Advising and Trial Guidance for Investigators

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Background

When investigators in departments outside the Clinical Trials Office (CTO) want to conduct institutional trials on a cancer patient population with a multicenter component, it is the responsibility of the CTO Multicenter team to provide guidance and ensure institutional policies and federal regulations are being followed. Since these investigators do not routinely conduct these types of trials and lack the appropriate infrastructure, they can be inexperienced or unfamiliar with specific requirements of multicenter, investigator-initiated trials. They may also be unaware of the resources available to them.

Goals

- Provide support and guidance to investigators outside the CTO that conduct multicenter trials
- Direct investigators to the resources available to them
- Ensure all trials are conducted in accordance with local institutional policies and federal regulations.

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Solution

Starting at protocol development, investigators are introduced to CTO Multicenter Clinical Research Coordinators (MCRC) for education and guidance. Over the course of several meetings, the MCRCs discuss multiple topics essential to multicenter trials such as:

- Multicenter template language for the protocol
- Contract requirements
- Use of IRBs
- Data collection and entry requirements
- Required regulatory document collection from sites
- Monitoring and auditing of the trial
- Sponsor-Investigator oversight
- Site training

Outcome

Prior to the current practice listed above, MCRCs would conducted ongoing monitoring on trials to provide appropriate oversight. However, the MCRC would not monitor these trials until after they were already opened and had subjects accrued. During this early process, the cancer center did not have sufficient staffing available to provide additional guidance and audited, usually for cause only. As the need arose, the cancer center approved additional staffing to provide support earlier in the startup process. MCRCs now meet with investigators and their study teams early in the trial startup to guide them on the many important factors involved in multicenter trials. It was determined that earlier intervention was beneficial to minimize audit findings. These trials have an elevated risk level due to the involvement of outside participating sites. At any given time, MCRCs are assisting 4-8 investigators from other departments with starting their multicenter trials. This proactive approach with the guidance and ongoing teaching/training of the MCRCs, have reduced the number of deviations and the monitoring and audit findings on multicenter trials from outside departments. The ability to utilize the MCRCs as a resource has aided in building trust, rapport, and relationships with outside departments.

Lessons Learned

This newer process has only been in effect for a short time. It is still too early to know the full benefit of early guidance for investigators and their staff. The cancer center and MCRCs have encountered some resistance by investigators and staff in outside departments, however, we have found that early introduction to the process has proven to be more successful than waiting until after a trial is open to accrual. Often, investigators and their staff are hesitant to reach out with their questions but when encouraged by MCRCs, the trial staff is more willing to ask questions and reach out in the future with additional concerns.