Canadian
Cancer Clinical
Trials Network

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Portfolio Trials Complexity Weighting System Guidelines

1. Background

3CTN will be providing incentive based funding (IBF) to its Network sites for meeting performance targets. IBF amounts will be stratified based on the assigned trial complexity. This document outlines the process to assign a trial complexity score to Portfolio trials to determine IBF credit amounts.

2. Process

Once a trial has been approved for Portfolio status, the Coordinating Centre will review the trial and assign a trial complexity score and rating. The trial complexity rating will be inputted into the EDGE Clinical Trials Management System and be viewable on the 3CTN Portfolio website.

3. Assessing Trial Complexity

Trial complexity will be assessed using the Complexity Weighting Scale (Appendix A). Each Portfolio trial will be assigned a complexity score (0 – 12 points). The following overarching principles will be used:

- All interventions the patient receives from study enrollment to study exit (standard of care and research interventions) will be used to assess complexity;
- 3CTN will use the www.clinicaltrials.gov trial record and the submitted Portfolio Application Form to assess trial complexity. 3CTN assumes the information provided is correct;
- If trial complexity cannot be assessed using the Complexity Weighting Scale (i.e., trial is unique and does not fit within the predefined framework), the Coordinating Centre may adjust the complexity rating. The rating will be reviewed and approved by an additional reviewer.

The trial complexity score will be used to determine an overall complexity rating:

Complexity Rating	Complexity Score
Low	0-3
Standard	4-6
High	7+
Other (e.g., Low/2, Low/10)	-

Appendix A – Portfolio Trial Complexity Weighting Scale

#	Element	Low complexity 0 point	Standard complexity 1 point	High complexity 2 points
1*	Phase of study	III, IV, NA Non-therapeutic trials	II, II/III, Pilot/Cohort/ Feasibility	I, I/II
2	Study population N/A if therapeutic intent is: • Supportive care • Symptom control • Palliative care	• Adjuvant • Primary (locally directed therapy)	• Advanced/metastatic • Hematologic malignancy	N/A
3**	Complexity of trial intervention/trial design elements *Score all interventions the patient receives from enrollment to study exit (SOC and research interventions)*	• Single treatment modality/ • intervention • Single agent • Health-related behaviour intervention • Non-therapeutic intervention • Pragmatic trial design	• Multiple treatment modalities/ interventions **OR** • Multiple drugs/agents	• Multiple treatment modalities/ interventions **AND** • Multiple drugs/agents
4	Anticipated length of treatment *(use longest arm)*	• < 6 months • N/A (i.e., non-therapeutic intervention)	6-12 months	>12 months
5	Total study time *(per patient; from enrollment to study exit, including follow up period)*	N/A	≥5 years	N/A
6	Ancillary studies:			
a	Correlative science/lab/imaging	• None • Blood and archival tumour at baseline • Imaging at baseline	• Anything more than baseline collection (i.e., repeated blood or imaging)	• Repeated tissue biopsies (i.e., on or after treatment) • Pharmacokinetics, pharmacodynamics
b***	Patient Reported Outcomes and Health Services Research (i.e., cost analysis)	None	1-2 Instruments	≥3 Instruments

POST WEIGHTING ADJUSTMENTS

- Unique trial designs
  - (-2): cluster design
  - (-1): low complexity trial methods (i.e., non-traditional trial methods/integrated consent model/verbal consent/no consent needed)
    - *Note: This is due to the emerging trend in real-world evidence. Real-world evidence is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of Real-world data. RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).*
- If after post weighing adjustment, the score becomes <0 (i.e., -2), PCF discount factors may be applied.
- If the trial complexity cannot be assessed using the Complexity Weighting Scale (i.e., trial is unique, does not fit within the predefined framework or the score appears to be contradictory to the study design) the Portfolio and Informatics Manager may adjust the complexity rating. The rating will be reviewed and approved by an additional reviewer.

*Pilot/cohort/feasibility studies are automatically standard complexity (i.e., phase is overridden)
** NIH definition of clinical trial interventions examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html
***QOL questionnaire over multiple time points is considered standard complexity. Multiple QOL questionnaires over multiple time points is considered high complexity

Document Revision History

Version	Date	Description	Approval
DRAFT	June 1, 2015	New document	
1.0	June 30, 2015	Final document	Steering Committee
2.0	October 9, 2019	• Updated document for consistency with 3CTN Strategic Plan 2018-22 and per case funding rates • Wording changes to accurately reflect the element and provide clarity • Adjustments in complexity levels for non-therapeutic trials (i.e., in treatment length, phase of study, complexity of trial intervention). • Adjustments to overall weighting scale for unique trial designs (i.e., cluster design, pragmatic trials)	Portfolio Committee September 26, 2019
3.0	August 4, 2022	• Updated to reflect incentive based funding model of 2022-2027	