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.

Relevant studies are entered into a REDCap survey to be ranked for consideration as a HPT. From the slate of studies to be considered, the respondents identify which studies they feel should not be considered for HPT-designation, and rank the remaining studies. A comment box is included to capture additional information.

Respondents are given the following criteria to assess priority:

- 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.

If there are studies not listed that respondents consider to be of high priority, then they are encouraged to provide the study name in the space provided in the survey. Studies are not restricted to those sponsored by C17, but they do need to meet 3CTN's Portfolio trial eligibility criteria.

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.

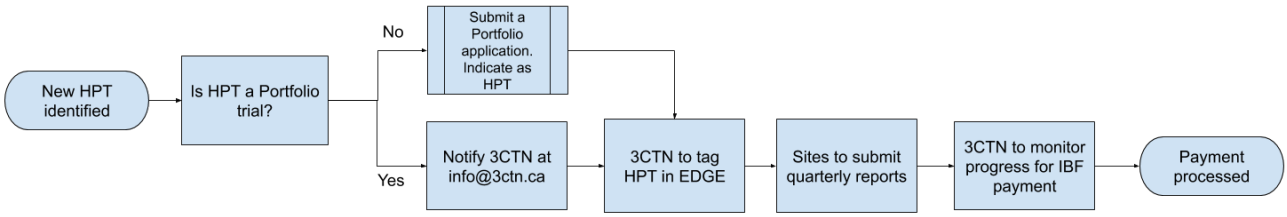

Figure 1. Pediatric High Priority Trials Process Map

2. 3CTN Process for HPT and IBF

Once C17 notifies 3CTN of a new high priority Portfolio trial, the 3CTN Portfolio Coordinator will mark the trial as a HPT in EDGE, for tracking purposes. Pediatric NACCs will submit trial activation data as part of the reporting requirements and 3CTN will monitor the progress of HPTs and determine eligibility for incentive based funding quarterly. Once an NACC has met the target timeline of 90 days from date of NOL to trial open to recruitment, 3CTN will process the IBF payment, as per the Site Agreement.

3. 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;
- Standing 3CTN Portfolio Committee meetings. The Committee provides scientific oversight of the Portfolio.

Document Revision History

Version	Date	Description	Author
1.0	1/5/2021	New document	D. Kato, R. Xu (3CTN) L. Young (C17)