Category: Investigator Initiated Trails – Completed Project

Increasing Interventional Treatment IITs in the Study Start-up Pipeline with an IIT Committee Approach

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1. Background

In preparation to seek NCI designation, the University of Cincinnati Cancer Center (UCCC) recognized the need to increase our volume of interventional treatment investigator initiated trials (IITs). In 2017, UCCC's Investigator Initiated Trials Committee (IITC) was formed to lower the barriers to entry for developing interventional treatment IITs for new PIs. The IITC acts as a centralized resource, providing protocol writing and feasibility support to new PIs to help make developing interventional treatment IITs achievable.

2. Goals

It was anticipated that by centralizing resources for developing IITs this would increase the number of interventional treatment IITs in our start-up pipeline, and increase the number of PIs supported by the UCCC CTO. Only interventional treatment IITs were analyzed for this project, although the IITC supports the development of non-treatment, non-interventional IITs.

3. Solutions and Methods

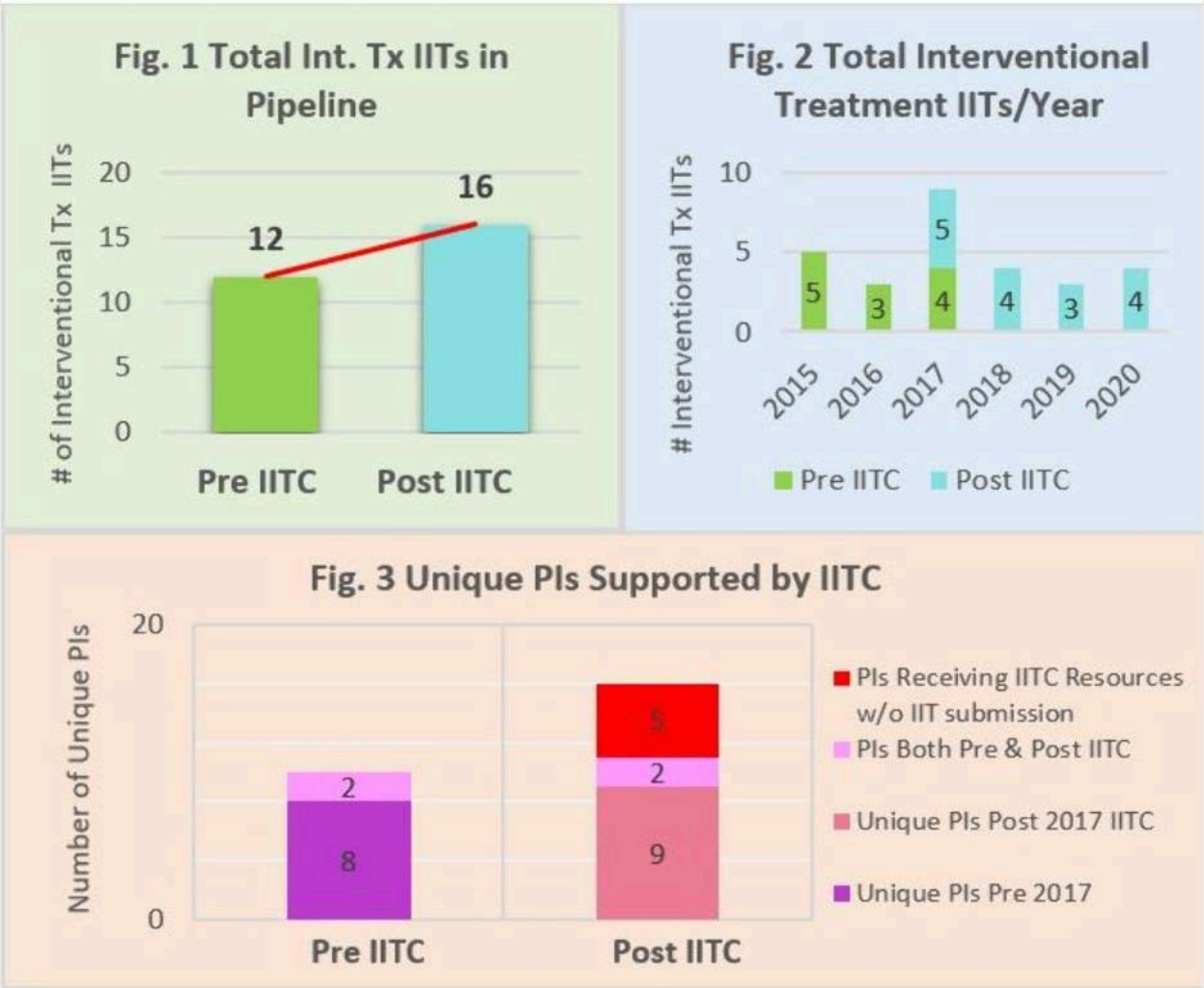
The NCI's protocol template was modified for institutional use and provided to PIs by the UCCC CTO staff who also coordinate monthly IITC meetings of key stakeholders (experienced physician-researchers/coordinators/statisticians/pharmacists/administrators). At the IITC the PI presents their protocol initial concept (no written protocol) or fully written protocol. The IITC sets realistic expectations around staffing, finances, and regulatory submission timelines and CTO staff facilitate protocol editing. The PRMC Charter was amended in 2019 to require IITC approval before PRMC review for interventional treatment IITs.

4. Outcomes

We focused our analysis on protocols that at least entered the start-up pipeline, rather than benchmarking against whether such protocols went on to receive IRB approval because many post-2017 IITs are still pending IRB review; and, because our goal was to establish whether IITC impacted new PI participation in IIT development. Pre-IITC data analyzed represent interventional treatment IITs that were at least submitted to PRMC. Post-IITC data analyzed represent interventional treatment IITs with at least an initial concept IITC submission. Non-Interventional/Treatment IITs, single patient INDs, and IITs where UC was a sub-site were excluded from both pre/post-IITC analysis.

After implementing centralized IITC review our data show a ~33% increase in total interventional treatment trial concepts proposed by PIs in our pipeline (from 12 to 16, Fig. 1). Although the total number of interventional treatment IITs per year remains similar to pre-IITC levels at ~4 per year (Fig. 2) we experienced engagement from a new cohort of unique PIs post-IITC (Fig. 3). Finally, because we are

now tracking IITC support services in the form of informal PI requests for protocol templates and pre-IITC consults we saw an overall increase in PI's supported post IITC (Fig. 3).



5. Lessons Learned

As our data show, providing PIs with centralized resources has increased the interventional treatment IITs in our pipeline and number of unique PI's supported. We learned it is important to have: a dedicated coordinator for the IITC to project manage; PI mentors to provide candid advice: and a shared online editing platform for documentation review. In the future we will examine time to opening, if these IITs enroll patients sooner, if the number of amendments are reduced, and completion & publication metrics. We hope to engage new PIs by increasing our online availability of resources and by conducting workshops on protocol development.