Canadian Cancer Clinical Trials Network

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Remote Access Incentive Based Funding Definition

1. Introduction

Access to clinical trials is limited for many Canadians. The distance to the nearest cancer centre currently precludes at least 10 million Canadians from participating in trials[1,2]. Trial recruitment and retention is challenging for these patients. Healthcare providers and patients cite the ability for attending study visits that take place at the cancer centre as a primary factor for considering trial participation[3]. Making trials more available in community healthcare centres would broaden treatment options for individuals.

Definitions:

Primary Trial Site	The cancer centre where a clinical trial is open to enrollment
Satellite Trial Site	• A health care provider other than the Primary Trial Site that is set-up to perform specific study related activities. Can be an alternate health care provider closer to the patient's home (e.g., family physician, community hospital, local oncology centre) or the primary oncology site, if the patient has travelled elsewhere to access a clinical trial. • To constitute a closer to home health care provider (C2H-HCP) as a satellite site, there should be a qualified healthcare professional who is trained in Health Canada Division 5 and Good Clinical Practice, as well as just-in-time training for the protocol. The C2H-HCP: ○ may be a licensed oncologist or other relevant medical specialist, general practitioner, or a nurse practitioner. ○ is responsible for ensuring the study tasks/treatments are completed and overseen as per protocol, such as data capture, AE capture/reporting as per protocol, dose modifications if required, concomitant medicines review, and data submission.
Primary oncology site (PO-site)	The regular oncology treatment centre for the patient
IBF	Incentive based funding

2. Remote Access 3CTN Incentive-Based Funding Objectives and Qualifying Scenarios

3CTN remote access IBF will focus on incentivizing closer-to-home clinical trial conduct. This is applicable but is not limited to the following scenarios:

[1] Statistics Canada. Focus on Geography Series, 2016 Census 2017 April 18, 2019; Available from: https://www12.statcan.gc.ca/census-recensement/2016/as-sa/fogs-spg/Facts-can-eng.cfm?Lang=Eng&GK=CAN&GC=01&TOPIC=1.

[2] Canadian Organization of Medical Physicists. *Canadian Cancer Centres*. February 2020]; Available from: https://www.comp-ocpm.ca/english/career-education/career-resources/canadian-cancer-centres.html.

[3] Humer, M.F. and B.G. Campling, The Role of Telemedicine in Providing Thoracic Oncology Care to Remote Areas of British Columbia. Curr Oncol Rep, 2017. 19(8): p. 52.

RA-1. The patient participates in a clinical trial at their PO-site. Arrangements are made for study-specific treatments/tests to be conducted and/or managed at a C2H-HCP.

RA-2. The patient is eligible for a clinical trial that their PO-site does not have open. As part of their participation in the clinical trial, arrangements are made for specific study treatments/tests to be conducted and/or managed at the patient's PO-site.

RA-3. The patient is eligible for a clinical trial that their PO-site does not have open and would otherwise be either unwilling or unable to access their PO-site for supported trial visits. Arrangements are made for specific study treatments/tests to be conducted/managed at a C2H-HCP.

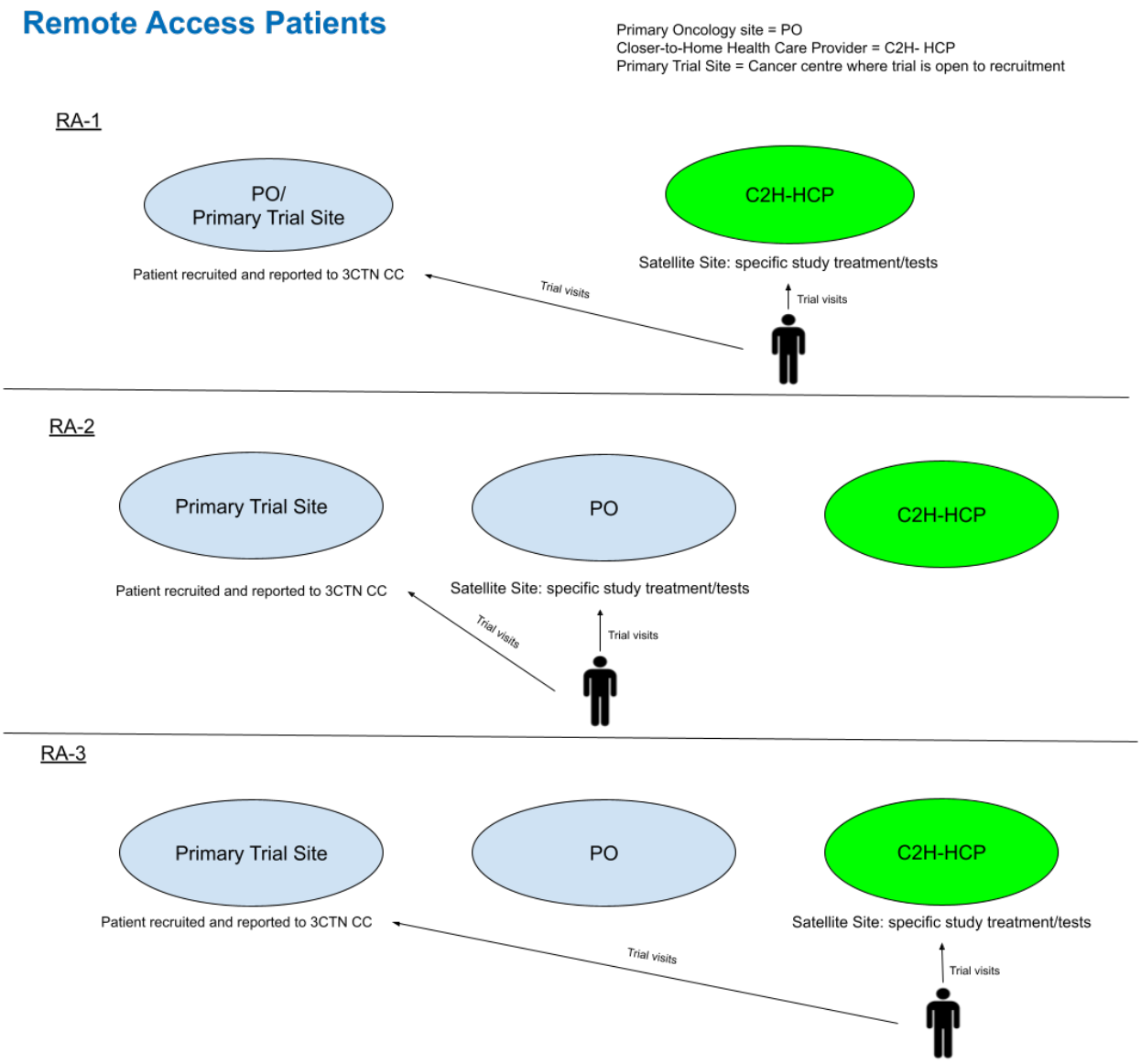

Figure 1. Possible scenarios for remote access patients

Qualifying examples of Satellite Site Clinical Trial Conduct

- Physical health exam, history, other wellness exams
- Remote patient follow-up, assessments
- Clinical management to adverse events in consultation with the study-site
- Data-capture for study-related conduct
- Administration of chemotherapy or other study-related treatments
- Administration of non-therapeutic trial interventions (e.g. imaging)
- Psychosocial and supportive care related to the study
- Administration of maintenance therapy
- Laboratory-based tests facilitated closer-to-home IF by doing so the number of patient visits, interpretation of results and trial patient management is delegated to the satellite site

Exceptions:

In keeping with the stated goals of IBF for promoting remote access to oncology clinical trials, the following situations would not qualify:

- Study-related activities that take place prior to enrollment (Informed consent, eligibility)
- Referrals from another PO-site

3. Assessment of IBF Eligibility

The Primary Trial Site will be responsible for reporting to 3CTN and use the reporting template to provide information related to the trial, involved sites and remote patients recruited. 3CTN may request additional information to ensure the trial and Primary Trial Site/PO/C2H-HCP structure meets the goal of remote access IBF. Reported remote patients may be ineligible for IBF if it does not meet the principles and definitions outlined in this document.

Similar to previous applications to Per Case Funding, trials with uniquely low complexity designs may be subjected to an IBF discounted factor.

4. Recommended Reading & Resources

- Canadian Remote Access Framework for Clinical Trials (CRAFT) (May 2020)
- Resources for Enabling Clinical Trials at Satellite Sites: https://3ctn.ca/for-researchers/craft/

5. Acknowledgements

This document was adapted from: C17 Pediatric Remote Access Definitions for 3CTN (Nov 2020).