Canadian Cancer Clinical Trials Network

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Pediatric High Priority Trials

The 3CTN-C17 pediatric node aims to expedite high priority trials that have the potential to improve access or advance novel initiatives, by providing incentive based funding to pediatric Network Affiliated Cancer Centres (NACCs) for a high priority trial (HPT) that opens for enrollment (date on CTSI) within 90 days of NOL/Sponsor activation date (whichever is latest). The identification of HPTs will be the responsibility of C17.

1. Process for C17 Identification of Pediatric High Priority Trials

Potential high priority trials will be selected annually by C17 clinical trial leadership consisting of:

- C17 Executive
- C17 Directors: the pediatric oncology/hematology division head at each site
- C17 Senior Medical Officers
- C17 DVL Co-Chairs
- PROFYLE Therapeutic Node (PTN) Co-Chairs (Precision Medicine)
- Parent/Patient representative

At the beginning of each fiscal year, or more frequently if required, relevant studies are entered into a survey to be assessed for consideration as a HPT. From the slate of studies to be considered, respondents are asked to rank qualifying studies based on alignment with the following criteria:

- Studies that target an important question for a patient population in need of new treatments
- New approaches to treatment, i.e., precision medicine
- Study critical to generate new knowledge, answer questions, provide access
- Important trial for Canada and C17 centres participation

A comment box is included to capture additional information. Study candidates are not restricted to those identified by C17. If there are studies not listed that respondents consider to be of high priority and meet 3CTN's Portfolio trial eligibility criteria, then they are encouraged to provide the study name in the space provided in the survey.

The HPT criteria are not further defined, each respondent considers the ranking in the context of:

- Their own centre (study availability; centre size)
- Treatment areas of expertise (e.g., CNS, relapse, BMT)
- Committees that they represent
- The importance of making the protocol treatment widely available to the patients that they treat

Once a HPT has been identified, 3CTN will be notified according to Figure 1.

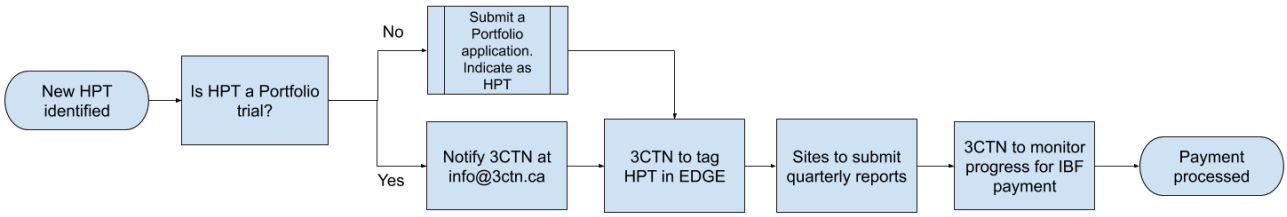

Figure 1. Pediatric High Priority Trials Process Map

2. Communication of HPTs

C17 will notify all sites of the HPTs as they are identified, including projected and finalized target opening dates. As outlined in 3CTN's Communications Plan, HPTs will be featured in:

- The Portfolio Watch, a monthly electronic newsletter circulated to 3CTN lead site contacts, Portfolio applicants, sponsor groups and research contacts
- 3CTN's social media accounts
- 3CTN Portfolio Sub-Committee meetings. The Committee provides scientific oversight of the Portfolio

3. 3CTN Process for HPT IBF Eligibility - tracking and IBF Payments

Once C17 notifies 3CTN, the trial will be marked as a HPT in EDGE, for tracking purposes. As pediatric NACCs submit trial activation data as part of their usual quarterly reporting requirements, eligibility for credit towards year-end IBF calculation will be assessed, and disbursements processed as per the Site Agreement.

Document Revision History

Version	Date	Description	Author
1.0	1/5/2021	New document	D. Kato, R. Xu (3CTN) L. Young (C17)
1.1	5/26/2021	Process updated to include timing of HPT identification	L. Young (C17)
1.2	6/7/2023	Communication and Process for IBF updated to align with Strategic Plan 2022-2027	D. Kato, S. Sundquist (3CTN), E. Goll (C17)