Canadian
Cancer Clinical
Trials Network

ADVANCING ACADEMIC CANCER CLINICAL TRIALS

2019/20 ANNUAL REPORT

Executive Opening Statement

The Canadian Cancer Clinical Trials Network's annual report for 2019-2020 highlights our accomplishments as the Network marks the midpoint of the renewed strategic plan for 2018-2022.

As with each year since the Network's formation, we have seen an overall increase in patient accrual to academic cancer clinical trials (ACCTs) in Canada. Highlights from the past year include further uptake of clinical trial management systems (CTMS) and greater functional use by trial teams. CTMS use not only supports better operating efficiency, but yields a richer, higher-quality dataset to describe and monitor Portfolio trials' status and activities. 3CTN Portfolio trial information and reporting has also been transformed through the development and roll out of a dynamic reporting interface. For the first time, stakeholders will independently have access to current trial information at a national, regional or individual cancer centre level.

In March, 3CTN's Scientific Advisory Board (SAB) completed the eighteen-month review of 3CTN. The SAB acknowledged the unique and comprehensive initiatives of the Network and suggested that Canadian cancer research funders and community can feel justifiably proud of its successes. The SAB noted that initiatives were being delivered in a well-organized, innovative and cost-effective manner. Highlighted achievements included the gains in embedding and advancing patient and public involvement (PPI) within individual cancer centres where the patient voice can be most effective in guiding the local conduct of cancer trials. The SAB supported 3CTN's greater strategic focus on prioritizing opportunities that are inclusive of all regions and patient populations. These specific initiatives are to create more equitable access to trial options for the significant number of Canadian patients residing in rural or remote communities as well as a refreshed approach for supporting the C17 paediatric network.

Continuing to add new Portfolio trials of high scientific interest and potential clinical impact is recognized as the driving mechanism for overall success. As 3CTN moves into the remaining two years of its strategic plan it will focus on sustaining accomplishments and advancements and address ongoing risks and challenges.

Reasons for under-performance to accrual targets within regions will be re-examined and priority given to developing a diversified funding model that is able to sustainably support trial centres' performance across regions.

3CTN continued to achieve its overall objectives for advancing the Canadian clinical trials environment at a crucial time for stakeholders. The global COVID-19 pandemic forced cancer centre trial units to halt accruals to ongoing trials as well as new trial openings in the final month of this fiscal year. Response to COVID underscored the need for innovative approaches to trial conduct that includes remote patient access and participation. Lessons learned will inform clinical trial practice in the post-COVID period.

By maintaining emphasis on scientific excellence, leveraging achievements and maximising patient benefit and PPI, we are confident that 3CTN is uniquely positioned to help navigate challenges and promote continued improvements to the Canadian cancer clinical trials landscape.

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Sincerest thanks to all whose commitment to advancing performance standards, patient involvement and accrual, enables cancer patients to access novel cancer screening and treatment options offered through academic clinical trials.

Stephen Sundquist
Executive Director

David Cameron
SAB Chair (Incoming)

Janet Dancey
Scientific Director

Peter Selby
SAB Chair (Retiring)

Improving Network Academic Cancer Clinical Trials Activities

The Canadian Cancer Clinical Trials Network aims to ensure that Canada remains a recognized global leader in academic cancer clinical trials (ACCT). We seek to broaden patient access and accrual to Portfolio trials across all Network sites, provide incentive funding to promote increased accrual, create indicators for trial performance and research quality standards and support a robust model for patient and public involvement (PPI) in trial activities.

Network-wide recruitment was 129 per cent above pre-3CTN (2011-2013) baseline levels and greatly surpassed the target objective for the year of a 60 per cent increase. While the majority of 3CTN member sites met or exceeded their recruitment target for the current four-year period, ongoing evaluation and targeted solutions are required to address persistent regional variations in accrual.

This past year, 5,700 cancer patients received innovative treatments or interventions through participation on trials supported by 3CTN

The 3CTN community supports continuous improvements and initiatives to enhance trial execution. Central access to a robust ACCT Portfolio, best-practice resources and trial management tools allow teams to focus on trial recruitment and conduct.

Substantial progress has been made to date towards achieving Network ACCT quality and performance goals of:

- Capturing trial activation data for analysis and benchmarking future gains in trial efficiency
- Clinical trial management system adoption by more centres to streamline records management and operational processes
- Ongoing PPI initiatives like the growing Patient Representative Community of Practice membership at Network sites designed to enhance research quality, effectiveness and priority setting in line with patient values and preferences

"It is important to both cancer care and research that we make access to clinical trials equitable by focussing especially on those who face barriers such as young people and those in remote communities,"

Dr. Janet Dancey, Scientific Director 3CTN

"I am particularly excited about the CRAFT initiative as it is important to make clinical trials accessible to a larger number of patients living in rural and remote regions. A successful rollout holds the promise to further improve, extend and even save the lives of people diagnosed with cancer." – Jill Hamer-Wilson, 3CTN Patient Representative

Next, 3CTN plans to match centres with challenges within a performance area, with directed mentoring and other means to those that have demonstrated effective solutions and best practices.

A Network strategic priority is to address barriers to trial participation and enable more patients to have access to the broadest range of trial options. **Two new initiatives to improve trial access that began this year are:**

- Strengthening the Canadian pediatric trial landscape and improving trial options for children, adolescents and younger adult patients through re-established agreements with the C17 pediatric network;

- Bringing more clinical trials to those who live outside urban areas through the Canadian Remote Access Framework for Trials, (CRAFT).

Both initiatives are supported by additional funding from the Canadian Partnership Against Cancer over the remainder of the current four-year plan.

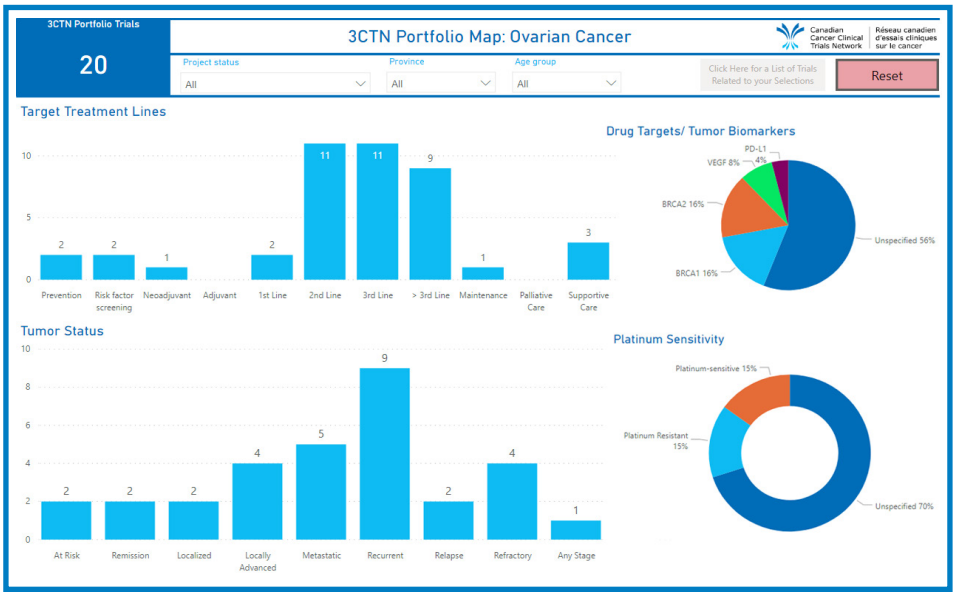
The Canadian Remote Access Framework for Trials, (CRAFT) emerged from a 3CTN-led national initiative this year. A multi-stakeholder workshop of experts from research centres, trial sponsors, patients, ethics boards and Health Canada convened in November. The group drew from available literature and existing models to put forward a Canadianized framework and set of key recommendations for implementation that were summarized in a widely publicized position paper. The necessary shift to more virtual trial processes with the COVID-19 pandemic, supports the feasibility and the imperative for remote trial delivery. Next, 3CTN will publish the CRAFT as a guideline and develop proof of concept implementation projects for Network Cancer Centres and satellite health centre sites in their local area.

We invite you to review the achievements detailed in this report as examples of how 3CTN demonstrates a high return on investment through supports for Canada's ACCT ecosystem and the effective delivery of promising new screening and therapeutic options for all cancer patients.

Mapping Canada's Cancer Trial Landscape: 3CTN Portfolio Disease Maps

One of 3CTN's priorities is to optimize its Portfolio of trials by showing trial impact and identifying trial gaps that can inform future research opportunities for new trials.

3CTN aims to develop Portfolio maps to provide a clear, visual representation of trial activity by disease site and research focus with links to detailed trial information.



Development and design of initial pilot versions in 2014 were modeled after existing National Cancer Research Institute (U.K.) Portfolio Maps. At that time, two Portfolio maps were generated but the process was found to be a manually-driven and labour-intensive and proved difficult to sustain.

In 2019, with the support from the 3CTN Management and Portfolio Committees, this initiative was revisited with a focus on automating the process and adding additional variables of interest by leveraging the current Portfolio database and embedded reporting capabilities using a data visualization software.

As each trial enters the 3CTN Portfolio, it is assessed for the standard categories of target treatment line, tumour status, drug targets/ tumour biomarkers and unique disease sub-categories such as platinum sensitivity or castrate resistance for ovarian and prostate cancer, respectively. Using this new process, categories will be set up and captured in a central repository that will allow for one report to be generated that can be easily filtered by disease sub-site to generate multiple maps.

"It is important to include patients early on in the development or planning stages of a clinical trial, to better integrate patient perspectives into discussions and decisions as the clinical trial comes to fruition"
- Don Wood, 3CTN Patient Representative

Identifying gaps: an example using Ovarian cancer.

3CTN began with the creation of the latest Portfolio map for ovarian cancer in an intuitive format that allows stakeholders to interact with the data and identify potential research gaps needing to be addressed in Canada.

From this report it can be seen that there are currently no 3CTN Portfolio trials that focus on adjuvant or palliative treatments for patients with ovarian cancer.

Development of future Portfolio maps for different disease sub-sites is planned to begin in the coming year. This will see the creation of two more disease sub-site Portfolio maps with the hope to expand to additional Portfolio maps in the near future. Further dissemination and stakeholder engagement over time will help inform the effectiveness of these Portfolio maps in addressing research gaps in the academic cancer clinical trial landscape.

Enhancing Canadian pediatric cancer clinical trials with real-time results: A case study using EDGE clinical trial management system

In 2018, when Stephanie Badour, Clinical Research Unit Manager at Montreal Children's Hospital (MCH), heard about the opportunity to implement the EDGE clinical trial management system (CTMS), she immediately jumped at the chance. In her previous role at another pediatric cancer centre, she experienced firsthand the challenges with developing accurate statistics for measuring Clinical Research Unit (CRU) performance.

Stephanie Badour
Clinical Research Unit Manager, Montreal Children's Hospital

"I needed to come up with evidence based solutions for some of the problems we were having," Stephanie said. "But it was very difficult to obtain the data when all your information is stored across numerous databases."

As Stephanie started to use EDGE, her initial expectations of what the system could do changed. Beyond typical applications for tracking status and performance of trials in the site trial portfolio, it soon became clear the system could be used in different ways. She discovered that an unexpected feature of EDGE was the ability to

customize the system's functionality to better support collaboration within their institution and externally with other pediatric cancer centres across Canada.

> **As a manager, I can see the value of having the information in real time, so we can adjust our processes in real time - Stephanie Badour**

Stephanie worked with the MCH pathology team to set up an improved process for coordinating sample procurement and processing during prescreening of potential clinical trial patients in order to maximize enrollment potential. Creating customized EDGE data fields allowed the pathology department and the CRU to track how many samples need to be taken and set aside to consent for the different research studies available and determine the amount of tissue leftover for future research following a procedure. Reviewing the resulting data against open protocol criteria helps the research team to better prioritize and coordinate the consent process with requests for the release of pathology samples. EDGE's capacity for tracking the enrollment decision and reason for screen failures for each patient makes it possible to create not only a pre-screen list per study but also one for all new patients that includes clinical and pathology requirements. This project has been highlighted within the pediatric community as an example of EDGE's capabilities and benefits that can be realized through the expanded use of the system's functionality.

In the coming year, Stephanie is looking to collaborate with the C17 pediatric network on a number of opportunities for using EDGE as a common platform to help improve trial management capacity and quality at the individual site, standardize clinical study processes as well as build network-wide oversight and reporting capabilities through the following:

- Improve and standardize tracking and retention of regulatory documents and principal investigator oversight documentation, such as review of new amendments, safety documents, as well as other study decisions to notify a research ethics board (REB) or delegated staff. Improved document management capabilities can better support retrieval of information for future reference or in the event of audit/monitoring queries from the study sponsor;

- Create common templates, data fields, simplify REB submission process and standardize workload assessments across all sites and track site finance in real time;

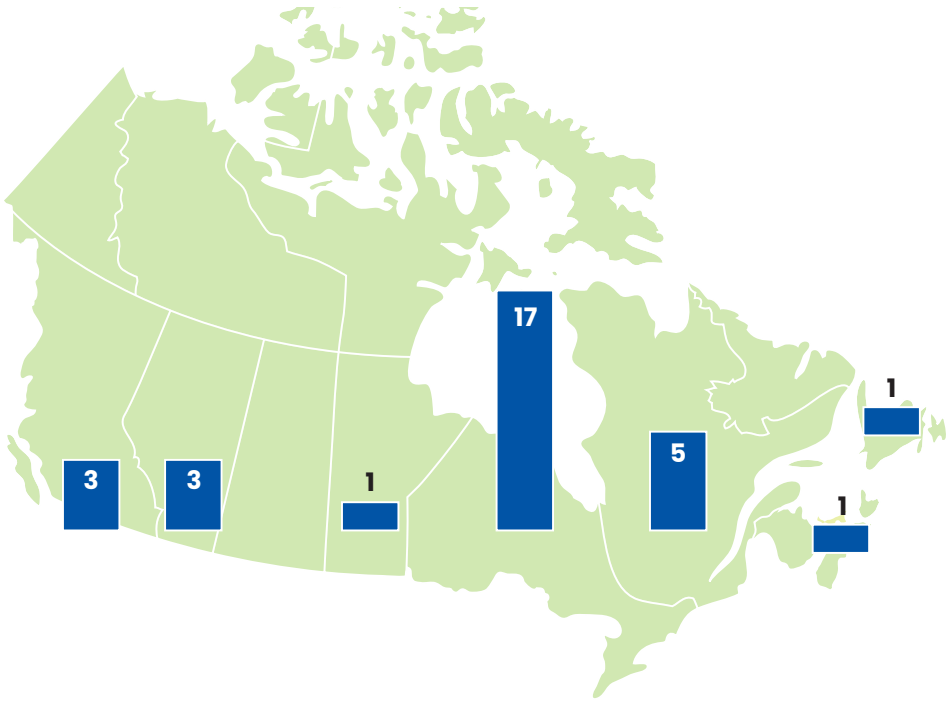
- Enhance C17 monitoring processes across Canadian sites by creating a centralized source for review of trial documents and providing an environment for logging query comments.

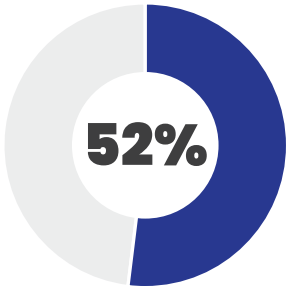
These initiatives align with the current culture of collaboration among the pediatric cancer clinical trial community and will each contribute to its continued success.

Patient and Public Involvement: Expansion of Patient Representatives across the Network

One of the key priorities of the 3CTN Strategic Plan 2018-2022 is to enhance patient and public involvement (PPI) across all Network centres.

Distribution of Patient Representatives across Canada:





24 Network centres have recruited a Patient Representative

Patient representatives provide a crucial perspective to clinical trials by providing feedback, insight, expertise and support towards trial activities and initiatives. The 3CTN Coordinating Centre and the Patient Representative Advisory Council (PRAC) continue to support Network centres in their efforts to recruit patient partners in research.

As of March 2020, more than half of Network centres have recruited a patient representative, with targeted support to assist remaining centres in completing onboarding by the end of 2022. In the coming year, 3CTN plans to assess the impact of patient representation at the centre level in order to address strategic gaps, identify new opportunities and fully capitalize on the potential for increasing the caliber of patient-centred trial activities.

"I am very proud of the patient representative community, its integrity and the diversity in the voices representing various regions, languages, values and ideas. When together, we are focused on trying to help bring awareness of clinical trials to others as they navigate through their cancer journey."
– Fred Clark, Chair of the PRAC

Network Achievements for FY2019–2020

British Columbia

Accrual to target 78% | Patient partners 3

- Coordinator hired to lead trial start up activities and identify process improvement opportunities;
- Provincial quality assurance initiatives implemented, including internal audits.

Alberta

Accrual to target 229% | Patient partners 3

- Supported Investigator Initiated Trials program to launch more academic trials at centres;
- Implemented 'action for improvement' for emerging performance issues and/or trends;
- Worked with patient advisors to review and refresh Alberta Cancer Clinical Trials website.

Manitoba

Accrual to target 33% | Patient partners 1

- Implemented process to support low recruiting trials within the first year of study activation;
- Created site profile information provided to sponsors in advance to their site selection visits. This reduced the number of questions, which significantly reduced visit times.

Ontario

Accrual to target 165% | Patient partners 5

- Implemented quality improvement initiatives such as a Quality Control Program, adding a standing monthly agenda topic called 'Process Series' to share and discuss clinical trials process best practices;

Ontario

- Developed policy for under performing trials and implemented several strategies including reviewing recruitment targets, implementing recruitment strategies;
- Partnered with a community wellness centre to host a clinical trials information session to increase trial awareness.

Quebec

Accrual to target 135% | Patient partners 5

- Launched oncoquebec.com, a user-friendly clinical trials website, listing all available trials in Quebec;
- Implemented strategies, standard operating procedures and training at sites to improve trial performance;
- Developed internal quality control procedures to provide periodical internal data monitoring.

Nova Scotia

Accrual to target 32% | Patient partners 1

- Partnered with Cape Breton Cancer Centre to improve access to trials for patients outside of Halifax;
- Process created to improve trial performance monitoring.

Newfoundland

Accrual to target 67% | Patient partners 1

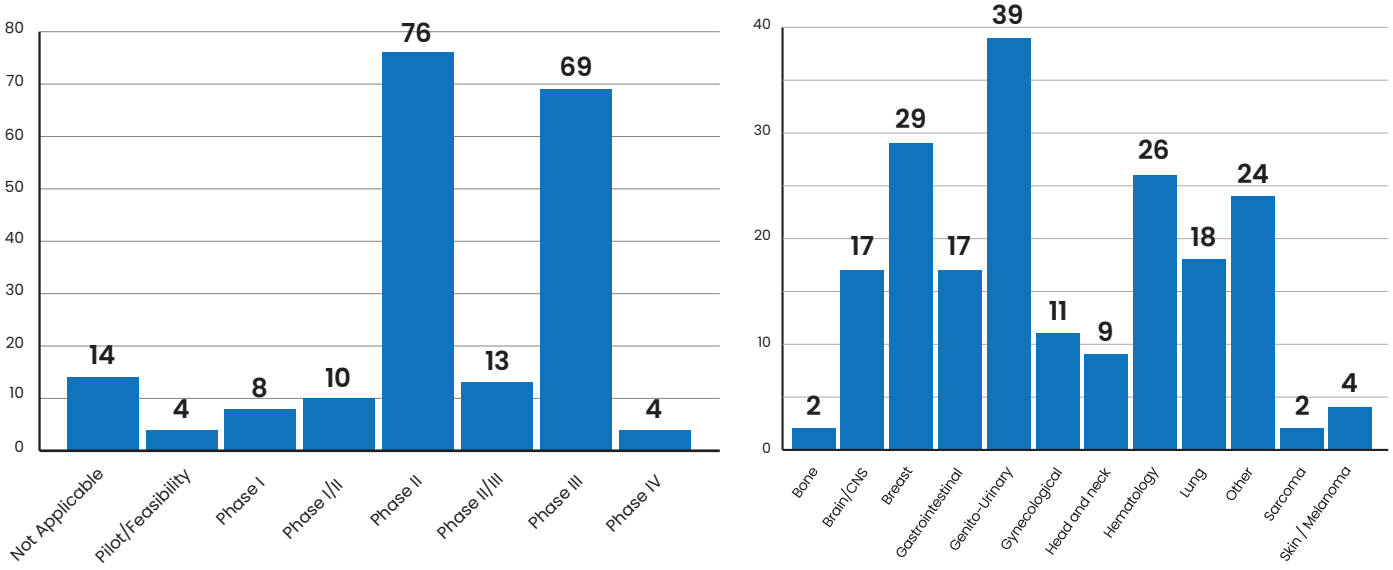
- Started implementation of EDGE, a clinical trials management system;
- Created study performance metrics and timelines for evaluation of open trials monthly.

Note: Network's annual target is 60% above the pre-3CTN baseline

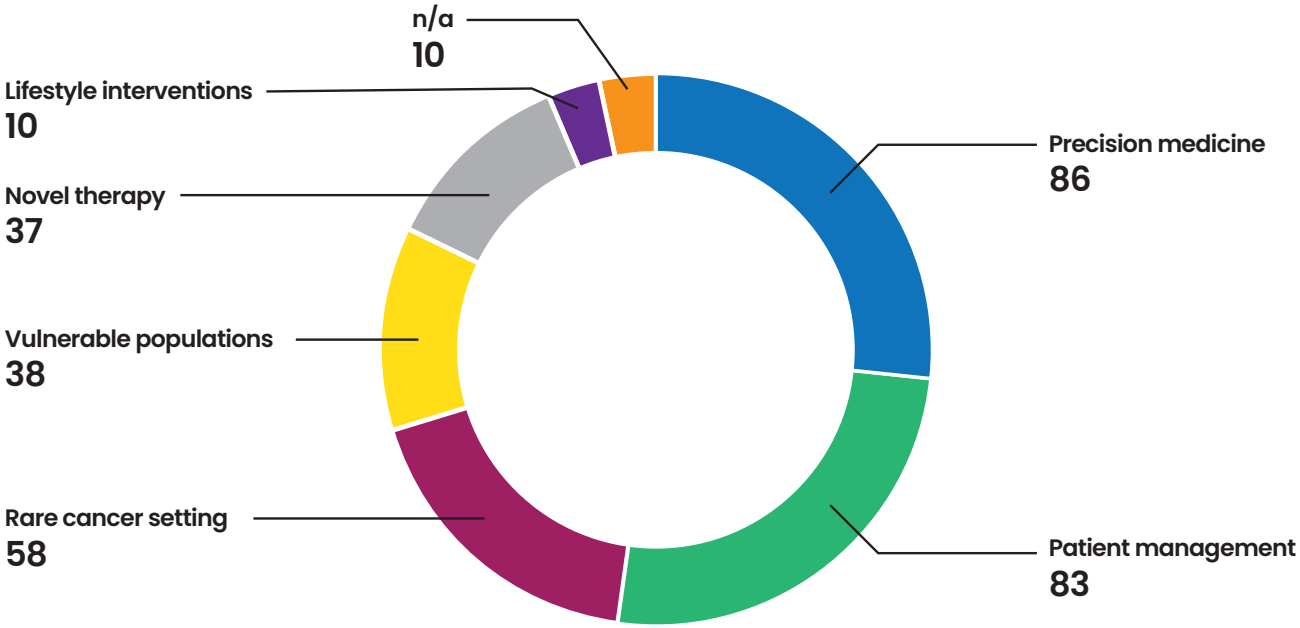
3CTN Performance Metrics, Year 6

Network Site	Type	Recruitment to Portfolio Trials				3CTN Objectives	
		Pre-3CTN Baseline	Total # Recruited	% of Baseline	% to Annual Target	Patient Rep Recruitment	CTRNet Registration
Ontario							
London Health Sciences Centre	NCC	186	942	506%	317%	in process	✓
Grand River Regional Cancer Centre	NACC	20	19	95%	59%	✓	✓
Windsor Regional Cancer Centre	NACC	14	3	21%	13%	in process	✓
Juravinski Cancer Centre	NCC	181	217	120%	75%	✓	✓
Cambridge Memorial Hospital	NACC	11	8	73%	45%	✓	✓
St. Joseph's Healthcare Hamilton	NACC	21	20	95%	60%	in process	
Walker Family Cancer Centre	NACC	17	40	235%	147%	in process	✓
Sunnybrook Health Sciences Centre	NCC	141	638	452%	283%	✓	✓
Humber River Hospital	NACC	1	3	300%	188%	in process	✓
Michael Garron Hospital	NACC	2	0	0%	0%	in process	
Princess Margaret Cancer Centre	NCC	396	543	137%	86%	✓	✓
Markham Stouffville Hospital	NACC	1	6	600%	375%	✓	✓
Mount Sinai Hospital	NACC	21	7	33%	21%	in process	✓
Northeast Cancer Centre	NACC	24	17	71%	44%	in process	✓
North York General Hospital	NACC	1	7	700%	438%	in process	✓
Royal Victoria Regional Health Centre	NACC	8	25	313%	195%	✓	✓
Southlake Regional Health Centre	NACC	10	32	320%	200%	✓	✓
St. Michael's Hospital	NACC	19	3	16%	10%	in process	✓
Thunder Bay Regional Health Sciences Centre	NACC	26	4	15%	10%	✓	✓
Trillium Health Partners - Credit Valley Hospital	NACC	27	10	37%	23%	✓	✓
William Osler Health System	NACC	1	16	1600%	1000%	in process	✓
The Ottawa Hospital Cancer Centre	NCC	132	804	609%	381%	in process	✓
Cancer Centre of Southeastern Ontario at Kingston General Hospital	NACC	41	89	217%	136%	in process	✓
R.S. McLaughlin Durham Regional Cancer Centre	NACC	22	36	164%	102%	✓	✓
Manitoba							
CancerCare Manitoba	NCC	99	51	52%	32%	✓	✓
Western Manitoba Cancer Centre	NACC	1	1	100%	63%	✓	
British Columbia							
BC Cancer – Vancouver	NCC	106	110	104%	65%	in process	✓
BC Cancer – Abbotsford	NACC	16	1	6%	4%	✓	✓
BC Cancer – Prince George	NACC	1	10	1000%	625%	✓	✓
BC Cancer – Kelowna	NACC	38	33	87%	54%	✓	✓
BC Cancer – Victoria	NACC	26	78	300%	188%	in process	✓
Alberta							
Cross Cancer Institute	NCC	102	310	304%	190%	✓	
Tom Baker Cancer Centre	NCC	76	341	449%	280%	✓	
Quebec							
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal (CIUSSS CODIM)	NACC	87	155	178%	111%	✓	
CISSS de l'Outaouais	NACC	3	5	167%	104%	in process	
CHU de Québec – Université Laval	NACC	180	309	172%	107%	in process	✓
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke	NACC	46	61	133%	83%	✓	✓
Centre Hospitalier de l'Université de Montréal (CHUM)	NACC	153	66	43%	27%	✓	✓
CIUSSS du Nord-de-l'Île-de-Montréal (CIUSSS NDIM)	NACC	3	539	17967%	11229%	in process	
CIUSSS de l'Est-de-l'Île-de-Montréal (CIUSSS-EDIM)	NACC	60	15	25%	16%	in process	✓
Nova Scotia							
Nova Scotia Health Authority	NCC	39	20	51%	32%	✓	✓
Newfoundland							
Eastern Regional Health Authority	NCC	15	16	107%	67%	✓	✓
Pediatrics							
CancerCare Manitoba	NACC	18	7	39%	NA	✓	✓
CHU de Québec-Université Laval / Centre Mère-Enfant Soleil	NACC	17	21	124%	NA	in process	
Centre hospitalier universitaire de Sainte-Justine	NACC	42	38	90%	NA	in process	✓
Montreal Children's Hospital	NACC	24	10	42%	NA	in process	
Janeway Children's Health and Rehabilitation Centre	NACC	4	0	0%	NA	✓	
Total (N=47)		**2479**	**5686**	**229%**		**(24) 52%**	**(36) 78%**
Adult Patient Sites (N=42)		**2374**	**5610**	**236%**	**148%**		
Pediatric Sites (N=5)		**105**	**76**	**72%**			
Number of sites achieving Y6 accural target					**20**		

Portfolio Trials by Disease Phase and Site



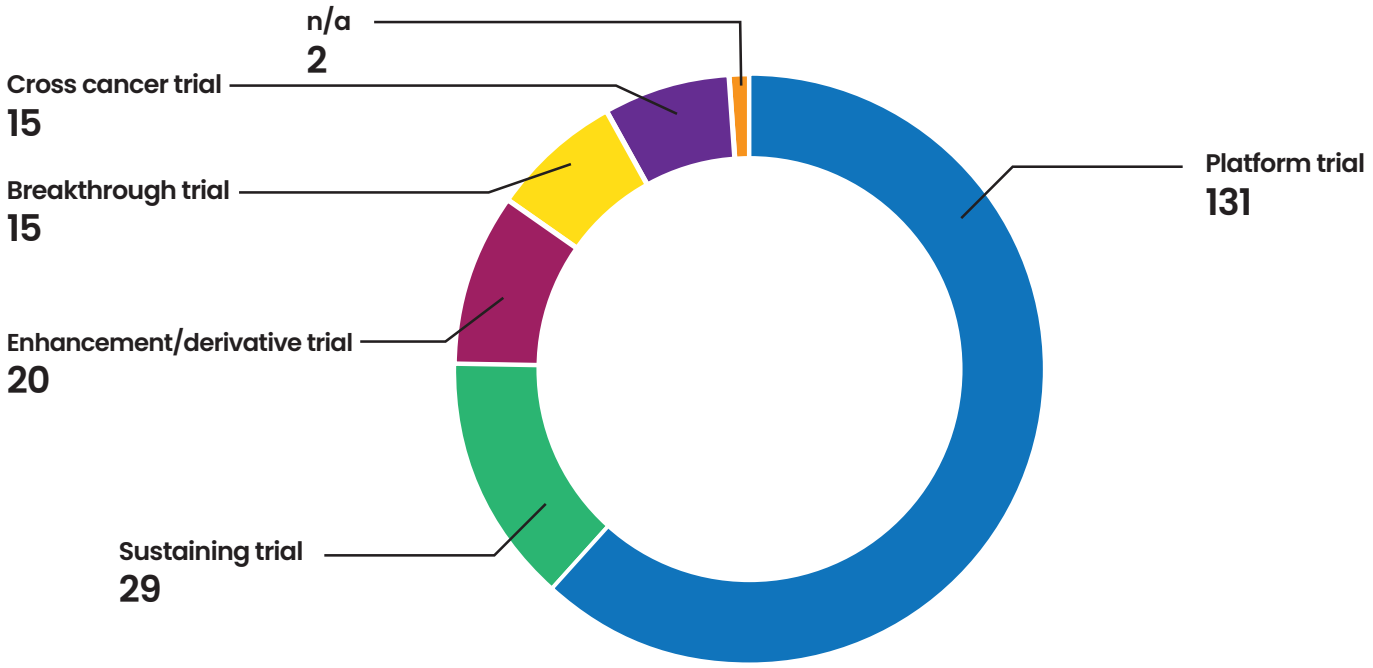
Portfolio Trials by Categories of Special Interest



17% of Active Y6 Portfolio trials were Immunotherapy Trials

33% of Active Y6 Portfolio trials were Randomized Phase 3 trials

Portfolio Trials by Potential Impact on Patient Population



198
Portfolio trials supported

87.5%
Application approval rate

32
Portfolio applications reviewed

5 day median application processing time

Top 5 Portfolio Trials (by number of member sites)

(CCTG) BR.31 | NCT02273375
A Phase III Prospective Double Blind Placebo Controlled Randomized Study of Adjuvant MEDI4736 In Completely Resected Non-Small Cell Lung Cancer
CURRENT SITES: 27 | DISEASE: LUNG / NON-SMALL CELL | TOTAL RECRUITMENT: 179

(CCTG) MA.39 / TAILOR RT | NCT03488693
Tailor RT: A randomized trial of regional radiotherapy in Biomarker low risk node positive breast cancer
CURRENT SITES: 24 | DISEASE: BREAST | TOTAL RECRUITMENT: 161

(CCTG) CE.8 / EORTC-1709-BTG | NCT03345095
A Phase III Trial of Marizomib in Combination with Standard Temozolomide-Based Radiochemotherapy versus Standard Temozolomide-Based Radiochemotherapy Alone in Patients with Newly-Diagnosed Glioblastoma
CURRENT SITES: 18 | DISEASE: BRAIN/CNS | TOTAL RECRUITMENT: 169

(CCTG) CX.5 / SHAPE | NCT01658930
A Randomized Phase III Trial Comparing Radical Hysterectomy and Pelvic Node Dissection vs Simple Hysterectomy and Pelvic Node Dissection in Patients With Low-Risk Early Stage Cervical Cancer
CURRENT SITES: 18 | DISEASE: GYNECOLOGICAL/CERVIX | TOTAL RECRUITMENT: 136

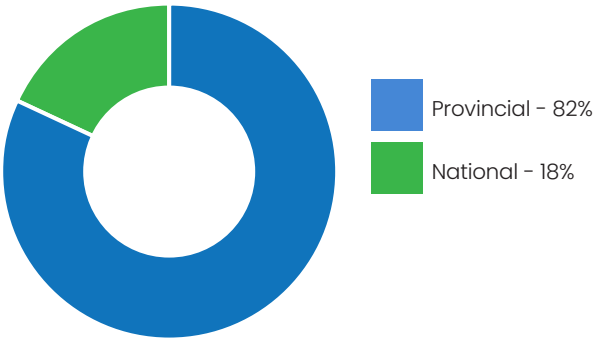
(CCTG) MAC.20/Alliance A011401/BWEL study | NCT02750826
Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women With Early Breast Cancer
CURRENT SITES: 16 | DISEASE: BREAST | TOTAL RECRUITMENT: 166

Revenue and Expenses for Fiscal Year 2019-2020

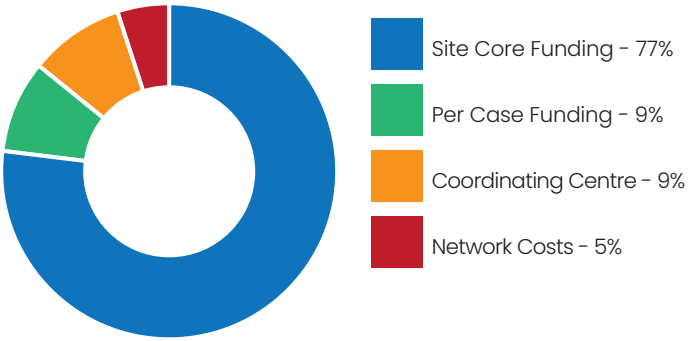
Period ending March 31, 2020	Amount in CDN $
Revenue	
National	1,000,000
Provincial	4,558,367
Total	5,558,367
Expenses	
Site Core Funding	4,356,538.40
Per Case Funding*	501,035.00
Coordinating Centre	530,880.98
Network Costs	275,543.78
Total	**5,663,998.16**
NET: Revenue Less Expenses	**(105,631.16)**

Note: *PCF amount reflects funds distributed for Y5 (18-19) and accounted for in Y6-Q1 (19-20)

Revenue



Expenses



Funding Partners

Alberta Cancer Foundation

BC Cancer Foundation

CancerCare Manitoba / ActionCancerManitoba

OICR Ontario Institute for Cancer Research

Canadian Partnership Against Cancer / Partenariat canadien contre le cancer

Q-CROC

Eastern Health Newfoundland & Labrador

QEII Health Sciences Centre Foundation

Collaborators

N2 Network of Networks / Réseau des réseaux

Canadian Tissue Repository Network / Réseau canadien de banques de tissus

ARCC Canadian Centre for Applied Research in Cancer Control

Canadian Cancer Trials Group / Groupe canadien des essais sur le cancer

edge

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University of British Columbia

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Executive Director,
3CTN

Janet Dancey, MD
Scientific Director,
3CTN

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Canadian Partnership Against Cancer

Rami Rahal
Vice President, Cancer Systems, Performance and Innovation
Canadian Partnership Against Cancer

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