

RESEARCHERS' CORNER

Clinical Study Start-Ups—Best Practices

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The increase over the last decade in the cost of running clinical trials is well documented. Phase III clinical trial costs account for 90% of the cost of drug development.¹ Several issues have contributed to this increase and the disproportionate costs of late-stage clinical trials in the drug development process. One of these issues is the duration of clinical trials. A Tufts University study showed that the average length of a clinical trial increased by 70% between 1999 and 2005.²

While the reasons for this are many and varied, delays in study start-ups are a significant contributor. A 2011 industry study showed that clinical trial delays were primarily due to contract and budget negotiations. Other frequent factors leading to delays were patient recruitment, protocol amendments, legal review, and review of consent forms.³

Both parties—the study sponsor as well as the investigator—can play a role in streamlining the start-up and therefore expediting the process. This article addresses how study investigators can prepare for the start-up of a study so it runs on time.

There are benefits to both physician and patient participation in clinical trials. Physicians gain greater awareness of new therapies and are able to provide them to their patients. Their practice becomes attractive to patients who are seeking the latest treatments. Additionally, investigators have opportunities to meet, collaborate, and network with leaders in the field.

The relationship between an investigator and a sponsor is important not only to ensure good science but also to prevent miscommunications and conflicts. We recommend several strategies to strengthen the sponsor-investigator relationship.

Dedicate an employee to staff the study. Larger multi-specialty medical groups and hospitals may have specially trained study coordinators. Working under the direction of the investigator, these specialized staff act as a single point of contact among the principals—the sponsor, the institutional review board (IRB), and the department, among others. Even if you do not have the resources to hire or retain a clinical research coordinator or research nurse, it is important to identify one employee as the point person to facilitate the administrative tasks critical to starting and running clinical trials. A coordinator can help the physician to prepare the regulatory documents for the IRB review, prepare a budget, maintain documentation and study-specific forms, and track source documents.

Another benefit to having a dedicated employee working on clinical trials is in responding to sponsors' monitoring visits and inspections by regulatory agencies. At least one person should be intimately familiar with all the study documentation and materials.

If you expect to participate in several clinical trials, it may be beneficial to invest in special training and education for your staff member. Training courses can familiarize your employee with fundamentals of clinical research, federal guidelines, ethics, and clinical trial budgeting.

Understand the process. In addition to an IRB review, the protocol may also need to undergo additional reviews by other committees. For example, some institutions have specialty-specific committees in oncology or surgery. While the IRB's focus is on protecting the rights and ensuring the welfare of research

subjects, other committees may consider additional issues such as the feasibility of the study or biohazard material safety. Additionally, there may be a conflict of interest committee to ensure possible or perceived conflicts are appropriately addressed and managed.

Create a template workflow approach. If you plan to participate in more than one clinical trial, you should consider developing a checklist of policies and procedures as well as expected timelines. You can then re-purpose this template across all your trials to ensure consistency and to avoid skipping any steps. Workflow can be managed through simple paper-based checklists or project management software. There are also Clinical Trials Management Systems (CTMS) specifically designed to track clinical trials.

Whichever system you choose, it should be detailed enough to allow for tracking of activities, timelines, and assignment of tasks.

Understand the timelines. Your workflow should include all the dates and deadlines for meetings. According to the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the mean time from submission of a research protocol to approval is 45.2 days.⁴

Consult with your colleagues. Before agreeing to participate in a trial, you may want to discuss it with others in your department. Your department chair may have questions, or there may be concerns about whether you have a large enough patient population to meet recruitment goals.

Develop a patient-participant recruitment plan. The holy grail of
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successful clinical trials is the recruitment and retention of participants. Clinical trial enrollment rates are dropping, and up to 20% of research sites never enroll a single patient.⁵

Be prepared to engage your colleagues to discuss clinical trial opportunities with their patients, and leverage other marketing and outreach activities in your community. These may include community lectures, traditional advertising, flyers, letters to colleagues in the commu-

nity, and listing trials on your website. Be aware that some of these activities require IRB review as well as sponsor approval.

Being awarded a study is just the beginning of the process. Having a clearly defined process for starting the study will improve relationships with the sponsors, making your site more likely to be included in future studies.

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