Collaboration: How Protocol Development and Multi-Center Teams Work to Manage Investigator-Initiated Trials(IITs)

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Background

Protocol Development (PD) services began in 2005 with a Multicenter (MC) team added to the Cancer Center in 2015. Both teams focus on Indiana University Investigator-Initiated Trials (IU IITs), with PD assisting the investigators in developing/writing protocols and the MC team acting as a Contract Research Organization (CRO) for trials wanting to open Statewide, Nationally, and Internationally. As the MC team has grown, cooperation and integration with the PD team has grown with it. In recent years, the need for PD and MC to work in tandem has led to a better overall experience for our investigators and more opportunities for our investigators to open trials as MC allowing them to include other institutions and geographical locations.

Goals

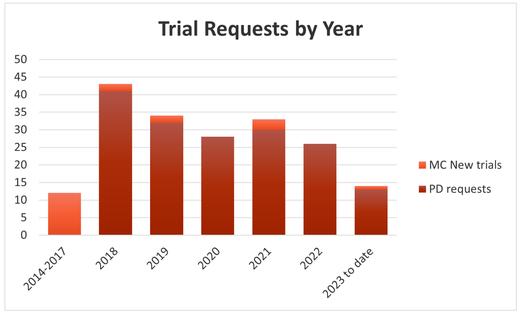
- Continue to expand research. Allow investigators the opportunity to include additional sites has made meeting accrual expectations that much more accessible.
- Additional Integration of study start up that processes with PD and MC teams to streamline and shorten start-up times.
- Continue to develop processes to make easier coordination throughout the life of the study including but not limited to amendments, subject safety, FDA reporting, CT.gov, study document creation, etc.
- Streamline study closeout between teams, sites, and investigators.

Solutions and Methods

Starting at PD, Investigators are informed of MC services and are consulted regarding opening their upcoming trial as a multi-site trial. If the investigators agree and there is funding available to support the MC team, then the following processes are implemented:

1. Protocol is listed on PD pipeline spreadsheet as a MC trial, where the MC team is informed of upcoming project.
2. Protocol is sent to MC Project Manager (MPM) for review and to check MC template language which is included for all Multisite IITs.
3. MPMs begin start-up processes – initiation of all study documents using template, initial contact with sites, contracts, feasibility, database builds, logistics… etc.
4. MPM works with PD on protocol, manuals, and databases.
5. MPM coordinates with PD for any safety updates through the life of the study.
6. PD coordinates with MPM for site-specific updates for FDA reporting, as well as updates for sites in CT.gov.

Outcomes



- With this process in place, the MC team has been able to initiate trials sooner which has allowed for seamless integration from a single center IIT to a multisite trial.

Lessons Learned and Future Directions

- As the PD and MC teams grow and expand, the depth, breadth and complexity of the MC trials themselves continues to grow at the same rate.
- Both teams have hired additional staff and have developed plans and system in order to accommodate the dozens of trials in our pipeline.
- We plan to continue our growth through the expansion of statewide teams, incorporating Affiliate sites, as well as navigating the complexities of trials in which manufacturing at IU is included.

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