UCSF Helen Diller Family Comprehensive Cancer Center

Implementation & Application of the Ontario Protocol Assessment Level Tool at the Helen Diller Family Comprehensive Cancer Center

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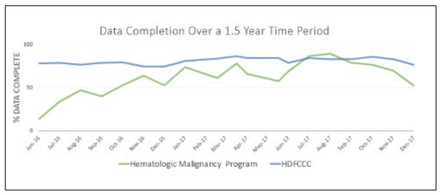
Background

The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) conducts over 460 clinical trials. These trials are conducted by 101 individual research staff in 13 programs across 3 campuses.

The HDFCCC previously estimated workload based on patient accrual and/or the average percentage of data that was completed each month by Clinical Research Coordinators (CRCs). These estimates did not account for the complexity of a clinical trial.

This project aims to develop and implement the Ontario Protocol Assessment Level (OPAL) Tool originally developed by Smuck, et al., (2011) to address inadequate staffing in the Hematologic Malignancy Research Program (HMRP) at UCSF's HDFCCC.

The HMRP was selected to pilot this project as the program struggled to meet and maintain HDFCCC's goal of 85% monthly data completion due to the fluctuations in patient accruals onto their complex clinical trials.



Goals

The goal of this project was to:

- Develop and implement a workload assessment tool referencing the OPAL model developed by Smuck, et al., (2011).
- Provide each Clinical Research Manager (CRM) with a monthly cumulative HDFCCC OPAL score for their staff. This would allow the CRM to determine a minimum and maximum workload that can be assigned to a CRC and proactively identify staffing needs.

HDFCCC Opal Tool Development & Implementation

The implementation of this project consisted of two key steps: development of the HDFCCC OPAL Tool Scoring Worksheet, followed by tracking the program's monthly HDFCCC OPAL Score.

This scoring worksheet was based off of the original tool produced by Smuck, et al., and tailored to fit the needs of HDFCCC (2011). The HDFCCC OPAL Tool Scoring Worksheet generated the HDFCCC OPAL base score specific to each clinical trials based on the complexity of the clinical trial.

HDFCCC OPAL Tool Scoring Worksheet

The Associate Director of Clinical Research Programs (ADCRP) and CRM of the HMRP met to review and tailor the OPAL Tool Scoring Worksheet developed by Smuck, et al., (2011).

At this time, the HDFCCC CRC Job Description, performance goals and existing workflows were reviewed to identify key tasks performed by CRCs. These tasks, as well as special procedures unique to oncology trials were incorporated into the HDFCCC OPAL Tool Scoring Worksheet.

The scoring worksheet generated the HDFCCC Base OPAL score specific to each clinical trial based on the trial's complexity.

What phase study? (Enter '0' for non-treatment studies e.g. bio-banking)	3
If interventional, does the study involve the use of a drug?	Yes
If non-interventional, how many # of contacts are required?	0
Optional elements	
Inpatient ≤5 days	No
Inpatient >5 days	Yes
On-site monitoring (every 3 months or more often) or 100% SDV	Yes
Duration follow-up visits >2 years	Yes
Industry sponsor/CRO factor [Coop/Consortium, mark No]	Yes
Multiple surveys/questionnaires [>3 timepoints]	Yes
Management and Oversight of one subsite	No
Management and Oversight of >1 subsite	No
Management of study visits require travel between campuses	No
Subsite - Management of only data entry guidance/specimen management only	No
0.5 for continuous follow up [e.g. ongoing until death, >5 years]	Yes
0.5 for infusion study (every 3 weeks or more frequently)	No
Requires fresh tissue biopsy requiring CRC effort	No
0.5 for mid-cycle study visit requiring CRC effort	No
0.25 for mid-cycle labs that require CRC effort (e.g. PK, PD)	Yes
0.5 if CRC process samples (clotting, centrifuging, aliquoting, packaging, shipping)	Yes
0.25 for Length of Treatment >18 months (or until disease progression)	No
(-) 0.25 for Length of Treatment 0-3 months	No
(-) 0.5 for visits less frequent than every 4 weeks	No
(-) 0.5 for no data entry	No

Special Procedures

Use of central lab	Yes
Pathology	No
Radiology (e.g. upload of scans)	Yes
Tumor banking	Yes
Archived tissue	No

PK sampling (pre & post infusion)	Yes
ECG (by CRC)	No
Serial lab or ECGs (in one visit)	No
Biomarker specimen collection	Yes
Blood banking (@ UCSF)	No
Eligibility biomarkers e.g. KRAS, FISH, HER2, P16	No

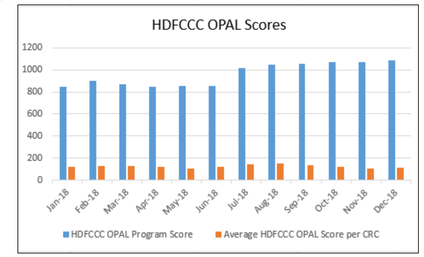
HDFCCC OPAL Program Summary

Monthly, the CRM updated the HDFCCC OPAL Program Report with current accrual information for each clinical trial, producing the HMRP's cumulative HDFCCC OPAL Score.

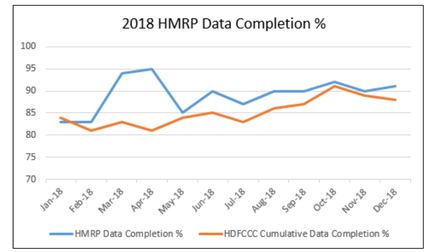
Staff	Study	Base OPAL	# patients consented	In-eligible	Active Patients	Active PTs Off Treatment or in Active follow up	# Patients in LTFU or Surv FU	HDFCCC OPAL Score	Data % Completion
CRC #1	Study 12345	12.25	8	3	2	0	4	41.65	
	Study 23456	9.25	31	12	0	0	2	20.35	
	Study 34567	8.5	21	3	0	0	7	14.45	
	Study 45678	0.75	354	0	10	0	35	10.875	
	Study 56789	10.5	39	1	0	0	18	29.4	
	Study 54321	3	2	0	2	0	0	9	
								0	
								0	
						Total Active Workload for CRC #1		125.725	89%

Results

The HMRP's cumulative HDFCCC OPAL score ranged from 847-1091. The average monthly HDFCCC OPAL score per CRC ranged from 107-150.



After implementation of the HDFCCC OPAL Tool in February 2018, the HMRP effectively used the HDFCCC OPAL scores to assign CRCs a workload that allowed the program to consistently maintain their data completion percentage of 85% or more from March 2018 through December 2018.



Conclusions

This pilot project demonstrates that the OPAL tool can be developed and implemented to evaluated the varying complexities inherent to staffing clinical trials. The application of the HDFCCC OPAL tool allows CRMs to identify the workload required for a clinical trial and make staffing adjustments proactively in order to ensure all trials are audit-ready.

Reference

Smuck, B., Bettello, P., Berghout, K., Hanna, T., Kowaleski, B., Phippard, L., Au, D., Friel, K. (2011). Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials. *Journal of Oncology Practice.* 7(2), 80 84. JOP.2010.000051.