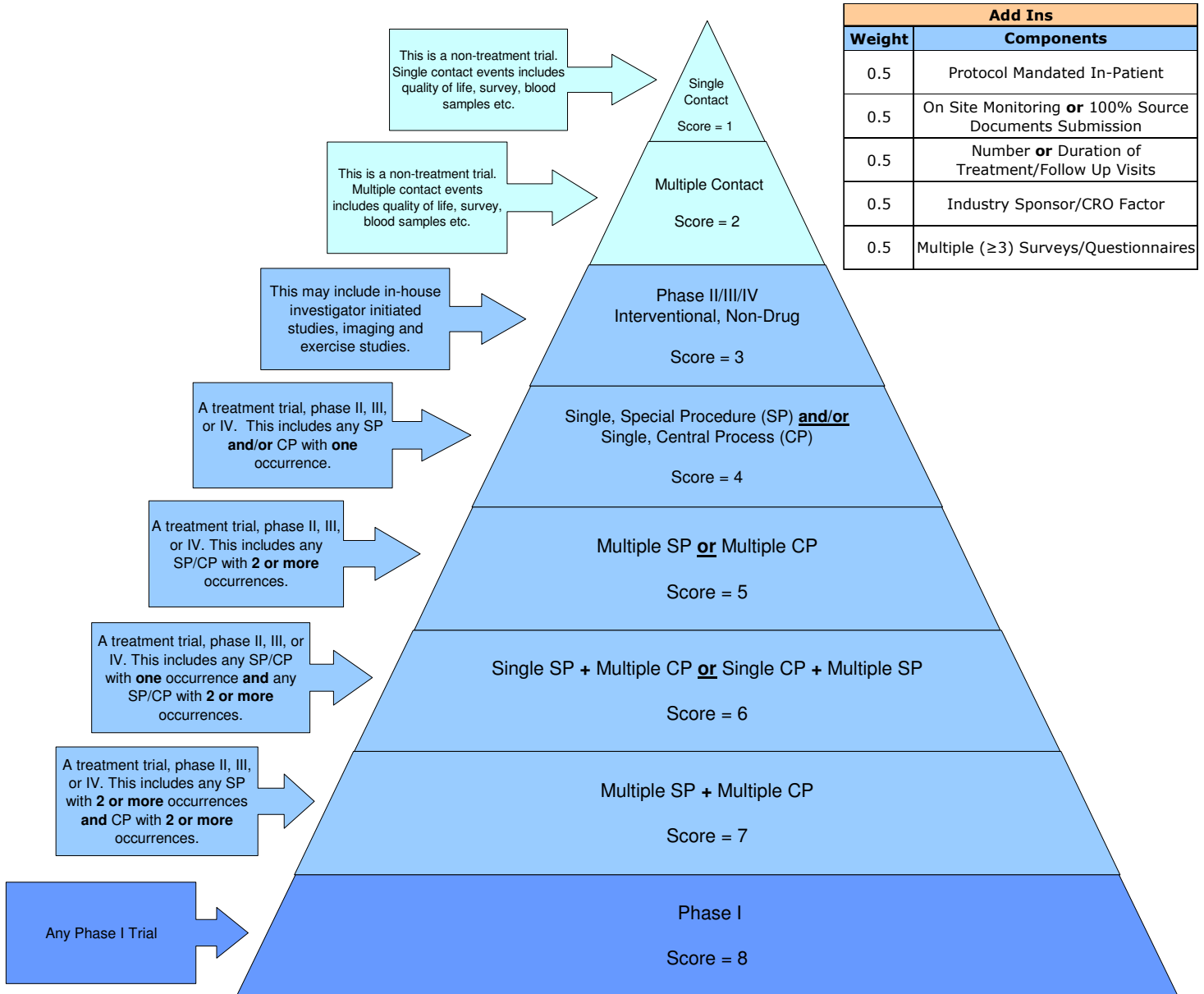




Ontario Protocol Assessment Level (OPAL)



Definitions:

Central process review (CP) may include: laboratory; pathology; radiology; tumour banking; archived tissues.

Special procedure (SP) may include: PK sampling (pre & post); ECG; serial lab/ECGs; biomarker specimens; blood banking; eligibility biomarkers such as KRAS, FISH, HER2.

Ontario Protocol Assessment Level (OPAL)

OPAL GLOSSARY	
Term	Definition
Single	Any single procedure or process with one occurrence or any multiple procedures or processes with one occurrence during the clinical trial.
Multiple	Any single procedure or process with 2 or more occurrences or any multiple procedures or processes with 2 or more occurrences during the clinical trial.
Central Process Review	This may include but is not limited to any of the following central processes: laboratory; pathology; radiology; tumour banking; archived tissues.
Special Procedure	This may include but is not limited to any of the following special procedures: PK sampling (pre & post); ECG; serial lab/ECGs; biomarker specimens; blood banking; eligibility biomarkers such as KRAS, FISH, HER2.
Multiple Surveys and Questionnaires	This may include three or more of the following: patient diaries, questionnaires and surveys for example quality of life, pain and vital sign monitoring.

Assumptions:

-This tool should not be used to measure procedures that are completed by staff outside the Clinical Trials Department

-Rating does not include site acting as a sponsor (CTA role)

-This tool does not measure academic benefit to the institution

-Sponsor requests for slides/blocks that are sent directly to your pathology dept. should not be factored as a central review process

-Trial mandated follow-ups must be greater than standard of care in either frequency (no. of visits) and/or duration (length of follow-up time) to trigger additional weighting level

OPAL Score = Trial Workload

Use the OPAL Score to calculate clinical trial workload

Case Workload = Trial Workload x Number of Cases

Total Workload = Trial Workload + Case Workload

Trial Workload drops down to half once the trial is on follow up

Application Example:

RESEARCH COORDINATOR WORKLOAD								
Coordinator	Trial	OPAL Score	Active Cases	Follow Up Cases	Closed Trials	Total Trial OPAL Score	Total Case Workload	Total Workload
Sue	MAC4	5	1			5	5	10
	MAC7	6	10			6	60	66
	RAPID	4	3			4	12	16
	R413	5	2			5	10	15
	Beatrice	6	3			6	18	24
	Abrax-B	6.5				6.5		
								131

Sample Calculation for Sue:

	Case Workload = 5 (OPAL Score) x 1 (Active Case) = 5
MAC4	Total Workload = 5 (OPAL Score) + 5 (Case Workload) = 10
	Case Workload = 6 (OPAL Score) x 10 (Active Cases) = 60
MAC7	Total Workload = 6 (OPAL Score) + 60 (Case Workload) = 66