

## 3CTN Year 8 Incentive Based Funding (IBF) Frequently Asked Questions & Answers

### **Adult Network Sites**

#### ***Why was the funding model changed from Per Case Funding (PCF) to Incentive Based Funding (IBF)?***

The change comes as part of the Network response to projected impacts on new trial activations and accrual to open studies experienced by the large majority of adult Cancer Centres. Given most Network sites are not projected to meet recruitment targets or earn PCF for Year 7 and the anticipated implications of COVID-19 extending well into Year 8, the new IBF elements collectively aim to facilitate a rapid recovery of academic cancer clinical trials activity in the period.

Input on possible options for the PCF funding envelope were elicited from Network members through the first half of the fiscal year and the 3CTN Management and Funders Oversight Committees approved the IBF model during meetings last fall. The funding criteria and rationale for each element/factor in the approved model has been circulated to all sites, presented at the 2020 Annual Stakeholder Meeting and at quarterly site meetings.

For details, refer to: [Year 8 IBF factors and rates](#).

#### ***Are sites still eligible to earn PCF in Year 7?***

Yes. Adult and eligible pediatric Network sites will receive Year 7 PCF up to max budget cap, as outlined in 3CTN-Site Agreements. Any remaining balance of funds in the PCF envelope will be rolled over to Year 8 and incorporated into the IBF budget.

#### ***Will sites that exceed their Year 8 accrual targets be eligible for PCF?***

Aside from eligible accruals involving remote patient management, there is no available PCF budget planned for Year 8.

#### ***Why do we need to report accrual data for our site's Portfolio trials if there is no PCF in Year 8?***

The change in funding model applicable to Year 8 is intended as a targeted response to extraordinary circumstances affecting all Cancer Centres' current capacity to conduct trials. The overarching 3CTN goal to increase recruitment to academic cancer clinical trials is one that is shared by all member Cancer Centres. Continuing to collect trial recruitment as well as other performance data is necessary for monitoring changes and reporting trends in Canada's ACCT ecosystem to Network funders and stakeholders as well as for helping define new PCF targets as well as other incentives that may be beneficial to addressing priorities in years ahead.

#### ***What trials would qualify for IBF? What does this mean for trials already active and recruiting?***

- Portfolio trials open to recruitment on or after April 1, 2021 would qualify.
- Incentive funding for remote patient management would apply to applicable patients accrued to open Portfolio trials on or after April 1, 2021

#### ***What is the definition of a remote patient?***

A remote patient is enrolled in a clinical trial at a cancer centre who has study visits conducted at a satellite site closer to home by their local clinical oncologist or other specialized care provider. For more information, visit [Canadian Remote Access Framework for Clinical Trials \(CRAFT\)](#).

***What are the trial activation metrics and definitions used to determine IBF eligibility?***

For trial activation metrics and definitions, visit <https://3ctn.ca/files/reporting-obligations-for-3ctn-award-recipients>. Please contact [info@3ctn.ca](mailto:info@3ctn.ca) if you have questions related to the defined trial activation process, measures or reporting.

**What is the start date to determine eligibility for trial activation IBF?**

The start date for trial activation is defined as the date the site has made the critical decision and has the full package to start the trial activation process (whichever date is later): 1) site receives the protocol; 2) site PI expresses interest in the trial; 3) site has confirmed its participation as a site, through a formal or informal review process.

NB: This definition, which considers possible scenarios for trial activation, was developed with consultation from sites in 2017 and reviewed again in 2019. 3CTN acknowledges that each site may have their own internal processes.

**The central REB review process may affect the timeliness of local REB review. Is this taken into consideration for IBF?**

As reflected in reported trial data, central REB processing timelines are almost uniformly  $\leq 60$  days, occur in parallel with other site startup activities and as such, have not typically been a primary contributor to delays in trial activation. Sites are encouraged to coordinate with the central REB applicant and local REBs to support an expedited review process.

***How was the target of 120 days for trial activation determined?***

Historically, 26% of Portfolio trials have been activated within 120 days and the current Network median is 173 days. The goal of this incentive is intended to help promote rapid recovery of the national ACCT Portfolio while also supporting an investment in process improvement activities that help bring trial activation timelines increasingly up to performance seen in the top 25<sup>th</sup> percentile. For more information and a breakdown of trial efficiency data by region, view the [3CTN Site Efficiency Report](#).

**What are the benefits of submitting Portfolio applications in Year 8?**

The benefits of submitting a Portfolio trial in Year 8 are:

- Sites have the potential to earn Year 8 IBF for Trial Activation and First Patient Recruited for Portfolio trials open to recruitment on or after April 1, 2021.
- Increased trial awareness/publicity to attract other sites to be involved in the trial.
- Year 8 IBF is a one-year adapted model to address rapid academic trial recovery and it may appear there are no benefits to submitting a trial to the Portfolio if it is already open. However, Year 9 is the beginning of a new 3CTN strategic plan and may have different funding models, and possibly the return of PCF. If PCF is available in Year 9, this trial will be part of the Portfolio and can benefit from the sites' involvement.

**If I am an EDGE user, how do I report remote access patients?**

For EDGE users, add the “priority patient attribute” to your local library entity from the list of global entities. Flag the remote patient and complete the patient attributes. Set up and download the “Remote patient report” and send to [james.schoales@oicr.on.ca](mailto:james.schoales@oicr.on.ca). These instructions will be included in your quarterly reporting reminder.

**Pediatric Network Sites**

***What is the period start date for data reporting obligations for 3CTN Portfolio trials?***

As outlined in the 3CTN-Site Agreement, sites are to report milestone dates and accruals for trials open after April 1, 2020.

However, any data and dates for trials open prior to April 1, 2020 reported would be valuable in improving the accuracy and consistency of summative reports used describe the academic pediatric trial landscape in Canada as well as for performance benchmarking.

***My pediatric site joined 3CTN in 2018. Am I still eligible for PCF in Year 8?***

Yes, pediatric Network sites that joined 3CTN in 2018 remain eligible to receive Year 8 PCF up to max budget cap, as outlined in their current 3CTN-Site Agreements for 2018-2022.

***What is the ‘budget cap’ and how was it calculated?***

This represents the total IBF budget indicated within a given 3CTN-pediatric NACC Agreement for a given fiscal year. Each site’s budget cap for IBF payment is based on projections to the three IBF factors: high priority trials, trials activation and remote access.

***What is the ‘hold back’ and what purpose does it serve?***

At the point where a site earns IBF over budget cap during a fiscal year, the surplus amount is accrued as a hold back. Due to limited available funding in the overall budget, this helps ensure there is funding available for all sites that meet their annual IBF targets. At the end of each fiscal year, the balance of the remaining overall budget is distributed towards fulfilling sites’ hold back and amounts are released as part of the Q4 payment. The overall pediatric IBF budget is dedicated to 3CTN pediatric sites, and funds remaining at the end of Year 7 will be rolled over to Year 8.