Development of a Clinical Research Coordinator Capacity Model

Jaidit Johnson, Milijana U. Petrovic, Erica Royster, Bucky Jones-Lombard, Brittany Mack, Anita Patel, Igor Krupitsky, Kira Hulse, Jay Lebsack

Background

Given the complexity of the clinical research coordinator (CRC) role it is essential to determine a sustainable workload and forecast the number of full-time equivalent employees (FTEs) needed to support clinical research. Currently, in Moffitt Cancer Center's Clinical Trials Office (CTO) team managers have utilized the Clinical Research Effort Study Tool (CREST) (Feb 22, 2016, Onsemble, 2016, Turner) which was derived from the OPAL (Journal of Oncology Practice, 2011, Smuck et al) to measure CRC activity by measuring protocol complexity. We reviewed literature on previous work such as the Clinical Research Coordinator Workload Estimation and Tracking tool by M. Repede, AACI 2022 abstract.

Goals

(1) To design a CRC workload capacity model that is efficient, effective and captures the time it takes a CRC to complete operational tasks at Moffitt.

(2) To develop a tool that will support operational managers' decision in projecting FTEs needed to coordinate active trials in the portfolio and trials in activation pipeline.

*Oncore–Clinical Trials Management System (CTMS)

Solutions and Methods

CRCs (n=30) used an "Effort Diary" for 8 weeks and noted how long it took to complete activities on each study. The diary included the study and subject ID associated with each activity, which was then mapped to the schedule of study activities in Oncore*. CRCs provided additional feedback to a project manager, who aggregated and analyzed data to calculate an average duration for each task per study. For the administrative tasks unrelated to protocol procedures, a weekly average time was given by each CRC. For clinical related tasks, an average duration was calculated and multiplied by the frequency of the tasks, as described in the calendar in CTMS. To estimate clinical hours, only patient-facing tasks were mapped, using an Office Data Connection report from CTMS.

CRC Workload Per Week and FTEs Variance

Current Calendar Week:	20	CRC Estimated Work Load (Hrs.)/Calendar Week																								
Management Group	RC Nam	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
CRO Heme Lymphoma/Myeloma		30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
CRO Heme Lymphoma/Myeloma		30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0
CRO Heme Lymphoma/Myeloma		31.8	32.3	34.5	31.5	31.5	32.3	37.5	32.3	35.3	34.0	33.8	33.3	33.3	30.3	31.5	32.5	32.0	30.3	31.8	32.3	32.8	31.3	30.5	30.5	31.0
CRO Heme Lymphoma/Myeloma		30.5	32.0	30.0	30.0	31.0	30.0	30.0	30.0	30.0	31.0	31.0	30.5	30.5	30.0	30.0	30.0	30.0	30.0	30.0	31.0	31.0	30.0	30.5	30.0	30.5
CRO Heme Lymphoma/Myeloma		34.0	31.5	31.5	32.0	32.5	30.0	33.5	33.5	33.0	31.0	32.0	31.0	33.0	31.0	30.5	33.5	31.5	30.0	30.5	30.5	31.5	30.0	30.5	30.5	31.0
CRO Heme Lymphoma/Myeloma		31.0	30.0	31.0	30.0	30.0	30.0	30.0	30.0	30.0	30.5	31.0	30.0	30.0	30.5	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	31.0	30.0
CRO Heme Lymphoma/Myeloma		34.3	34.3	36.8	35.3	35.8	33.8	37.0	37.5	34.5	35.8	35.5	35.5	34.5	33.0	35.0	35.0	33.5	33.0	33.5	33.5	33.0	32.5	33.8	33.0	33.0
CRO Heme Lymphoma/Myeloma		36.3	31.5	35.8	40.8	34.8	33.3	35.8	39.8	32.3	31.8	32.8	40.8	35.5	36.5	41.5	37.3	34.0	32.5	35.0	34.0	34.5	30.5	34.5	32.5	33.5
CRO Heme Lymphoma/Myeloma		30.0	30.0	30.0	30.0	30.0	30.0	30.0	31.3	30.3	30.0	31.0	30.3	30.0	30.0	30.0	30.0	30.3	30.0	30.0	30.3	30.0	30.0	30.0	30.3	30.0
CRO Heme Lymphoma/Myeloma		30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	33.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0	30.0

Current Calendar Week:	20	Capacity/Calendar Week																								Capacity Legend
Management Group	CRC Name	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
CRO Heme Lymphoma/Myeloma		75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	< 70%
CRO Heme Lymphoma/Myeloma		75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	70% - 79.9%
CRO Heme Lymphoma/Myeloma		79.4%	80.6%	86.3%	78.8%	78.8%	80.6%	93.8%	80.6%	88.1%	85.0%	84.4%	83.1%	82.5%	75.6%	78.8%	81.3%	80.0%	75.6%	79.4%	80.6%	81.9%	78.1%	76.3%	76.3%	77.5%	80% - 89.9%
CRO Heme Lymphoma/Myeloma		76.3%	80.0%	75.0%	75.0%	77.5%	75.0%	75.0%	75.0%	75.0%	77.5%	77.5%	76.3%	76.3%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	77.5%	77.5%	75.0%	76.3%	75.0%	76.3%	90% - 100%
CRO Heme Lymphoma/Myeloma		85.0%	78.8%	78.8%	80.0%	81.3%	75.0%	83.8%	83.8%	82.5%	77.5%	80.0%	77.5%	82.5%	77.5%	76.3%	83.8%	78.8%	75.0%	76.3%	76.3%	78.8%	75.0%	76.3%	76.3%	77.5%	>100%
CRO Heme Lymphoma/Myeloma		77.5%	75.0%	77.5%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	76.3%	77.5%	75.0%	75.0%	76.3%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	77.5%	75.0%	
CRO Heme Lymphoma/Myeloma		85.0%	85.6%	91.9%	88.1%	89.4%	84.4%	92.5%	93.8%	86.3%	89.4%	88.8%	88.8%	86.3%	82.5%	87.5%	87.5%	83.8%	82.5%	83.8%	82.5%	81.3%	84.4%	82.5%	82.5%	82.5%	
CRO Heme Lymphoma/Myeloma		90.6%	78.8%	89.4%	101.9%	86.9%	83.1%	89.4%	99.4%	80.6%	79.4%	81.9%	101.9%	88.8%	91.3%	103.8%	93.1%	85.0%	81.3%	87.5%	85.0%	86.3%	76.3%	86.3%	81.3%	83.8%	
CRO Heme Lymphoma/Myeloma		75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	78.1%	75.6%	75.0%	77.5%	75.6%	75.0%	75.0%	75.6%	75.0%	75.0%	75.0%	75.6%	75.0%	75.0%	75.0%	75.0%	75.6%	75.0%	
CRO Heme Lymphoma/Myeloma		75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	82.5%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	75.0%	

Current Calendar Week:	20	Estimated CRC FTE Requirement/Calendar Week																										
Management Group		3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	Current No. of FTEs	FTE Variance
CRO Blood and Marrow Transplant		9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	11.0	2.0
CRO Breast		8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	10.0	2.0
CRO Cutaneous		11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	11.0	13.0	2.0
CRO Gastrointestinal Tumor		6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	6.0	7.0	1.0
CRO Genitourinary		9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	11.0	2.0
CRO Gynecological Tumor		3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	3.0	
CRO Head & Neck		4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	
CRO Heme Lymphoma/Myeloma		8.0	9.0	8.0	8.0	9.0	8.0	8.0	9.0	9.0	8.0	9.0	9.0	8.0	8.0	8.0	9.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	10.0	1.7
CRO Heme Myeloid		9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	10.0	1.3
CRO-CE-T		15.0	15.0	15.0	15.0	16.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	19.0	4.0
CRO Neurologic Oncology		2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	3.0	
CRO Phase I		4.0	4.0	4.0	4.0	5.0	4.0	4.0	5.0	4.0	4.0	4.0	3.0	5.0	5.0	5.0	4.0	4.0	3.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	5.0	0.7
CRO Pivot		2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
CRO Radiation Oncology		10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	9.0	10.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	9.0	11.0	1.6
CRO Radiology Services		2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
CRO Sarcoma		4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	5.0	1.0
CRO Senior Adult		2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0	
CRO Thoracic		15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	15.0	19.0	4.0

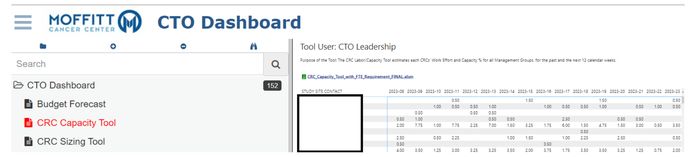
Capacity Legend	Capacity Assesment
< 70%	Capacity Available
70% - 79.9%	At Capacity
80% - 89.9%	10% over capacity; needs support with prioritizing responsibilities
90% - 100%	20% over capacity; plan for redisributing workload
>100%	30+ % overcapacity; plan for additional staff resources

Outcomes

The workload capacity tool can estimate CRC workload per hours of the week and %, number of hours spent in clinic by disease site-based team per calendar week. The distinctive ability of the tool is that it can pull number of hours that are needed to support clinical trial based on schedule of events. The tool pulls 12 weeks of prospective and retrospective capacity assessments based on the real time data from CTMS without the need for additional effort tracking by staff.

Refinements and Next Steps

Future steps will focus on validation and refinement of the tool to account for the variance in coordinator's capacity based on coordinator level of experience, involvement in projects and mentorship. Additionally, development of the reference guide for CTO managers and Supervisors to use for Fiscal Year(FY) FTE planning. Lastly, build out of the capacity model Research Data Coordinators (RDC) is a focus in FY24.



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