



Moving IUSCCC Protocol Development Team to a Disease Team-Based Model for Workload Management

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Background

As the protocol development team (PDT) has grown at Indiana University (IU), the need to diversify workload has made itself more apparent. In the last 2 years we have hired 2 new protocol development coordinators (PDCs) and are continuing to expand as our Investigator Initiated Trials (IITs) portfolio grows.

Once the current team onboarded it became clear that using the old model at IU of assigning projects as PDCs had availability was becoming unsustainable. Last summer, the team made the decision to move to a disease team-based model.

Goals

- Diversify the workload among the team to help prevent burnout and uneven workloads
- Allow for disease teams to have a stable PDC contact, allowing the PDC to become an expert on specific diseases, rather than knowledge in all diseases researched at IU
- Reduce burden on PDC related to time spent on administrative activities

Solutions and Methods

- Create a levels of service guidance document (GD) outlining trial complexity by levels (Low-High) and giving a corresponding score of 1-3:
 - Level 1: Basic (retrospective, non-CTO, non therapeutic studies, observational studies)
 - Level 2: Moderate (correlative studies, non-drug interventional studies, radiation oncology studies etc.)
 - Level 3: High (phase 1, therapeutic trials that require an IND, multicenter studies etc.)
- Moved to a disease team-based model for assigning trials
- Create an acuity tracker for PDC workload

Outcomes

The disease team-based model has reduced administrative burden on PDCs. This provides consistency for Investigators and study team members, giving them a stable contact for new trials and amendments.

Creating an acuity score and tracker has mitigated potential burnout and improved consistency in workflow.

Acuity Tracker Template

Initial Submissions	Protocol number	PI	Current Status	Service Level number:
Amendments	Protocol number	PI	Current Status	
Other updates	Protocol number	PI	Current Status	
total acuity Score:				
Service Level number key:				
1-Basic (retrospective, non therapeutic, observational studies)				
2- Moderate (correlative, non-drug interventional, Rad/Onc)				
3-High (phase 1, IND trials, MC studies)				

Lessons Learned and Future Directions

By moving to a disease team-based model, we can use our GD to provide consistent timelines to Investigators and disease teams. Though workload may not be balanced, the team has the flexibility to assist PDCs who may have a higher workload to reduce burden across the team. This model also allows for real-time evaluation of team assignments, trends, and capacity to modify assignments as necessary as our team grows. This new model will allow the PDCs to become more knowledgeable on their specific diseases, which enhances overall protocol development services to our Investigators.

