Building & Marketing Clinical Research Site

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My opinion

Building Clinical Research Site

For conducting Clinical Trials at hospital/Site proper facility should be there to meet study requirements, hence a Sponsor/CRO/SMO access the study site before selecting the site by conducting on-site qualifying visit whether facility meets study requirements. A dedicated research area within practice is ultimate; if this is not feasible at first, ensure that the space using is not only functional for research purposes, but would also meet the basic requirements for most clinical trials. For setting up the site the following things should be taken in to consideration

General environment:

Research site areas where subjects will be seen and research office activities will take place should be clean and well-organized. The waiting area for study subjects should be comfortable and well-lit.

Investigational Product (IP)/Drug room/Pharmacy:

where the IP will be stored should be secure only authorized person should have access. Most of the sponsors/CRO’s look for the Drug storage facility, secure of IP and temperature maintenance. Hence the IP room should be locked and have access to the authorized person. Some trials require Refrigerator, freezer and shelving to store products. Refrigerators should be clearly labeled for food, specimens, or study drug. Protocols will state the temperature range for investigational drug storage. Demonstrate your compliance with this requirement by providing daily documentation of the temperature of the area where drug is stored (e.g., the room, refrigerator, etc.) and also should consider back up plan for loss of electricity to maintain storage requirements

Exam room:

should comply with the local and state requirements if any Other Storage Areas: The site should have a dedicated space to house other study related materials like:-

1. Laboratory kits. If a central lab will be used for a study, all supplies necessary to obtain biological specimens will be provided to the site.
2. Medical records and subject case report form books (also called casebooks or CRFs). These are usually the standard 3-ring binder size but can be rather thick.
3. Filing cabinet(s) for storage of study-specific regulatory files or binders and other study-related documentation
4. Post-study storage of materials (If your space is limited, you will need to identify climate-controlled off-site storage space)

Work space for study coordinator and Monitor:

A dedicated office space is required for study coordinator to meet with enrolled subjects and to conduct the operational aspects of the study. Many studies will require frequent on-site visits by the sponsor’s or the CRO’s monitor. The ideal space for a monitor is in a quiet location where other studies confidentiality should not compromised, and will provide enough desk space to accommodate both an open medical record and an open case book. In addition, easy access to a telephone, copier and fax machine are beneficial.

Computer area with internet facility:

Few studies involve the electronic CRF and involve capturing subject data electronically. A site conducting several studies involving electronic data may have to accommodate several computers or laptops. Site computers with subject/patient data should be secure and password-protected.

Laboratory:

If site has its own laboratory, sponsors will require documentation of Accreditation and Lab manual with GLP certificate. Any entity that is preparing dangerous goods for shipping (e.g., infectious specimens, dry ice) must complete required training. The lab equipment should be maintained/calibrated according to manufacturer’s specifications.

Marketing Research site

For getting Clinical trials to the site should be well known to the Sponsors/CRO. Initially getting trials to
site will be a challenge, but consistently meeting enrollment goals, Quality work and data will build reputation in the industry. For getting trials to the site the following strategies should be applied.

1. Networking with the colleague’s investigators/Doctors who are already conducting clinical research should be done by requesting them to refer the site to Sponsor or CRO.
2. To market site develop the site profile explaining uniqueness of site, staff and specialties, physical facilities, storage facilities, dedicated research unit& staff. Also list any trial experience particularly explaining enrollment goals etc...
3. Many sponsors may request an updated and revised CV. Hence create Site staff CV’s in a standardized format with relevant information and keep ready.
4. Marketing materials should be developed for the distribution. A standard one page covering letter should be developed in a formal business tone with site contacts. A logo should be developed and used on the covering letter as well as business cards if it is not available. Site should be listed in the internet site listing services such as centerwatch or clinical investigators networks. Register your site in the sponsor or CRO websites.
5. Attend health fairs, seminars and setup display of site, provide handouts with disease education, areas of research which helps to attract volunteers/patients.
6. Apply other strategies like talking to sales representatives, making cold calls to sponsors/CROs, setting exhibits booths, advertising in industry publications, yellow pages and social networks like twitter face book, LinkedIn and YouTube.
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