How to get involved in Clinical Research

Investigator and Site Selection

Perspective from a sponsor
Disclosure

Speaker name:

LIEVE CORNELIS

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
Investigator and Site Selection

- Defining Investigator and Site Requirements
- Identifying Potential Investigators and Sites
- Collecting Investigator and Site Information
- Selecting/Approving Investigators and Sites
Defining Investigator and Site Requirements

Study Specific objective criteria are determined upfront. The minimum selection criteria include the following:

• Investigator is qualified and legally entitled to practice
• Investigator has expertise in the research or therapy area
• Site has adequate facilities for the conduct of clinical research
• Investigator/site is in good standing with regulatory authorities
• Investigator/site is trained and qualified to assist in the conduct of the research
• Investigator/site is trained and/or familiar with the study device and study procedures
Defining Investigator and Site Requirements

• Investigator/site is willing to attend therapeutic or investigational device training, in the case of novel therapy

• Investigator/site is familiar with the background and requirements of the clinical investigation methodology

• Investigator/site has access to a sufficient number of eligible subjects to meet enrollment expectations

• Investigator doesn’t have any conflicts of interest that appears, or could appear to affect the clinical study

• Investigator/site has access to equipment (e.g. imaging, specialized laboratory equipment) necessary to execute the clinical study per protocol
Defining Investigator and Site Requirements

Additional criteria can be used for selection:

- Past history of an investigator/site in previous studies (e.g. compliance to protocol, ability to achieve expected subject enrollment, accuracy and timeliness of data)
- Any concurrent study conducted by the investigator/site that may conflict with the proposed investigation
- Any issues preventing the site from being approved to enroll in a timely manner (e.g. contract and budget negotiations, lengthy approval timelines, responsiveness).
Identifying Potential Investigators and Sites

Nominations are received through different channels:

• Clinical Management (e.g. Project Managers, Regional Managers, monitors, Data Managers)
• Research and Development
• Health Economics and Reimbursement
• Medical Safety Directors / Chief Medical Officers
• Contract Research Organizations
Identifying Potential Investigators and Sites

Due to the risk of bias, input from Sales and Marketing may only be provided when:

• Nominations of potential clinical investigators and sites, meeting pre-specified objective criteria, are requested
• A potential clinical investigator expresses an unsolicited interest in conducting research
• A sales representative believes that a particular clinical investigator would conduct high quality research
• A specific request is made regarding the suitability of a proposed investigator or site.
Collecting Investigator and Site Information

All necessary information is gathered via different ways:

• Compiling historical data from previous studies
• Evaluating completed Site Selection Questionnaires
• Reviewing on-site Qualification Visit Reports

An on-site qualification visit is considered when:

• The site or the Principal Investigator (PI) has never participated in a Clinical Study from the Sponsor OR
• The site has participated and the PI has not OR
• The PI has participated but the site has not
Selecting/Approving Investigators and Sites

Based on all of the information obtained, a selection committee will decide whether to accept or decline a site and/or investigator.

When selecting the Coordinating Principal Investigator, consideration shall be given to:

• Good standing within the medical community and with Regulatory Authorities
• Expertise in the field (therapeutic area, device...) to be studied
• Leadership, podium presence, presentation skills
• Publication history
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