Category: Trial Start-up, Activation, and Protocol Development – Work in Progress

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

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1. Background

Protocol Development (PD) services began in 2005 with a multi-center (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 multi-center team acting as a contract research organization (CRO) for trials wanting to open statewide, nationally, and internationally. as the multi-center team has grown, cooperation and integration with the Protocol Development 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.

2. Goals

- Continue to expand research; allowing investigators, the opportunity to include additional sites has made meeting accrual expectations that much more accessible
- Integrate study start-up processes with protocol development and multi-center teams to streamline and shorten start-up timelines
- 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

3. Solutions and Methods

Starting at protocol development, investigators are informed of multi-center 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:

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

4. Outcomes

Since 2018, there have been 15 studies that have utilized the process listed above and counting, including eight high-, four moderate-, and three low-risk trials. 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 multi-site trial. Both teams are growing as Indiana University investigators are continuing to use this process more and more.

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5. Lessons Learned and Future Directions

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