Protocol Development Services for Investigator-Initiated Trials (IITs)

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Background

Protocol Development (PD) services began in 2005 to provide trial activation, management, and completion services for Indiana University Investigator initiated trials (IU IITs) at the IU Simon Comprehensive Cancer Center. PD assists investigators in developing/writing protocols and all documents required for the conduct of a trial, as well as project managing trials through the initial regulatory processes including Scientific, IRB, and FDA reviews. We also provide clinical trials.gov registration support.

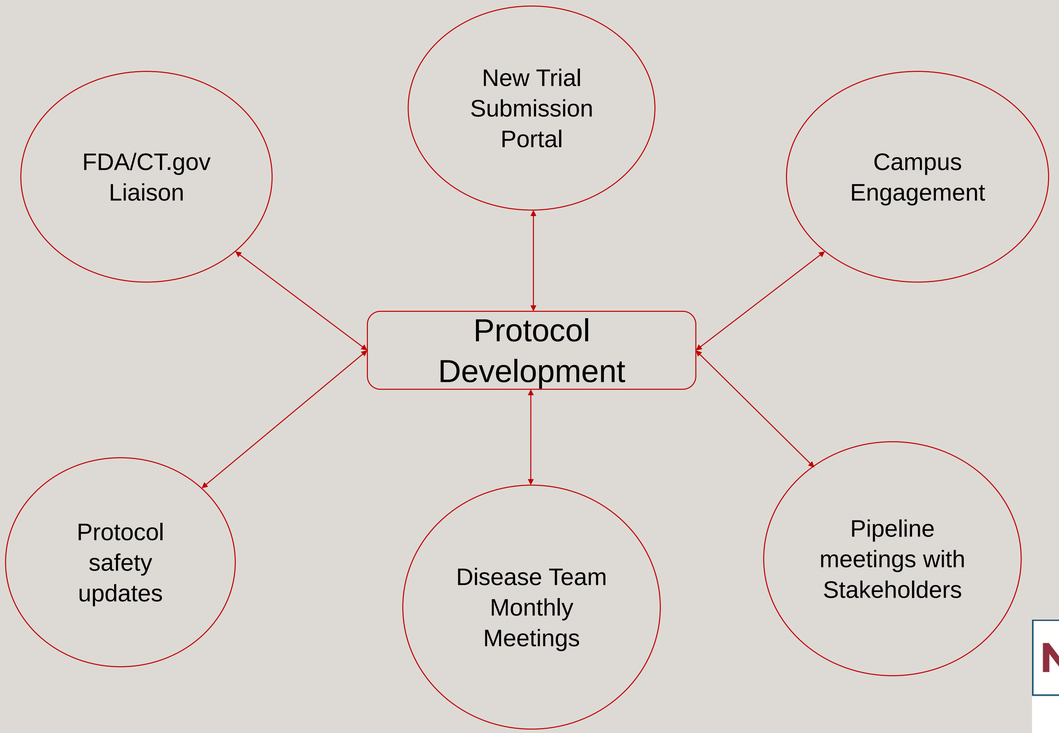
Through the life of the trials, PD provides assistance in amending trial docs when required, all FDA and CT.gov maintenance, including annual reports/updates, amendments, SAE reporting, and results reporting.

Goals

- Continue to expand research. Allowing cancer center members the opportunity to receive PD services to help meet institutional expectations, regardless of their department on campus.
- 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 transition from PD to coordinators actually conducting the research.

Solutions and Methods

- Protocol development has created a submission portal, to create a better workflow for requests for our services.
- PD has begun to engage with other departments on campus earlier to foster relationships and expand our reach outside of just the cancer center for cancer focused research
- PD host monthly ‘pipeline’ meetings with stakeholders in various departments to keep everyone engaged and knowledgeable about upcoming trials
- PD attends monthly disease team meetings to engage with teams throughout trial for amendments and FDA reporting
- PD coordinates with study teams for any safety updates through the life of the study
- PD acts as the liaison for FDA reporting, as well as CT.gov maintenance



Outcomes

By engaging with other departments and schools on campus we have been able to facilitate the creation of a new team and trial management connections within our clinical trials office. Our presence in team meetings assists teams with clarifications regarding protocol interpretation, and facilitates our ability to capture the need for amendments and any safety reporting in an expedited fashion

Lessons Learned and Future Directions

As the protocol development team grows, the expanse, depth, breath and complexity of the trials themselves continues to grow at the same, or faster rate. PD is in the process of hiring additional staff and has developed plans and systems in order to accommodate the dozens of trials in the pipeline; including utilizing our submission portal more, as well as navigating the complexities of trials in which manufacturing at IU is included.

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