

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

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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 (IIT). Of the 56 therapeutic accruals in 2020, 47 were to IITs and 9 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. 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.

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.

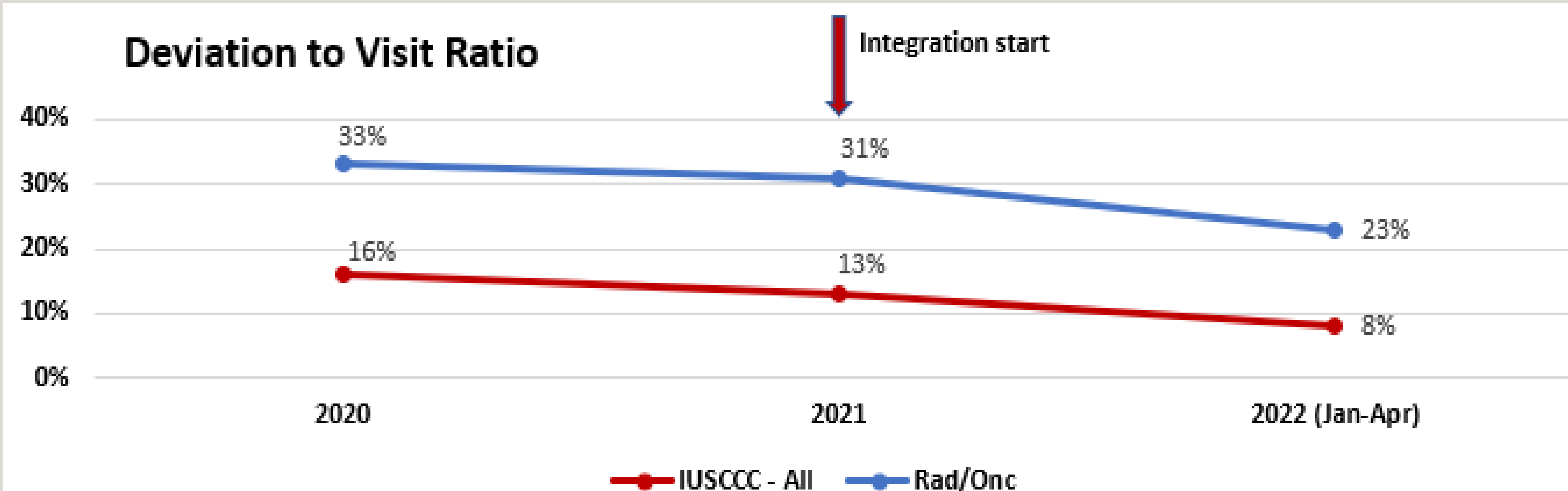
Methods

- 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.

Results

RO integration proceeded from January to July 2021. The first step was a change in reporting of existing RO staff to an experienced CTO team manager, 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 CTO services for IITs. The final step was the full transition of existing RO employees into the CTO, including cost-shifting salaries. Despite a CC wide charge back to the PIs department for support of active IITs, clinical research costs for the RO department are 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, three out of five employees resigned during the transition. Currently 5 CTO FTE plus a shared manager are assigned to RO trials. No change in number or quality of RO PI complaints is noted. Deviations are falling.

	2020		2021		2022 (Jan-April)	
	IUSCCC -all	Radonc	IUSCCC -all	Radonc	IUSCCC -all	Radonc
#total visits	7342	510	6925	440	2415	82
#total deviations	1152	170	892	138	192	19
%deviations to visits	16%	33%	13%	31%	8%	23%



Conclusions:

Longstanding efforts for RO integration led to initiation of integration in 2021. RO integration was successfully completed using a six-month transition plan, with deviations continuing to fall now over 24 months since start of the integration.