Pediatric Remote Access 3CTN Incentive-Based Funding

Definitions

Closer to home health care provider (C2H-HCP)	A health care provider other than the study-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 adult oncology centre) or the primary pediatric oncology site, if the patient has travelled elsewhere to access a clinical trial.
Primary pediatric oncology site (PPO-site)	The regular pediatric oncology treatment centre for the patient
IBF	Incentive based funding
Study-site	The pediatric cancer centre where a clinical trial is open to enrollment

Introduction

There are 17 sites in Canada that are responsible for treatment of pediatric oncology patients, and it has been estimated that 34% of Canadian children live more than 100 km from one of these sites (Klein-Geltink 2005). Many of these sites serve vast geographical areas, as there may be only 1-2 sites for the province and/or sites may serve remote out-of-province areas.

Reducing geographical/travel barriers to equitable access to clinical trials can be achieved by two overarching and inter-related mechanisms.

1. **Bringing a patient to a study:** Facilitating the enrollment of patient to a clinical trial that is not available at the patient's primary pediatric oncology site (PPO-site). This may involve preliminary telemedicine visits between the study-site and the patient/family, before the patient temporarily relocates to participate in the clinical trial. It may also include arranging to for selected procedures to be conducted and/or managed closer to home (see below).
2. **Bringing components of the study closer to the patient (closer-to-home study conduct):** Reducing the visits to the study-site by facilitating specific study procedures to be conducted by a closer-to-home healthcare provider (C2H-HCP).

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The goal of incentive based funding (IBF) for remote access to pediatric oncology clinical trials is to increase the accessibility of clinical trials by reducing the barrier of distance (geographical, travel time) from the patient's home to the clinical trial site (study-site). Note that, for the purpose of IBF, 3CTN will not consider the enrollment of a patient from a different PPO-site to be sufficient to release remote access IBF.

3CTN remote access IBF will focus on incentivizing closer-to-home clinical trial conduct. This is applicable to the following scenarios:

RA-1. The patient participates in a clinical trial at their PPO-site (study-site is the PPO-site). The study staff arrange for specific study treatments/tests to be conducted and/or managed at a C2H-HCP.

RA-2. The patient is eligible for a clinical trial that their PPO-site cannot open. As part of their participation in the clinical trial, the study staff arrange for specific study treatments/tests to be conducted and/or managed at the patient's PPO-site.

RA-3. The patient is eligible for a clinical trial that their PPO-site cannot open. The patient does not live close to their PPO-site. As part of their participation in the clinical trial, the study-site arranges for specific study treatments/tests to be conducted/managed at a C2H-HCP.

Examples of Closer-to-Home Clinical Trial Conduct

- Physical health exam, history, other wellness exams

- Screening for adverse events
- Clinical responses to adverse events in consultation with the study-site
- Data-capture for study-related conduct
- Psychosocial and supportive care related to the study
- Administration of chemotherapy or other study-related treatments, as appropriate
- Administration of maintenance therapy
- Laboratory-based tests facilitated closer-to-home IF by doing so the number of visits to the study-site is reduced
    - For example, a patient requires regular blood work to monitor for hematology based AE development. Instead of traveling to the study-site only for the purpose of lab tests (no study visit scheduled), the study-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 study 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 study-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 study-site has not been reduced.

Note that 3CTN has determined that study-related activities that take place prior to enrollment (Informed consent, eligibility) do not constitute remote access for the purpose of IBF.

Definition of Closer-to-Home Health Care Provider (C2H-HCP)

- Includes, but is not restricted to formal satellite programs such as the POGO Satellite Program in Ontario and the Atlantic Provinces Pediatric Hematology Oncology Network.
- To constitute a C2H-HCP, there should be one person (a physician) 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 physician can be a family doctor, pediatrician or adult oncologist.
    - The C2H-HCP physician 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.
    - A second person such as a research manager or CRA also may be trained and is recommended, but is not required.

Resources—Recommended Reading

Includes pediatric oncology specific documentation and tools for selecting C2H-appropriate sites and study-related activities.

Atlantic Provinces Pediatric Hematology Oncology Network. Levels of care approach for hematology/ oncology care of adolescents and children within the Atlantic Provinces (2018)

POGO Provincial Pediatric Oncology Satellite Manual (rev Oct 2016) https://www.pogo.ca/satellite-manual/

Additional References and Resources

Canadian Remote Access Framework for Clinical Trials (CRAFT) (May 2020)

Childhood Cancer Care Plan: A Roadmap for Ontario, 2018-2023. Toronto: Pediatric Oncology Group of Ontario (POGO);2018

Klein-Geltink, J.E., Pogany, L.M., Barr, R.D., Greenberg, M.L. and Mery, L.S. (2005), Waiting times for cancer care in Canadian children: Impact of distance, clinical, and demographic factors. Pediatr. Blood Cancer, 44: 318-327. doi:10.1002/pbc.20156