



Ontario Institute
for Cancer Research

science → discoveries → solutions

ONTARIO PROTOCOL ASSESSMENT LEVEL

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2011-OCT-20

Clinical Trials
Quality Speed Access





OPAL Working Group Formation

- At the 2008 OICR Clinical Trials Program Annual Meeting, sites expressed interest in developing procedure/tool for assisting in site resource allocation
- OICR called for members, working group was formed





Working Group Members

- **Chair:**

- Bobbi Smuck – *London Regional Cancer Program*

- **Members:**

- Brenda Kowaleski – *Juravinski Cancer Centre*
- Diana Au – *Ontario Institute for Cancer Research*
- Kay Friel – *Ontario Institute for Cancer Research*
- Koralee Berghout – *The Ottawa Hospital Cancer Centre*
- Lynda Phippard – *R.S. McLaughlin Durham Regional Cancer Centre*
- Phyllis Bettello – *Algoma District Cancer Program*
- Tracie Hanna – *Cancer Centre of Southeastern Ontario at Kingston General Hospital*





Objectives

- To develop a standard rating scale to evaluate Clinical Trial complexity
- To facilitate and educate Ontario cancer research sites to apply that scale to workload measurement





Guiding Principles

- The format must:
 - be simple to apply;
 - measure work task specific to clinical trial professionals;
 - be useful for determining workload capacity;
 - include all phases of trials;
 - not be intended for academic review.





Development

- Literature review identified few articles on protocol weighting directly but did reveal several on workload in clinical trials
- There has been a 6.5% increase in 'unique trial procedures' from 1999-2005¹
- CTEP/NCIC developed a protocol rating scale that would assist central data management sites vs clinical sites

¹Getz, Kenneth. (2008). Protocol Design Trends and their Effect on Clinical Trial Performance. *RAJ Pharma*, 315-316.





Development (continued)

- Members of the committee shared their present tools
 - London:
 - Scale 1-10
 - Kingston:
 - Feasibility Checklist
 - Oshawa:
 - New Trial Impact Assessment sheet





Development (continued)

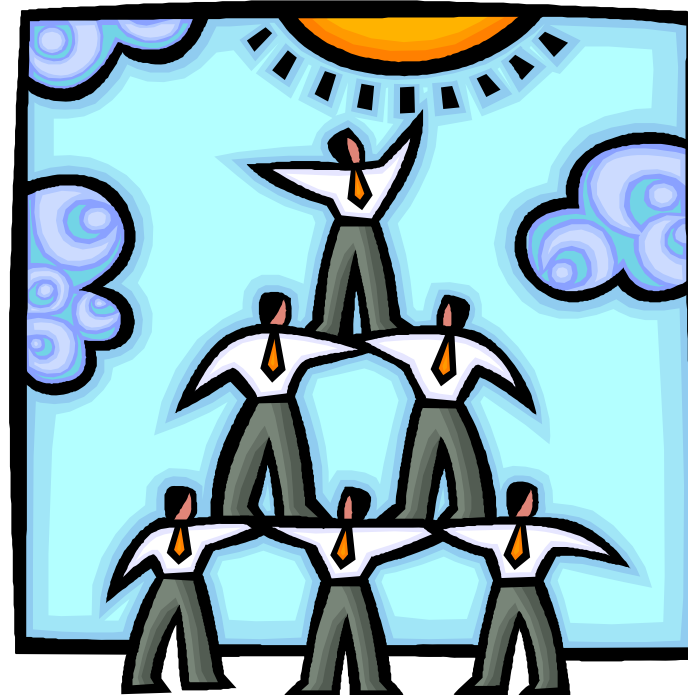
- Tool is used to determine workload capacity in the department:
 - Not for academic benefit
- Tasks were defined
- All phases of trials to be included
- Keep the tool **SIMPLE!**





The Three Phases

- Three phases for all trials:
 - Activation
 - Recruitment/Conduct
 - Follow Up





The Three Phases (continued)

- The following were identified in each of the three phases:
 - Core Tasks
 - Special Procedures





Core Tasks

- Core tasks are common procedures for all trials
- “Special/Unique” procedures determine the level of increased complexity for each trial
- Assumption:
 - Specific tasks are associated with the type of trial
 - For example: Phase I: multiple blood samples
- Group decision for a 1-10 simple pyramid scale





Activation – Core Tasks

- Protocol review
- REB - informed consent form (ICF)
- Committee review
- Cost/impact
- Sponsor regulated documents
- Site startup tools
- Inter-department coordination:
 - Pharmacy procedures
 - Chemo procedures
 - Radiotherapy – physics
 - Radiology
 - Pathology/lab
- Training
 - CRFS
 - Procedure





Activation – Special Procedures

- Budget/contracts
- Site selection visit
- Investigator Meeting
- Site Initiation- start up meeting
- CRO
- Special Equipment (storage, computer, centrifuge, ECG, lab kits etc)





Study Conduct – Core Tasks

Protocol Administration

- CRFs, edata
- Source documentation
- Safety reports - SAE's (local)
- Queries
- Ongoing protocol administration
 - Safety reports
 - Amendments
 - Annual renew
 - study documents
- Monitoring
 - Central/local
 - On site
 - Audits/inspections

Study Specific Parameters

- Recruitment
- Prescreening → consent → screening
- Consent process → baseline work up
- Registration and Randomization
- Study visit
 - Special procedures
- Intervention
 - Chemo/oral/RT





Study Conduct – Special Procedures

- Central radiology
- Central pathology
- Central labs/local kits
- Study Specific
- Quality of life questionnaires
- Special procedures
- Drug compliance





Follow Up - Core Tasks

Protocol Administration

- Ongoing protocol administration
- Sponsor related safety reporting
- Close out

Study Specific Parameters

- Visits
 - Special tests
- CRF's
- Source documents
- Adverse Events
- Re-consent (following amendments)
- Queries
 - Data lock





The Scale



- The rating scale is between 1-8 with optional elements, to a maximum total rating of 10
- Focuses on the recruitment/conduct phase of a trial



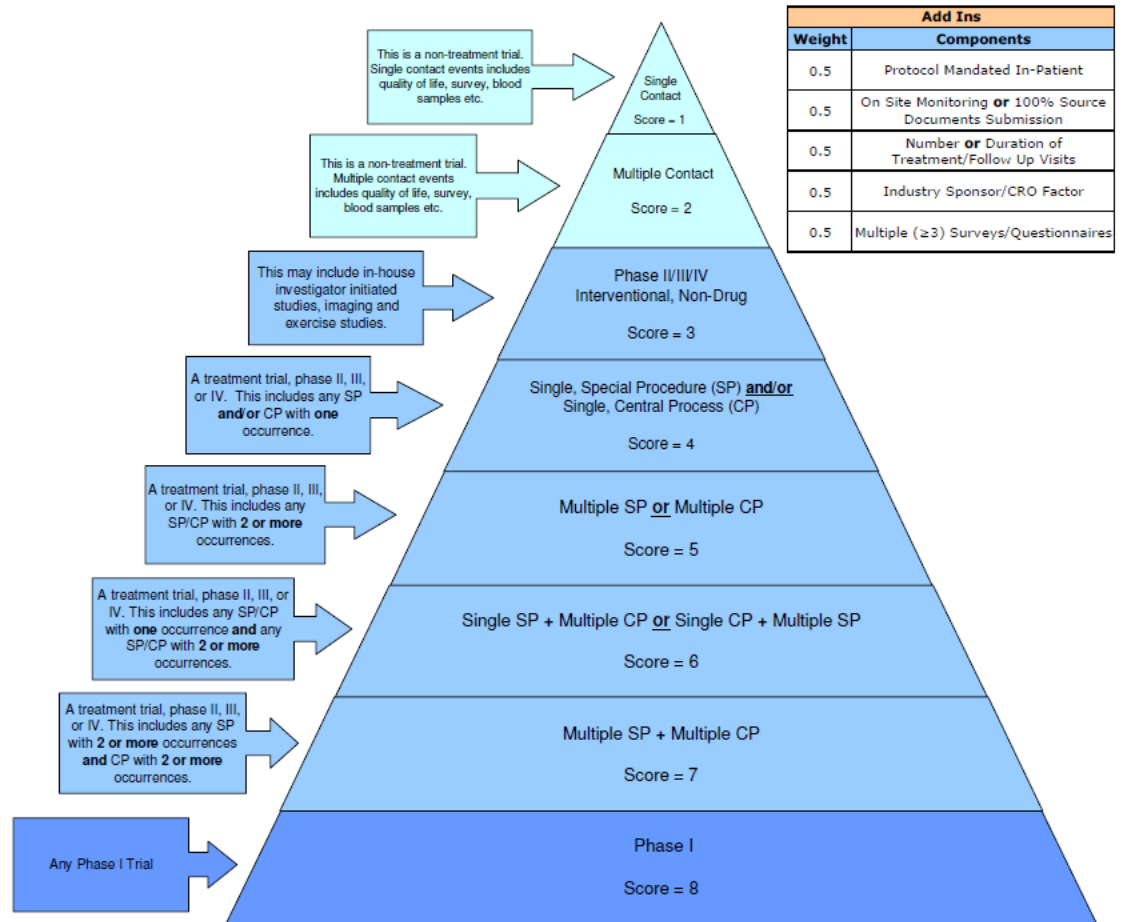


Basic Assumptions

- Core tasks are common procedures for all trials
- “Special/Unique” procedures determine the level of increased complexity for each trial
- Assumption:
 - Specific tasks are associated with the type of trial
 - For example: Phase I – multiple blood samples
- Working group opted for a 1-10 simple pyramid scale



Ontario Protocol Assessment Level (OPAL)



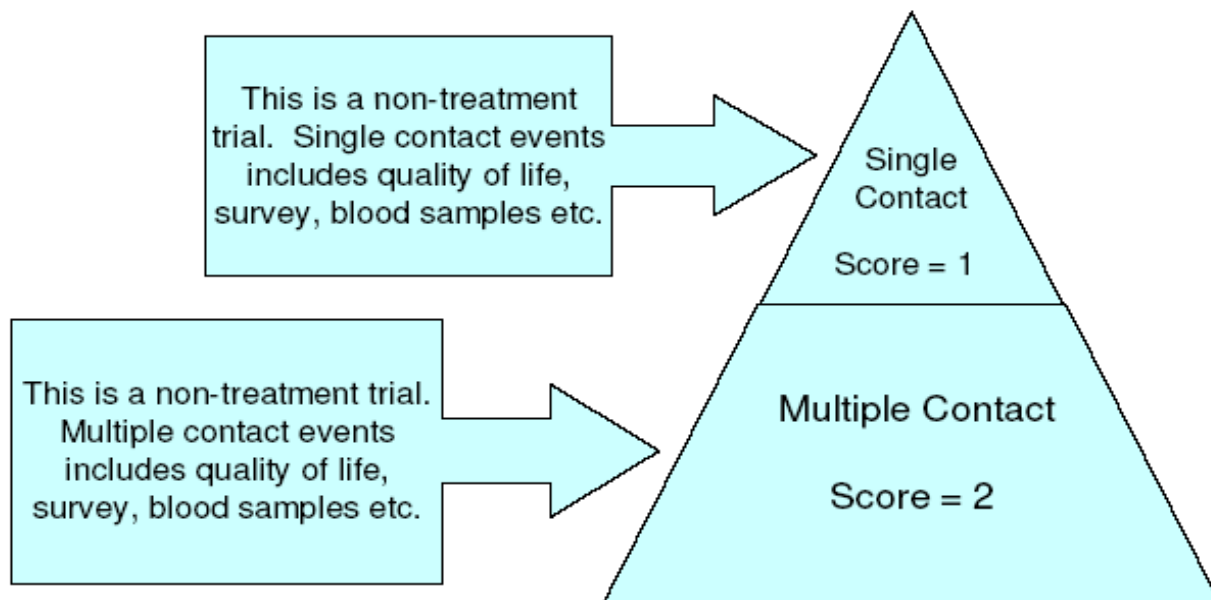


What is OPAL?

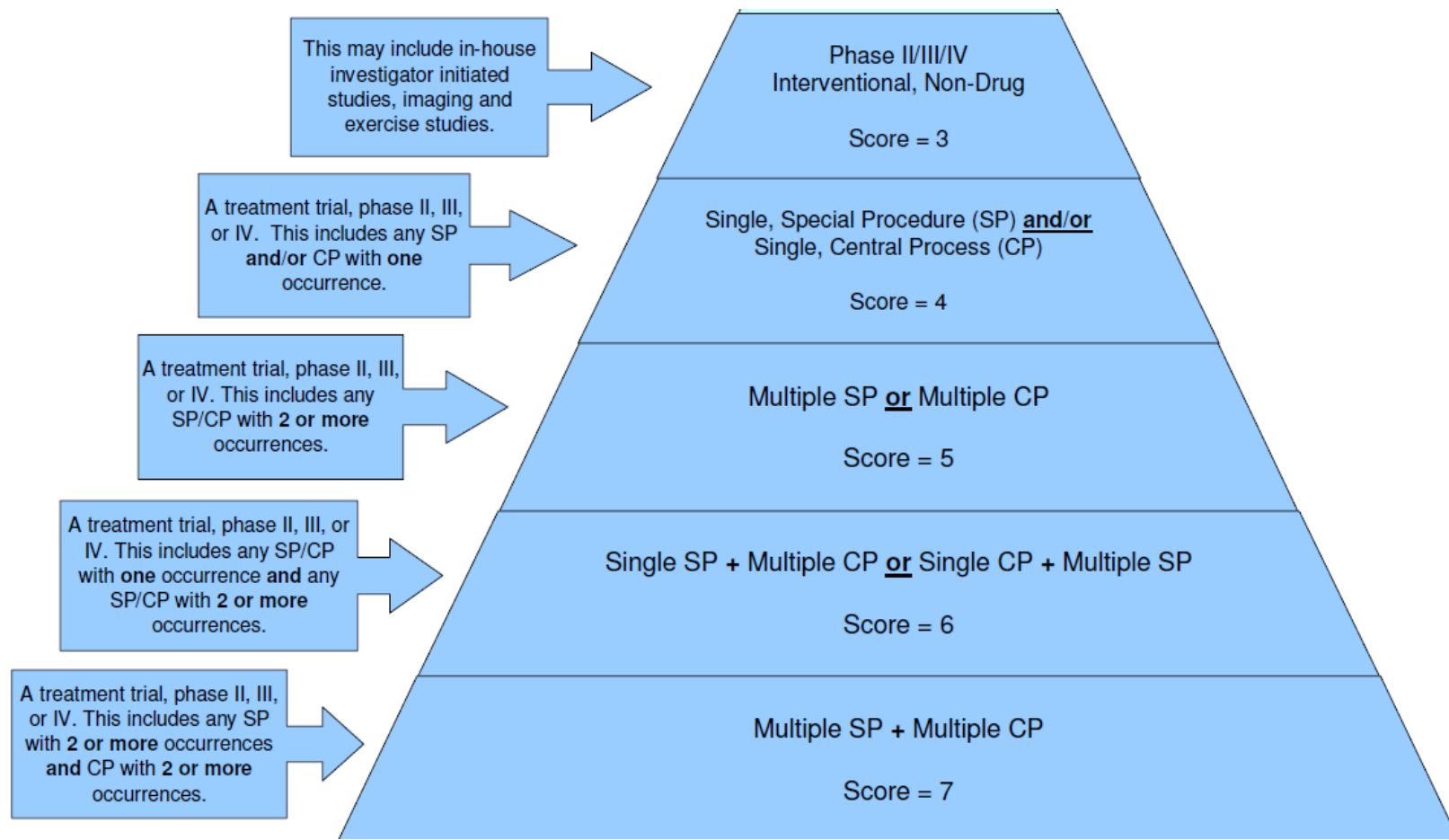
- A protocol complexity rating scale
- Begins with non-treatment trials at levels 1 and 2
- Progressively advances to complex Phase I intervention trials at level 8
- Additional weighting factors at 0.5 increments



OPAL - Levels 1 and 2 (Non-treatment trials)



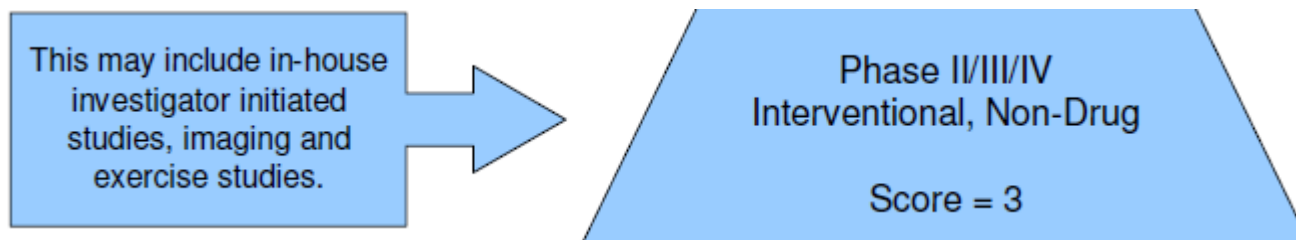
OPAL: Levels 3 to 7





OPAL - Level 3

- Interventional, Non-Drug





Definitions – Level 4 to 7

- Occurrences During the Clinical Trial:
 - Single Occurrence:
 - Any single procedure or process with **one** occurrence or any multiple procedures or processes with **one** occurrence
 - Multiple Occurrence:
 - Any single procedure or process with **2 or more** occurrences or any multiple procedures or processes with **2 or more** occurrences





Definitions – Level 4 to 7 (continued)

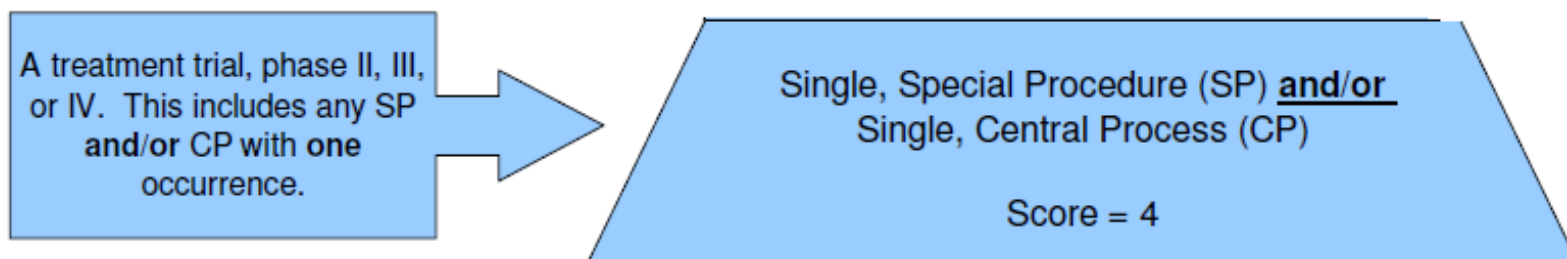
- **Central Process Review (CP)** may include: laboratory, pathology, radiology, tumour banking, archived tissues
- **Special Procedures (SP)** may include: PK sampling (pre & post), ECG, serial lab/ECGs, biomarker specimens, blood banking, eligibility biomarkers such as KRAS, EGFR, HER2





OPAL - Level 4

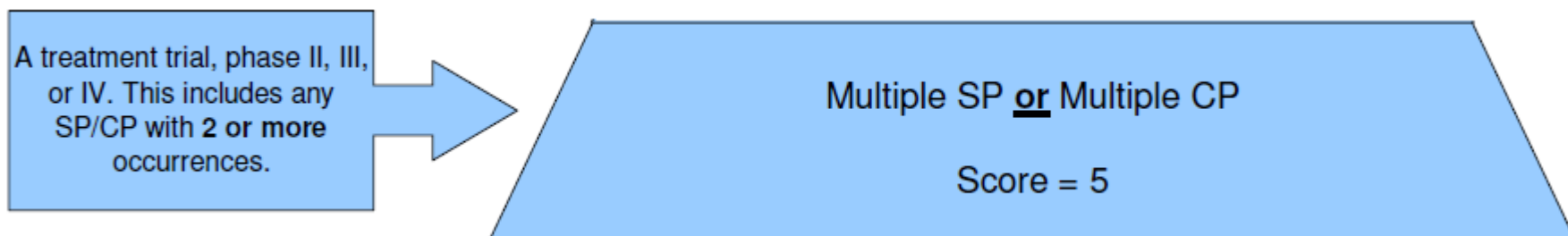
- Treatment trial, single occurrence





OPAL - Level 5

- Treatment trial, 2 or more occurrences





OPAL - Level 6

- Treatment trial, SP/CP with one occurrence **and** SP/CP with 2 or more occurrences

A treatment trial, phase II, III, or IV. This includes any SP/CP with **one** occurrence **and** any SP/CP with **2 or more** occurrences.

Single SP + Multiple CP or Single CP + Multiple SP

Score = 6



OPAL - Level 7

- Treatment trial, SP with 2 or more occurrences **and** CP with 2 or more occurrences

A treatment trial, phase II, III, or IV. This includes any SP with 2 or more occurrences **and** CP with 2 or more occurrences.

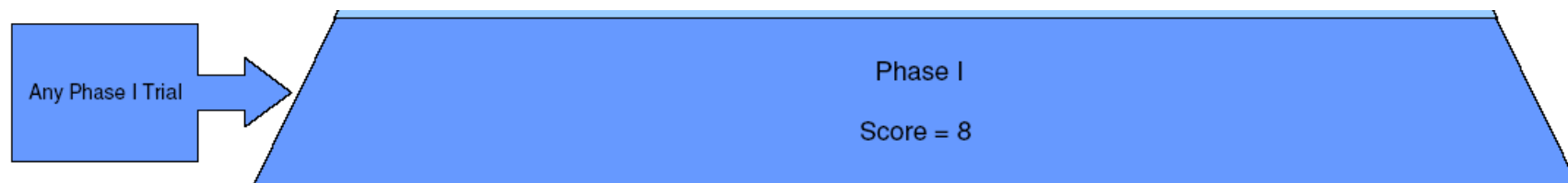
Multiple SP + Multiple CP

Score = 7



OPAL - Level 8

- Phase 1 trial





OPAL - Additional Components

- Add 0.5 to each level for the following:

Add Ins	
Weight	Components
0.5	Protocol Mandated In-Patient
0.5	On Site Monitoring or 100% Source Documents Submission
0.5	Number or Duration of Treatment/Follow Up Visits
0.5	Industry Sponsor/CRO Factor
0.5	Multiple (≥ 3) Surveys/Questionnaires



THE C.R.A. COMES BACK TO WORK AFTER A 3-DAY VACATION:



(c) Don Mayne



Why use OPAL?

Application of OPAL:

- The ability to provide a snapshot of the department's activity
- Used to determine workload capacity
- Demonstrates difference in actual workload based on complexity of the trials





Calculating Workload

Four steps:

1. Determine protocol complexity
2. Calculate patient or case workload
3. Total workload for the trial
4. Total workload for each individual





Step One

Determine protocol complexity:

- Rate all clinical trial protocols using OPAL
- The assigned OPAL score represents the protocol workload





Protocol Workload

- The work required to maintain the clinical trial protocol





Protocol Administration

- Protocol review
- Informed consent form
- Committee review
- Cost/impact
- Sponsor regulated documents
- Site startup tools
- CRFs, edata
- Source documentation
- SAEs
- Queries
- Amendments
- Annual review
- Maintaining study documents





Step Two

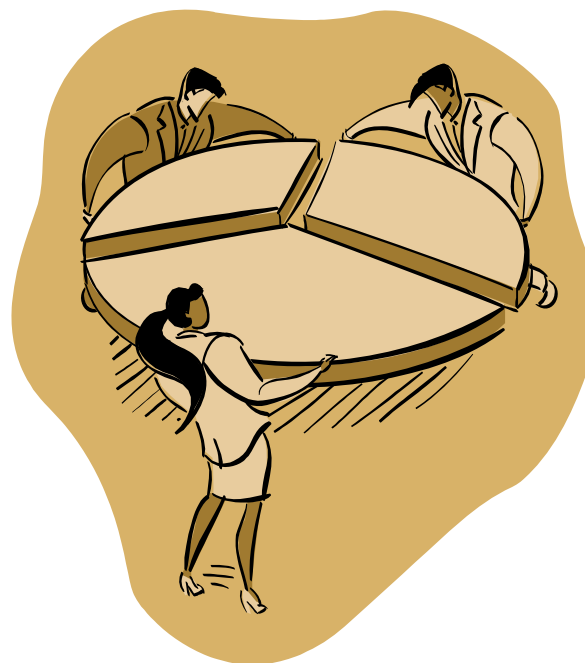
Calculating patient or case workload:

- Multiply the number of **active cases** by the OPAL score:
 - OPAL Score x Active Cases
- Multiply the number of **follow up cases** by half the OPAL score:
 - OPAL Score/2 x Follow Up Cases



Shared Workload

- If workload is divided between staff members, a percentage of patient or case workload is allocated accordingly





Step Three

Total workload for the trial:

- Total Case Workload + Total Trial OPAL Score
- Process is repeated for each study protocol





Example of Calculating Total Trial Workload

- Coordinator enrolls 4 subjects to a trial protocol with an OPAL score of 5
- Active Case Workload = $5 \times 4 = 20$
- Total Workload = $20 + 5$ (OPAL score) = 25





Step Four

Total workload for each individual:

- Add each trial workload together for each individual within the clinical trials department



Example – Staff #1

Trial	OPAL Level	Active Cases	Follow Up Cases	Workload
A	4	5	1	26
B	5	12	0	65
C	7	3	1	31.5
D	5	4	0	25
Total	-	24	2	147.5

Example – Staff #2

Trial	OPAL Level	Active Cases	Follow Up Cases	Workload
E	6	3	1	27
F	7	2	0	21
G	2	14	0	30
H	6	5	1	39
Total	-	24	2	117

Comparing Total Workload Between Staff

Reporting Period: 01/01/2010 - 03/31/2010

Staff	Average OPAL Score	Total Active Cases	Total Follow Up Cases	Total Workload
Sue	5.00	20	4	106.0
John	7.00	16	4	142.5
Mary	4.25	16	4	98.0
Joe	4.25	16	4	83.0





Analyze the Results

- John, Mary and Joe have the same number of cases, but John has the highest workload
- Sue has the most active cases, but her workload is not the heaviest
- Joe may have the same number of active cases, but by using OPAL it is obvious that his workload is lighter than his peers
- *Conclusion: the application of OPAL demonstrates difference in actual workload based on complexity of the trials*





Total Workload

Total workload scores can provide:

- Average number of cases managed per staff
- Average number of trials per staff
- Total workload per staff
- Ability to equalize or capture distribution of workload
- Objective data to assess need for additional or reallocation of resources





For More Information:

Smuck B, Bettello P, Berghout K, et al:

Ontario Protocol Assessment Level: Clinical Trial Complexity Rating Tool for Workload Planning in Oncology Clinical Trials

Journal of Oncology Practice 7: 80-84, 2011





Questions

