Creation and Structure of an Investigator Initiated Trials (IIT) Support Group to Assist Investigators in the IIT Development Process

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Background

Starting and successfully activating an Investigator Initiated Trial (IIT) can be an incredibly daunting and overwhelming task, especially with the ongoing clinical pressures that investigators face. To help mitigate these hurdles, the University of Arizona Cancer Center Clinical and Translational Oncology Program (UACC CTOP) developed an IIT Support Group.

Goals

The goal of this group is to provide support and feedback to investigators, especially junior faculty, who have come up with an LOI concept for an IIT or have an idea and need assistance with LOI concept development. Support and feedback are provided throughout the process from protocol development through trial activation. With continuous support, the group aims to identify gaps early in the process and to increase the number of active IITs at UACC.
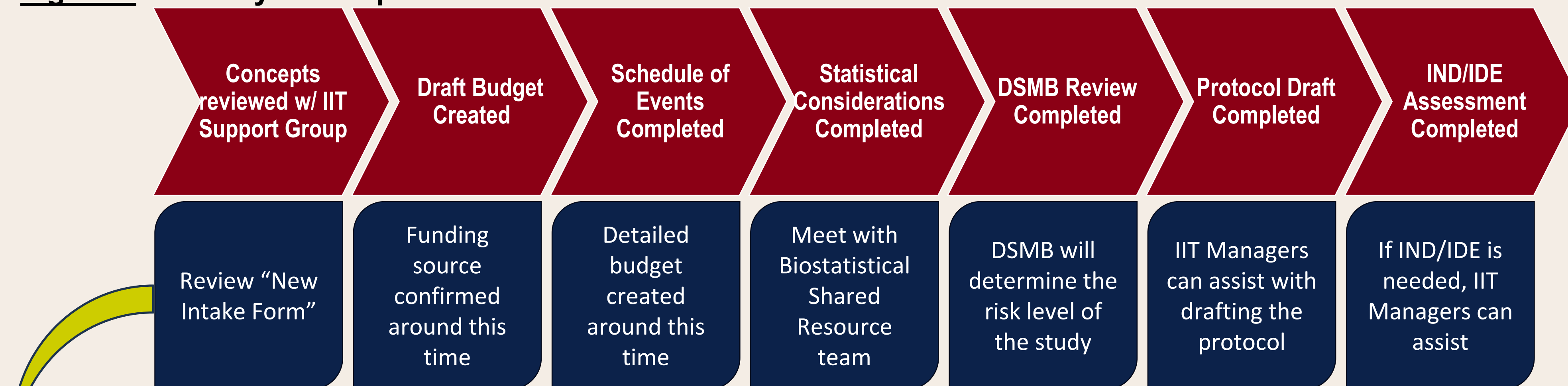
Outcomes

Thus far, we have had three meetings: April 2024, July 2024, and January 2025. In the April meeting, three therapeutic concepts were reviewed, one of which is industry funded and has moved forward with plans to open to accrual in May 2025. In the January 2025 meeting, three additional new therapeutic concepts were presented across multiple teams. Not only has the group empowered investigators with the knowledge of resources available to them to assist with IIT development, but it has also fostered stronger collaboration with the budget and biostatistics teams in knowing what is in the pipeline, thereby improving the efficiency of the start-up process. Prior to the creation of this group and the structure of quarterly meetings, IITs were opened by only a few investigators who had prior experience with IIT development. Since this support group's initiation, four IITs with therapeutic intent are in process.

Solutions and Methods

Group members consist of: 3 clinical research mentors, including a mentor to provide Community Outreach and Engagement (COE) input; 3 translational/basic science mentor(s) (2 standing, 1 ad hoc); 1 statistician; 1 budgets/contracts staff; 2 IIT Project Managers. The group meets quarterly and ad hoc as needed.

Figure 1: IIT Early Development Timeline

Concepts reviewed w/ IIT Support Group	Draft Budget Created	Schedule of Events Completed	Statistical Considerations Completed	DSMB Review Completed	Protocol Draft Completed	IND/IDE Assessment Completed
Review "New Intake Form"	Funding source confirmed around this time	Detailed budget created around this time	Meet with Biostatistical Shared Resource team	DSMB will determine the risk level of the study	IIT Managers can assist with drafting the protocol	If IND/IDE is needed, IIT Managers can assist

The group reviews the intake forms at their meetings with the investigators and provides feedback on:
- Scientific merit
- Study objectives and endpoints
- Eligibility
- The schedule of events
- Correlatives
- Funding including creation of a budget
- Statistics
- IND determination

Lessons Learned and Future Directions

A large lesson our investigators learned this year is that even preliminary concepts are valuable, and it does not hurt to present ideas early to industry/grant sponsors. Some of these ideas may be turned down but eventually, they will get a win. Persistence and patience are key.

In the future, we hope to reach more investigators and encourage the development of more IITs at our center as they see the success of the IITs currently in our workflow.

We also plan to obtain metrics of trial activation timelines to solidify the value of the group's involvement early in the IIT development process.