



## Background

The University of Arizona Cancer Center (UACC) needed an objective tool to measure staff workload. The UACC utilized the Ontario Protocol Assessment Level (OPAL) model but realized we needed a model that would fit the unique staffing structure at our cancer center. The UACC clinical staff were grouped into clinical research teams (CRT) composed of clinical research coordinators (CRC), research data coordinators (RDC), and research nurses (RN).

## Solutions and Methods

A task force was created in December 2020 composed of cancer center leadership and staff members representing each job function. The task force used OPAL as a guide adding grading criteria that fits our staffing structure and study acuity of the current UACC portfolio. A workload grading tool was created and tested on protocols across several CRTs.

OPAL was modified in the following ways:

- Modified the base score definitions and certain scoring criteria
- Added the number of data platforms to the monitoring category
- Separated the treatment and follow up visits into two categories
- Removed the Industry sponsor/CRO factor
- Updated the survey and questionnaire category to include diaries and considered the frequency per cycle
- Factored in patients in screening whereas OPAL only considered patients on treatment and follow-up.
- Created a calculation to capture acuity for each job function removing the categories that do not apply.

Base Score (definition below) If IIT with research staff with Sponsor duties, assign Base Score = 7	Inpatient (max 0.5) HEM ONC STUDIES	Monitorings amt. and Data Platforms Add 0.1 if monitor visit frequency >= quarterly 3 = 0.4 pts 2 = 0.3 pts 1 = 0.25 pts	# or Duration of Treatment Visits (max 0.5) For "regular" cycles 0.5 = 4xM 0.4 = 3xM 0.3 = 2xM 0.2 = 1xM 0.1 = 1x2M 0 = more	Surveys, Questionnaires, and Diaries per CYCLE (max 0.5) >1 item/cycle = 0.5 1 item/cycle = 0.4 1 item @ CID1 + EOT = 0.25	Follow up Schedule Rating Criteria: (1) Duration FU: >= 5 yrs of visits (2) Type FU: Mainly in person visits (3) Frequency FU: At least 4X in 1st year of follow up 3 Factors = 0.5 pts 2 Factors = 0.4 pts 1 Factors = 0.25 pts	Total Protocol Score	Patients on treatment (1 pt per patient)	Patients on Follow Up (0.25 pt per patient)	Patients in Screening (0.5 pt per patient)	Total Workload	Research RN Workload (Without patients in Follow Up)
Single Contact Score = 1											
Multiple Contact Score = 2											
Phase II/III/IV Interstitial, Nondrug Score = 3											
Single, Special Procedure (SP) and/or Single, Central Process (CP) Score = 4											
Multiple SP or Multiple CP Score = 5											
Single SP + Multiple CP or Single CP + Multiple SP Score = 6											
Multiple SP + Multiple CP Score = 7											
Phase I Score = 8											

Image 2: Revised Workload Calculation

## Outcomes

The final manual calculation tool took 9 months to create and was presented to clinical trials office leadership on August 6, 2021. Once the tool was approved, the task force worked with OnCore to integrate the model for timely reporting and began teaching the staff to grade each protocol. In March of 2023 the model was officially implemented and utilized with ability to run reports from OnCore. The tool is utilized regularly for discussions regarding clinical research team staffing and coverage needs across teams.

This model did not work for specimen management coordinator workloads.

The clinical job functions also changed over time with the research data coordinator's team dissolving, which required another review of the model.

## Lessons Learned and Future Directions

This model is not perfect. There are many staff duties that are not directly captured. We attempt to include these by rounding up the final calculation of number of staff needed to support a CRT. Some of the tasks and situations that are not taken into consideration include: assisting with other disease teams with quality checks, pre-screening, employee knowledge and productivity levels, and staff vacations and coverage needs.

This model does not evaluate an individual employee's performance and workload; it works best on the disease team level. Additionally, there are still improvements that can be made with the University of Arizona OnCore team in improving the reports.

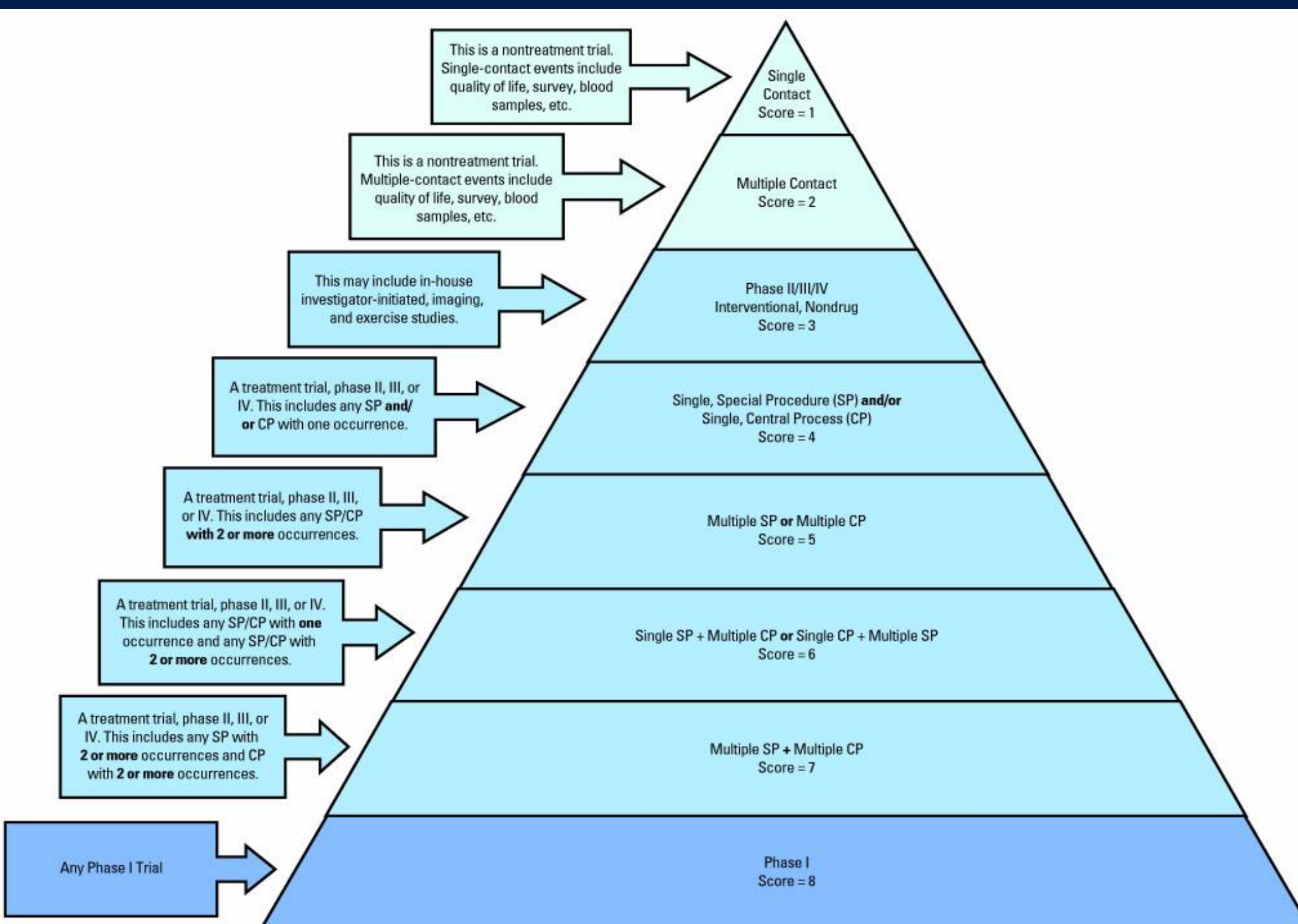


Image 1: The OPAL Pyramid Scale  
Smuck B, Bettello P, Berghout K, Hanna T, Kowaleski B, Phippard L, Au D, Friel K. Ontario protocol assessment level: clinical trial complexity rating tool for workload planning in oncology clinical trials. J Oncol Pract. 2011 Mar;7(2):80-4. doi: 10.1200/JOP.2010.000051. PMID: 21731513; PMCID: PMC3051866.

## Goals

The goal was to create an institutional specific acuity model utilizing OPAL as a guide. This model needed to include calculations for the unique job duties for CRCs, RDCs and RNs. The data needed to be easy to access by running a report from our Clinical Trials Management System (CTMS), OnCore.

