Category: Clinical Trial Operations – Completed Project

Single Institution Experience of Integrating Radiation Oncology Clinical Research Into Comprehensive Cancer Center CTO

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1. Background

Radiation oncology (RO) clinical research experienced significant growth under new leadership from 2 therapeutic accruals in 2015 to 56 in 2020. This growth was mainly driven through a newly established departmental program supporting development of investigator-initiated trials. Of the 56 therapeutic accruals in 2020, 47 were to investigator-initiated clinical trials and 9 were to NCI's National Clinical Trials Network (NCTN) trials. Corresponding non-therapeutic and non-interventional accruals were 0 in 2015 and 22 in 2020. RO clinical research operations were supported by 5 full-time equivalent (FTE) staff funded by the RO department with some minor cost recovery through grants. The RO office was following most cancer center (CC) clinical trials office (CTO) standard operating procedures (SOPs) but was not under operational control of CTO.

2. Goals

- Provide operational oversight of RO clinical research activity
- Support RO principal investigators (PIs) with existing central CTO services including protocol development, regulatory, and finance support

3. Solutions and Methods

- Discussed rationale and need for radiation oncology research to be under CTO operational control with RO and CC leadership
- Identified stakeholder concerns and financial implications
- Crafted shared vision for expanded support of RO research and combined operations under a unified CTO
- Crafted transition plan in collaboration with RO leadership

4. Outcomes

RO stepwise integration proceeded from January to July 2021. Integration conditions, including funds flow and indirect cost distribution, was modeled based on previous CC CTO integration efforts. The first step was a change in reporting of existing RO staff to an experienced CTO team manager (previously reported to RO department administrator with limited research experience), tasked with review of training and processes to identify differences or deficiencies.

A key element of the second step was providing full access to central CTO resources to RO PIs, requiring use of these services for investigator-initiated trials (IITs) being submitted to the CC's scientific review committee (SRC) starting April 2021. The final step was the full transition of existing RO employees into the CTO, including cost-shifting salary for those employees to the CTO.

5. Lessons Learned and Future Directions

Despite a CC-wide charge back to the PI's department for support of active IITs, clinical research costs for the RO department are estimated to be significantly lower than before the transition. 2021 therapeutic clinical trial accruals were reduced in comparison to 2020 to n=27 (n=25 to IITs, 2 to NCTN), likely secondary due to staff turnover and COVID-19 pandemic. 2021 non-therapeutic and non-

interventional accruals were stable at n=19. Of note, 3 out of 5 employees resigned during the transition despite significant efforts to avoid this. Currently 5 FTEs managed by a team manager are assigned to RO trials. In addition, full protocol development, finance, and dedicated regulatory support is in place. No change in number or overall quality of RO PI complaints is noted.