Category: Resource Management and Finance - Work in Progress

Development of an Enhanced Clinical Trial Workload Assessment Tool – The BC Clinical Trial Complexity Tool

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BC Cancer

1. Background

The complexity of cancer clinical trials and the associated workload has significantly increased over time, requiring more research personnel to perform study-related activities. This situation poses human resource challenges for Clinical Research Unit (CRU) leaders to overcome. BC Cancer comprises six regional centers, each with a CRU, that combined, conduct approximately 400 clinical trials of varying complexity, accruing over 800 patients per year. CRU managers do not have validated tools to evaluate the workload and staffing resources required for any given trial, therefore, allocations are made subjectively. A tool that can proactively evaluate, quantify, and document the expected work required to execute a clinical trial effectively would be invaluable to clinical trial sites to determinate appropriate staffing levels and allocations.

2. Goals

The objective of this project was to develop an enhanced workload assessment tool that can reliably evaluate and predict staff workload based on measures of individual trial complexity, enable proper distribution of workload, and be reproducible across clinical trial sites.

3. Solutions and Methods

Clinical research stakeholders who had significant knowledge of this topic were initially engaged. A comprehensive literature review was carried out which confirmed the need for an improved tool to capture clinical trial workload. An online survey was distributed to clinical trial managers across Canada through the Canadian Cancer Clinical Trials Network (3CTN) to understand their current practices for staff workload assessment and gauge their interest in using an enhanced tool.

Prior validated assessment tools, such as IRST Workload Assessment Tool (IWAT), Ontario Protocol Assessment Level (OPAL), 3CTN Academic Cancer Trial Portfolio Complexity Tool, and the National Cancer Institute (NCI)Trial Complexity and Elements Scoring Model, were analyzed for strengths and weaknesses and incorporated into the development of an enhanced tool.

4. Outcomes

Literature review revealed that current workload assessment tools were focused on specific elements or created for another effort and fell short of adequately capturing trial-associated workload. The online survey revealed only 21 percent of CRU managers currently use a tool to measure trial associated workload and 73 percent of CRU managers considered adopting a tool a high-priority need.

Findings from literature, established tools, survey results, and work experience were integrated to develop the BC Clinical Trial Complexity Tool (BC-CT2) in 2022. The BC-CT2 allows for objective measurements of protocol-specific and activity-specific complexity associated with the trial patient caseload. This tool is designed to focus on protocol complexity, administrative workload, data, and patient-related procedures. Trials are assigned low-, medium-, and high-complexity protocol scores and

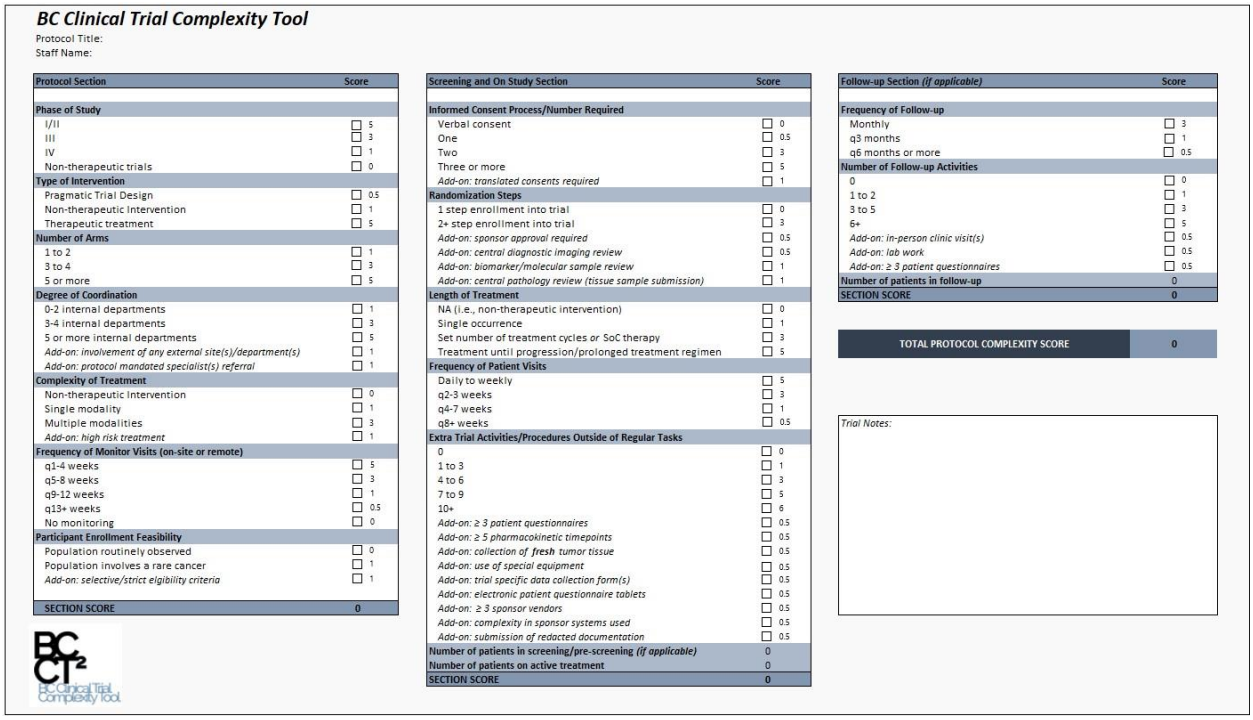
maximum workload capacity scores. The tool is simple and easy to use and allows for electronic completion and auto-calculation of scoring.

5. Lessons Learned and Future Directions

With the increasing complexity of clinical trials, a workload assessment tool was identified as a high-priority need. We attempt to resolve this issue by creating an objective workload assessment tool that is simple and easy to use.

Next steps involve validating the tool by evaluating clinical trial workload across the six BC Cancer CRUs as well as a retrospective comparison of BC-CT2 against other tools, such as OPAL, to determine accuracy in measuring trial workload.

Figure



BC Clinical Trial Complexity Tool

Protocol Title:
Staff Name:

Protocol Section	Score
Phase of Study	
I/II	☐ 5
III	☐ 3
IV	☐ 1
Non-therapeutic trials	☐ 0
Type of Intervention	
Pragmatic Trial Design	☐ 0.5
Non-therapeutic Intervention	☐ 1
Therapeutic treatment	☐ 5
Number of Arms	
1 to 2	☐ 1
3 to 4	☐ 3
5 or more	☐ 5
Degree of Coordination	
0-2 internal departments	☐ 1
3-4 internal departments	☐ 3
5 or more internal departments	☐ 5
Add-on: involvement of any external site(s)/department(s)	☐ 1
Add-on: protocol mandated specialist(s) referral	☐ 1
Complexity of Treatment	
Non-therapeutic Intervention	☐ 0
Single modality	☐ 1
Multiple modalities	☐ 3
Add-on: high risk treatment	☐ 1
Frequency of Monitor Visits (on-site or remote)	
q1-4 weeks	☐ 5
q5-8 weeks	☐ 3
q9-12 weeks	☐ 1
q13+ weeks	☐ 0.5
No monitoring	☐ 0
Participant Enrollment Feasibility	
Population routinely observed	☐ 0
Population involves a rare cancer	☐ 1
Add-on: selective/strict elgibility criteria	☐ 1
SECTION SCORE	**0**

Screening and On Study Section	Score
Informed Consent Process/Number Required	
Verbal consent	☐ 0
One	☐ 0.5
Two	☐ 3
Three or more	☐ 5
Add-on: translated consents required	☐ 1
Randomization Steps	
1 step enrollment into trial	☐ 0
2+ step enrollment into trial	☐ 3
Add-on: sponsor approval required	☐ 0.5
Add-on: central diagnostic imaging review	☐ 0.5
Add-on: biomarker/molecular sample review	☐ 1
Add-on: central pathology review (tissue sample submission)	☐ 1
Length of Treatment	
NA (i.e., non-therapeutic intervention)	☐ 0
Single occurrence	☐ 1
Set number of treatment cycles or SoC therapy	☐ 3
Treatment until progression/prolonged treatment regimen	☐ 5
Frequency of Patient Visits	
Daily to weekly	☐ 5
q2-3 weeks	☐ 3
q4-7 weeks	☐ 1
q8+ weeks	☐ 0.5
Extra Trial Activities/Procedures Outside of Regular Tasks	
0	☐ 0
1 to 3	☐ 1
4 to 6	☐ 3
7 to 9	☐ 5
10+	☐ 6
Add-on: ≥ 3 patient questionnaires	☐ 0.5
Add-on: ≥ 5 pharmacokinetic timepoints	☐ 0.5
*Add-on: collection of **fresh** tumor tissue*	☐ 0.5
Add-on: use of special equipment	☐ 0.5
Add-on: trial specific data collection form(s)	☐ 0.5
Add-on: electronic patient questionnaire tablets	☐ 0.5
Add-on: ≥ 3 sponsor vendors	☐ 0.5
Add-on: complexity in sponsor systems used	☐ 0.5
Add-on: submission of redacted documentation	☐ 0.5
Number of patients in screening/pre-screening *(if applicable)*	0
Number of patients on active treatment	0
SECTION SCORE	**0**

Follow-up Section *(if applicable)*	Score
Frequency of Follow-up	
Monthly	☐ 3
q3 months	☐ 1
q6 months or more	☐ 0.5
Number of Follow-up Activities	
0	☐ 0
1 to 2	☐ 1
3 to 5	☐ 3
6+	☐ 5
Add-on: in-person clinic visit(s)	☐ 0.5
Add-on: lab work	☐ 0.5
Add-on: ≥ 3 patient questionnaires	☐ 0.5
Number of patients in follow-up	0
SECTION SCORE	**0**

TOTAL PROTOCOL COMPLEXITY SCORE	0

Trial Notes:

BC CT2 BC Clinical Trial Complexity Tool