Clinical Trial Site Engagement and Commitment Through Direct Physician Interaction with Investigators

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Background:
The development of more effective oncology therapy is critically dependent on the timely completion of clinical trials. Unfortunately, up to 40% of trials exceed projected timelines, potentially delaying the availability of improved treatment options to pts. Finding the right sites is one of the most crucial steps in the timely completion of a clinical study. The site must be capable of conducting the study with access to the eligible patient population, a thorough understanding and belief in the study rationale, as well as commitment to the study by keeping it ‘top-of-mind’. Engagement of sites with high accrual potential is a key priority for sponsors; however, many of these priority sites may decline to participate or underperform in accrual. Commonly used methods to engage sites include mass communications, such as email and fax, targeting site coordinators and research staff. As clinical investigators (PI) have a significant impact on the site’s decision to participate in a trial, we evaluated a model that focuses on engagement and commitment of these sites through a physician-to-physician approach.

Methods:
Site recruitment was initially attempted by the sponsor through mass communications, which resulted in a low rate of responsiveness and interest. High-potential sites that had declined the sponsor representatives were then prioritized for physician outreach by a DAVA Medical Oncologist. During the MD to MD interaction, we analyzed the site’s capability of conducting the clinical study by discussing the practice pattern as well as the resources available to the site. Phone calls and personal visits were made to sites to discuss study and scientific rationale along with key eligibility criteria to elicit interest and site enrollment feasibility from the investigator. Once a site expressed interest in the study and our medical oncologists felt comfortable about the site’s capabilities and resources to conduct the study, we worked with the sites in completing the study-specific confidentiality agreement (CDA) and feasibility questionnaires. Sites were recommended to the sponsor after rigorous evaluation of accrual capabilities and investigator commitment.

Identification
- DAVA uses a proprietary database to generate a comprehensive list of potential sites
- Selections are based upon study criteria, our experience with the sites and DAVA MD relationships

Results:
Each PI was contacted 8 times on average. Personal calls and visits accounted for 37% of the physician communications and were the most effective means of enlisting PI support for the trial. A total of 47 sites were recommended to the sponsor; 22/47 (47%) sites were originally unresponsive and 22/47 (47%) sites had previously declined. Consequently, the number of participating sites for this study increased from 36 to 68, an 89% increase.

Analysis
- DAVA MDs analyze sites and evaluate their qualifications, capabilities and potential enrollment through site specific questions
- DAVA MD contacts site MDs to discuss study rationale and any potential hurdles to the protocol

Site Selection is a critical step in the timely completion of a clinical study.

DAVA Site Recommendation

Previously unresponsive to sponsor
Previously declined sponsor
Were not contacted by the sponsor

Commitment
- DAVA MDs obtain site interest
- Once interest is expressed, Clinical Trial Specialists contact sites to complete site documents to determine qualification and gain commitment
- DAVA discusses recommended sites with the sponsor

Conclusion:
Utilizing a direct physician-to-physician approach to engage potential investigators is effective in generating interest and commitment at the site level. This model reflects a finding by Coomis et al (J Onc Prac. 2009; 5: p50) that 73% of overall clinical trial awareness was generated by physicians’ interest in the scientific rationale of the study.

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