

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

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### **1. 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. Due to the unpredictable nature of clinical trials and high turnover rate, clinical research programs struggle to adequately staff and assign clinical trial related work to their study teams.

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). This excludes the complexity of a clinical trial in the workload assessment and results in a delayed feedback loop, as hiring managers are making staffing decisions after the data completion percentage dropped.

### **2. Goals**

The goals were to develop and implement a workload assessment tool developed referencing the OPAL model developed by Smuck et., al (2011) so that the Clinical Research Manager (CRM) could determine a maximum and minimum workload assigned to a CRC. Once implemented, the workload assessment tool would provide a monthly score HDFCCC OPAL score. This score would begin to provide data and allow the CRMs to establish an HDFCCC OPAL score range that ensures the CRCs have adequate bandwidth to fulfil their job responsibilities of conducting their assigned clinical trials.

### **References:**

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. doi:10.1200/JOP.2010.000051.

### **3. Solutions and Methods**

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 (Smuck et al., 2011). 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. in 2011. This scoring worksheet was created in Microsoft Excel and generated the HDFCCC OPAL base score specific to each clinical trial based on the complexity of the clinical trial. Monthly, the CRM modified the HDFCCC OPAL Program Report and incorporated the accrual information for each clinical trial, producing the program's cumulative HDFCCC OPAL score.

Category: Clinical Research Operations – Work in Progress

The Hematologic Malignancy Research Program (HMRP) was selected to pilot the project as the program had completed a mere 14% of their monthly data entry requirements in June 2016. As the program increased their overall data completion, the program struggled to consistently meet the HDFCCC goal of 85% monthly data completion due to fluctuations in accruals onto their complex clinical trials.

#### 4. Outcomes and Future Directions

The CRM demonstrated that the program’s cumulative HDFCCC OPAL score ranged from 847-898 and with a team of 7 CRCs, the average monthly HDFCCC OPAL score for CRC ranged from 121 to 128 (as demonstrated in Figure 2 and Figure 3). Ongoing data collection is taking place to further refine the maximum and minimum range using the HDFCCC OPAL values.

