

Canadian Cancer Clinical Trials Network Portfolio Trials Complexity Weighting System Guidelines

1. Background

3CTN will be providing per case funding (PCF) to its Network sites for recruitment above baseline to its Portfolio trials. PCF 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 calculate PCF.

2. Process

Once a trial has been approved for inclusion on the 3CTN Portfolio, the Manager, Operations will review the trial and assign a trial complexity score which will be translated into a complexity rating (low, standard or high). The trial complexity rating will be recorded in the EDGE Clinical Trials Management System at the 3CTN Coordinating Centre and be viewable on the 3CTN Portfolio website.

3. Assessing Trial Complexity

Trial complexity will be assessed using the 3CTN Trial Complexity Weighting Scale (TCWS)*. Each portfolio trial will be assigned a complexity score (0 – 12 points). The following overarching principles are used during complexity score assessment:

- 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 TCWS (i.e., trial is unique and does not fit within the predefined framework), the Manager, Operations may adjust the complexity rating. If this is the case, the rating for the trial in question will be reviewed and approved by an additional reviewer.

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

Complexity Score	Complexity Rating	PCF
0-3	Low	\$1000
4-6	Standard	\$1500
7+	High	\$2000

*for more information on the 3CTN Trial Complexity Weighting Scale, contact info@3ctn.ca.

4. Application to Per Case Funding

Network sites are eligible for PCF once recruitment to Portfolio trials has exceeded their previously established baseline. The 3CTN Coordinating Centre will then determine total PCF for each site based on the site quarterly recruitment reports and the assigned complexity rating of each trial. The PCF amounts are subject to the availability of funding and may be modified.

Document Revision History

Version	Date	Description
DRAFT	June 1, 2015	New document
1.0	June 30, 2015	Final document approved by the Steering Committee.