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. Patient is recruited by the Primary Trial Site that is operating a trial with a Secondary Trial Site through Joint Trial Management. Arrangements are made for study-specific activities to be conducted or managed at a PO site not part of the Joint Trial Management setup.

RA-4. Patient is recruited by the Primary Trial Site that is operating a trial with a Secondary Trial Site through Joint Trial Management. Arrangements are made for study-specific activities to be conducted or managed at a C2H-HCP not part of the Joint Trial Management setup.

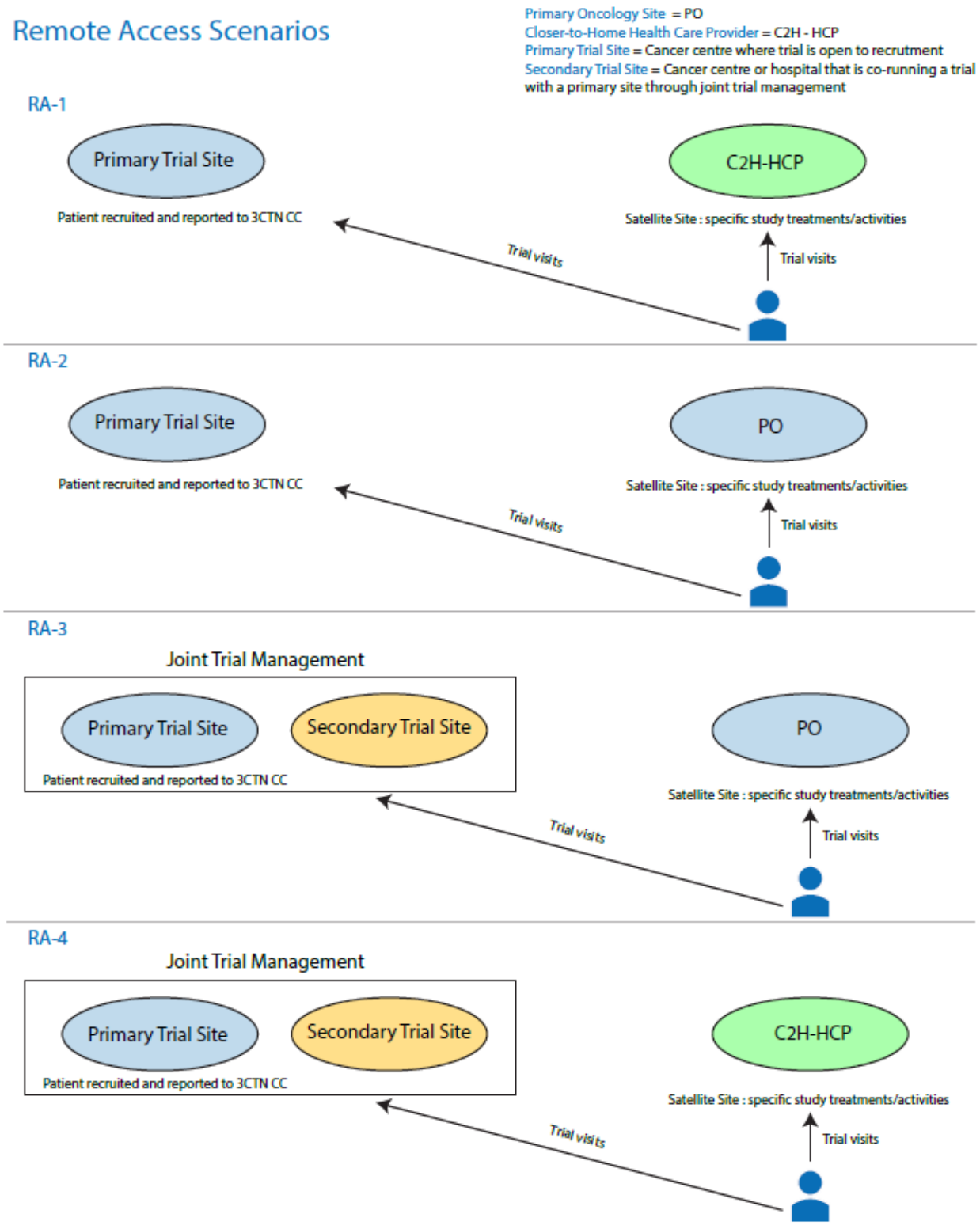

Figure 1. Possible scenarios for remote access patients

Qualifying examples of Satellite Site Clinical Trial Conduct

- Physical health exam, history, other wellness exams
- Remote patient follow-up, assessments
- Clinical responses 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 visits to the primary trial site is reduced
    - For example, a patient requires regular blood work to monitor for hematology based AE development. Instead of traveling to the primary trial site only for the purpose of lab tests (no study visit scheduled), the primary trial site arranges for the patient to perform the lab tests closer-to-home. The lab sends the results to the delegated physician to be reviewed; the patient does not need to come into the primary trial site for the tests or review of the tests.
    - Conversely, if lab tests are performed at an outside lab to be reviewed during the patients upcoming study visit, the number of visits to the primary trial site has not been eliminated. Although this is beneficial to the patient as the study visit may be shortened, the need burden of travel to the primary trial site has not been reduced.

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
- Joint trial management, whereby a primary trial site is unable to conduct all aspects of the trial and needs to collaborate with secondary trial site(s) (i.e., a patient, if they choose to, cannot attend all trial visits at the primary trial site and will need to travel to the secondary trial 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).

Document Revision History

Version	Date	Description	Author
1.0	3/1/2021	New Document	D. Kato, J. Schoales
2.0	10/4/2023	Updated exceptions and added new remote access patient scenarios RA-4, RA-5	D. Kato, J. Schoales Approved: 3CTN Management Committee