ability to recruit patients
- Financial implications for cancelled studies
- Financial implications from delayed milestones

So, keeping in view all these sites have undertaken five activities as [11]:

- Halting new patient recruitment for an ongoing trial
- Switching patients to virtual/telemedicine
- Delaying a study
- Extending patient study visit windows
- Amending study protocols

In this pandemic, **sites** on the frontline suggest [11]:

- Examine the global impact of decisions
- Provide greater flexibility and understanding
- Adopt telemedicine
- Provide additional financial support
- Develop contingency plans

CONCLUSION:

Site selection is anall-inclusive process for study participation [12]. A standard site should aim for Patient, Protocol and Performance as focus areas that lead to success of a clinical trial [13].Though global pandemic has impacted sites and resources negatively but adopting new approach towards public health by new innovations like virtual and hybrid clinical trials, patient-centered protocol, platform trials and case studies have opened new doors for site-selection in COVID-era [14][15].

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