Canadian
Cancer Clinical
Trials Network

ANNUAL REPORT - 2017-18

Building Capacity in a Changing Landscape

Supporting Canada's Cancer Research Centres in Delivering Clinical Trial Options



On behalf of our members, funders, collaborators and stakeholders, we proudly present the Canadian Cancer Clinical Trials Network (3CTN) annual report for the 2017-2018 fiscal year.

This report summarizes the accomplishments of the 3CTN four-year funding cycle and reflects the culmination of 3CTN's mandate to enhance patient involvement as well as to improve performance and quality of trial conduct.

Over the past year 3CTN has successfully expanded, attracting cancer centres and affiliated centres from across Canada to participate in 3CTN initiatives by offering a robust framework for the planning, delivery and conduct of academic cancer clinical trials. Having increased the capacity for clinical research in Canada since inception, we have seen a consistent year-over-year trend of increased patient accrual to Canadian academic clinical trials. Other significant achievements over the past year include continued improvements in trial recruitment within each provincial region, wider uptake in use of clinical trials management systems and increased communication and collaboration among sites within the Network.

3CTN's stakeholders can take pride in the strides that have been taken to increase Patient and Public Involvement (PPI) in cancer research. Significant PPI achievements include promoting Network-wide adoption of PPI throughout the development and conduct of trials, identification of lay representatives at each centre and the incorporation of lay membership throughout 3CTN's governance framework.

Taken as a whole, these collective improvements in the Canadian cancer research landscape will continue to translate into more widespread access to clinical trials and treatment options for patients.

3CTN Scientific Advisory Board (SAB) members offered their unanimous congratulations to 3CTN Coordinating Centre, the Network Cancer Centres and stakeholders for successfully establishing this inclusive, pan-Canadian approach during the recent 36-month review. The SAB consensus was that 3CTN's organizational model places it at the international forefront of innovation within clinical cancer research. While giving credit for its realized achievements, the SAB also highlighted the need for continued focus on expanding patient engagement and for ensuring research opportunities are as inclusive of all regions and populations as possible. These are reflected in the Network's ongoing priorities and objectives, along with creating a robust funding model that includes exploring new partnership opportunities to strengthen commitments for supporting core infrastructure and promoting trial performance.

With the completion of the final year of our initial four-year business plan, we hope this report captures and conveys the full scope of achievements made possible by the dedicated commitment from 3CTN's members across Canada's cancer research community, including patients, our funders and stakeholders. In particular, we thank Karen Arts, founding Executive Director of the 3CTN for her tireless efforts to ensure the success of 3CTN.

Stephen Sundquist, Executive Director
Janet Dancey, Scientific Director
Peter Selby, SAB Chair

Building Capacity in a Changing Landscape – Supporting Canada's Cancer Research Centres in Delivering Clinical Trial Options to Patients

In its first four years, the overarching goals of the Canadian Cancer Clinical Trials Network (3CTN) have been to ensure that Canada continues to be a world leader in academic cancer clinical trials (ACCT), that lives of patients with cancer are improved through increased opportunities to access new therapeutic options, and that cancer outcomes continue to improve. Throughout its mandate, 3CTN has focused on successfully fulling its vision and mission:

Vision: Canadians will have access to the best available cancer treatments through successful execution of academic clinical trials.

Mission: To ensure access to, and efficient execution of, ACCTs across the Network.

While the clinical trials supported by 3CTN have and will have measurable impact on the lives of cancer patients, the clinical trial environment continues to change. Advances in the understanding of cancer biology, immunology, and molecular profiling have led to segmentation of traditional cancer populations into rare cancer subtypes defined by histologic, genomics and molecular criteria. Trial designs involve smaller patient populations and increased complexity of data collection, data library sources, novel endpoints and analysis. For example, the last three years have seen rapid growth in trials testing immunotherapy and precision medicine strategies with novel designs and endpoints, as well as a reduction in traditional large Phase III treatment trials. While contributing to new insights into cancer biology, innovative treatments and standards of care, these changes have added trial management activities and costs. Smaller trials also limit recruitment potential, driving the need for greater efficiencies at all stages in trial conduct to expand patient recruitment. 3CTN has been successful in improving trial activity and increasing recruitment by 50 per cent over the past four years by addressing the known challenges within the ACCT enterprise by supporting cancer centres and partner institutions participating in multi-centre trials in key ways:

- Facilitating patient access and involvement in academic clinical trials
- Improving research capacity at both the national- and regional-level trial environment through collaboration and facilitation of important national trial initiatives
- Improving site performance of academic trials by promoting adoption of best practices, standards and tools, and monitoring of key efficiency measures
- Demonstrating impact of the Network and academic trials on the Canadian health system through increased trial activity.

Improving collaboration and communication between Canada's cancer centres conducting trials and facilitating connections between sites helps overcome systemic challenges to initiation and efficient conduct of trials. Foundational to being able to achieve its mission is the 3CTN Portfolio, created and maintained to provide an up-to-date, web-accessible and searchable repository of national, multi-centred ACCTs. The Portfolio provides Canadians with a unique resource for identifying, prioritizing and supporting high-impact studies. The Portfolio listing is compiled based on robust selection criteria and overseen by a governing Portfolio Committee. The processes assure the Portfolio continues to evolve to include new trials that address therapeutic gaps, accesses target populations, retains focus on scientific priorities and reflects emerging research trends. Central access to up-to-date trial listings and information, provision of trial resources and study management tools means site teams are able to focus their activities on increasing capacity and optimizing performance.

Since 2014, 3CTN has supported over 400 academic multi-centre trials and the Portfolio. In the last year, the Portfolio comprised over 227 studies. Moreover, 43 per cent of current trials have a precision medicine component, reflecting the strategic importance of this area of research. On average, there are six active sites for each trial, reflecting a measure of the uptake and extent of distribution of trials by Network centres.

The leadership and scope of 3CTN Portfolio trials nationally and internationally is also noteworthy. Among all trials currently underway at adult Network sites, 63 per cent are led by a Canadian institution and 7 per cent are international, multi-centered studies. To illustrate the overall breadth of impact of Portfolio trials, the top 15 recruiting studies saw 1100 patients enrolled across almost 120 sites nationally. Further, 13 of these studies were Canadian-sponsored. The listings included personalized medicine and immunotherapy investigations and spanned Phase I-IV trials with interventions targeting breast, gastro-intestinal, hematological, lung, genitourinary and other cancers.

Portfolio trials have led to new standards of care, tested novel therapeutic approaches and designs and contributed new insights into cancer biology and patient experience. Some recent examples:

Multicentre Randomized Phase III Trial Comparing 6-Month Adjuvant Chemotherapy With Gemcitabine Versus 5-fluorouracil, Leucovorin, Irinotecan and Oxaliplatin (mFolfirinox) In Patients With Resected Pancreatic Adenocarcinoma. (62/400 patients, 20 Canadian sites) [CCTG PA.6/Prodige 24/Accord 24 / NCT01526135]

A Pragmatic Cluster-Randomized Trial of Ambulatory Toxicity Management in Patients Receiving Adjuvant or Neo-adjuvant Chemotherapy for Early Stage Breast Cancer (AToM) Sub-study. (501/1460 patients, 18 Canadian sites) [OCOG-2015-ATOM (PRO) /NCT02485678]

Impact of 18F-FDG PET-CT versus Conventional Staging in the Management of Patients Presenting with Clinical Stage III Breast Cancer. (153/370 patients, 6 Canadian sites) [OCOG-2016-PETABC/ NCT02751710]

Risk-Adapted Chemotherapy in Treating Younger Patients With Newly Diagnosed Standard-Risk Acute Lymphoblastic Leukemia or Localized B-Lineage Lymphoblastic Lymphoma (332/5872 pediatric patients, 13 Canadian sites, and 220+ international sites) [COG-AALL0932/ NCT01190930]

While 3CTN has delivered on all the objectives laid out its first 2014-2018 business plan, the most easily assessed is the marked turnaround in recruitment to ACCTs. This fiscal year, the Network has surpassed its four-year objective to increase the numbers of patients recruited to trials by 50% over established pre-3CTN (2011-2013) baseline levels. Over 4 years, the number of Canadians who have received innovative treatments or interventions through participation on 3CTN portfolio trials has increased to over 12,000.

In the past year, over 3750 adult and 360 pediatric patients enrolled in trials listed within our database. Trial recruitment over baseline increased by 53 per cent in 2017-2018 and rates have more than doubled from the first year. We are extremely proud to report that C-17 pediatric network sites surpassed their enrollment objectives for the period, with recruitment at 104 per cent above pre-3CTN baseline. Other notable achievements were observed in Quebec where that province's centres realized an impressive 116 per cent above target with limited core funding.

These recruitment results occurred despite the reduced numbers of large Phase III trials. The success is due to both the increase in volume of trial availability across Canada and widespread performance improvements by Network cancer centres. While a majority of 3CTN-affiliated sites met or exceeded their overall recruitment target for the current four-year period, moving forward, there will be a focused effort to assist centres that may be facing challenges by leveraging knowledge and expertise from within the Network and by providing guided access to trial management resources, recruitment workshops or other customized solutions.

There has been substantial progress towards improved quality and performance of trial activities. Today, 100 per cent of sites have achieved regulatory compliance for implementing standard operating procedures for Good Clinical Practice, 40 per cent of Network cancer centres have adopted clinical trial management systems (CTMS), and over 50 per cent have registered with the Canadian Tissue Repository Network (CTRNet) to ensure best practices are adopted in biospecimen management. 3CTN has provided funding and hosted scientific meetings, courses and educational opportunities to promote knowledge and skills development for over 200 qualified research personnel. These activities collectively create greater cohesion among cancer centres, facilitate uptake of best practices and inform the broader community of the value of trials, 3CTN's contribution and that of 3CTN's funders.

While creating connections between Canada's cancer research organizations is important, it is also integral to engage and collaborate with cancer patients. Patient and Public Involvement (PPI) is a key component of 3CTN, as involving patients in the planning and conduct of research has been shown to improve the quality and efficiency of healthcare research. A section of this report is devoted to sharing exciting developments seen in PPI for 3CTN this year.

Having completed the final year of its original business plan, the 3CTN leadership, with input from funders, undertook renewal planning activities throughout the past year. There were two primary components of activities: i) renewal plan development through stakeholder engagement and, ii) demonstrating return on investment related to objectives for federal and provincial-level funding organizations. Budget development and funding agreements executed throughout the last half of this year have culminated in a new four year strategic plan that will help assure needed continuity for 3CTN stakeholders. From earlier years' objectives that focused on creating the foundational framework, current priorities centre on expanding and optimizing the available library of resources and the coordinating infrastructure and governance support to ensure the Network can continue to meet the cancer research community's diverse and evolving needs. 3CTN will adopt more modest incremental recruitment goals in upcoming years, shifting focus to improving patient involvement, trial performance and providing tailored support for sites that have struggled to meet the recruitment targets.

At the conclusion of the 3CTN Strategic Advisory Board's 36-month review, the Chair, Dr. Peter Selby, noted that "the entire Network should be congratulated for the remarkable success over the past three years and these achievements should be celebrated." Across Canada, researchers, research staff, healthcare workers and patients have come together to make real improvements in ACCTs. With the broader ACCT community, 3CTN is proud to lead this development and will continue to optimize ACCT activities and impact nationwide.

3CTN and Academic Cancer Clinical Trials: Identifying Opportunities, Supporting Trial Activities and Demonstrating Impact

3CTN's ongoing priority is assisting the execution of a Portfolio of academic cancer clinical trials (ACCT). More specifically, that means promoting trials that meet pre-defined selection criteria designed to ensure the Portfolio's resources are directed at supporting scientifically worthy and potentially practice changing trials from the Canadian research community. The Portfolio serves several key purposes: i) the communication of trial opportunities to sites and public; ii) the direction of resources to a range of academic trials; iii) facilitation of central reporting on site and Network trial activities; and iv) a description Canada's ACCT environment over time, according to factors of interest (e.g., use of precision medicine, study design elements, target systems, modalities, special populations).

Portfolio Criteria

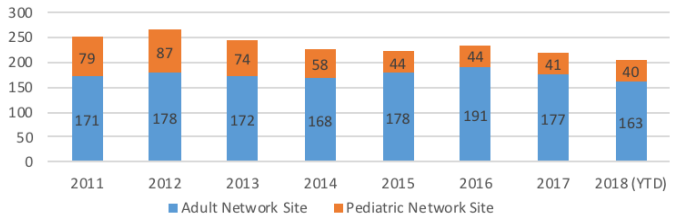
- Interventional
- Academically-sponsored
- Multi-centre
- Independently funded
- Peer-reviewed

Scientific oversight of the Portfolio criteria, composition and management is provided by the Portfolio Committee, whose membership is representative of the cancer research stakeholder community. The Committee is tasked with ensuring that 3CTN maintains a strategic balance of trials that are relevant to Canadian health care system and the needs of Canadians.

The 3CTN Coordinating Centre has developed a robust Portfolio application process. Trials are submitted through a web based system and standardized application template. Trial applications are assessed through a comprehensive review designed to ensure all portfolio trials fulfill the criteria and, in addition, trials are weighted by complexity. The Coordinating Centre is active in ensuring broad access to the Portfolio by facilitating and coordinating the peer review process for trials that have not previously undergone such review. Beyond helping bring new trials into the Portfolio, all trial sites benefit from improved quality of communication of trial opportunities across the network.

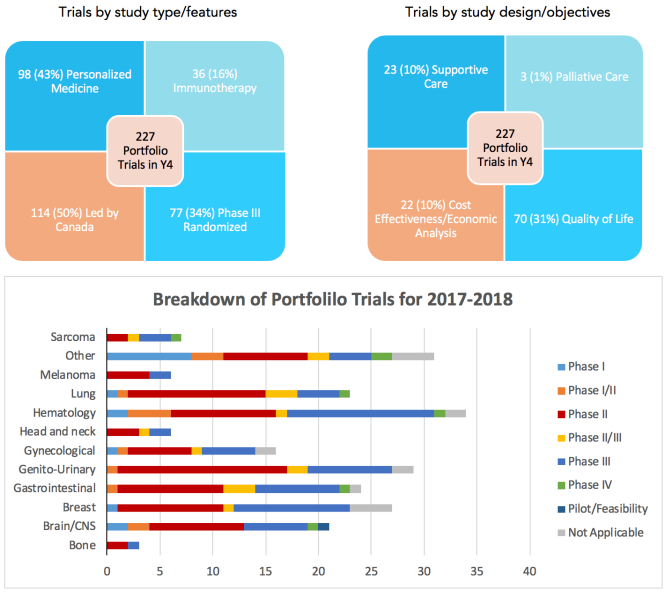
3CTN clinical trial reporting requirements and its promotion of the use of clinical trial management systems by Network sites, has led to a rich set of data describing ACCT in Canada that includes study design features, key metrics and other metadata. These data enable 3CTN to analyze and respond to trends in the academic clinical trial landscape, monitor Portfolio performance and report trial and Network impact to our stakeholders.

Total Portfolio Trial by Calender Year for Network Sites (2011-2018 YTD)



Since the launch of the Portfolio in January 2015, there have been more than 550 trials listed, averaging approximately 200 active trials per year. During the same period, over 220 academic cancer trials have been reviewed for inclusion and 185 were approved (82 per cent acceptance rate), which speaks to the high standard of applications. On average, the 3CTN team receives five trial applications per month with an approval process requiring only a median time of six days. Over the last year, 48 applications resulted in 39 new studies being added to make up this year's total of 227 Portfolio trials.

Overview of Active ACCTs in the Portfolio for 2017-2018



3CTN has enhanced communication of new trial opportunities to the Network. One tool is the Portfolio Newsletter, which aims to raise awareness of Portfolio trials by highlighting new trials, and report on Portfolio composition to identify new opportunities and trends that exist in cancer clinical trial research. Real-time trial listings are accessible to researchers, patients and the public on the 3CTN website.

Through the Portfolio offerings, 3CTN aims to assist clinicians, researchers and patients in accessing cancer clinical trials. While not inclusive of all trials conducted in Canada, 3CTN Portfolio studies address areas of priority to the cancer research and funder communities, and all have a pan-Canadian focus. The 3CTN Portfolio provides a powerful tool for identifying gaps and investigating emerging trends in cancer trials, a level of insight that is invaluable for advising future priorities for 3CTN, its stakeholder community and funders.

"I think the Portfolio Committee has succeeded in ensuring there is a fair, transparent and easy-to-navigate process for getting relevant trials listed on the 3CTN Portfolio. This is important because, as described, the Portfolio itself is a very useful tool. In the coming years, the Committee will need to focus more on identifying priorities and gaps – a challenging task" – **Joe Pater, Chair of the Portfolio Committee**

PPI: Ensuring the Patient's Voice is Heard in Canadian Cancer Research

Ensuring the patient and caregiver perspective is present in agenda-setting, planning and the conduct of healthcare research, referred to as "Patient and Public Involvement" (PPI), has been one of 3CTN's most important goals since its inception. During its initial four years, 3CTN has successfully included PPI at all levels of the Network, from representation on all governance committees to facilitating adoption by cancer centres across Canada. PPI activities have focused not only on ensuring central PPI roles were implemented effectively, but also on introducing a framework for PPI programs for adoption at member sites.

The Lay Representative Advisory Committee (LRAC), formed at the inception of 3CTN, is comprised of survivors and family members with cancer clinical trial experience. They provide insight, expertise and support to the Network by actively ensuring the lay perspective in the development and evaluation of 3CTN activities. The LRAC's depth of personal insight and expertise has contributed to the great strides made in educating member centre staff on the anticipated benefits and best approaches to incorporating PPI into clinical research oversight, and communication activities. Lay representatives have also contributed tremendously as active participants in 3CTN workshops and courses, providing unique knowledge and experience and crucial feedback during presentations and discussions.

The LRAC has contributed to the development of a framework and tools for PPI adoption. Publication of 3CTN's Guide to PPI, as a "one-stop-shop" for everything related to PPI, allowed cancer centre staff to educate themselves on its importance for their local clinical trial activities. Tool kits and features accompanying the guide introduce the concept and benefits for site staff, including a "World of Clinical Trials" primer for all lay representatives joining the Network, and "PPI in Action" examples for all readers to gain an understanding of the many ways that PPI can assist with healthcare research. Implementation success stories are included and shared in quarterly 3CTN Newsletters. Another achievement has been the implementation of the "Ask Me" campaign designed specifically to educate patients with cancer about clinical trials across 3CTN centres.

3CTN is building a community culture of PPI consultation and engagement where the patient voice is considered throughout in establishing clinical trial priorities, research activities' review and education approaches. Respecting and integrating this perspective within all these aspects promotes not only the success of specific clinical trials, but a healthier trial environment that benefits patients.

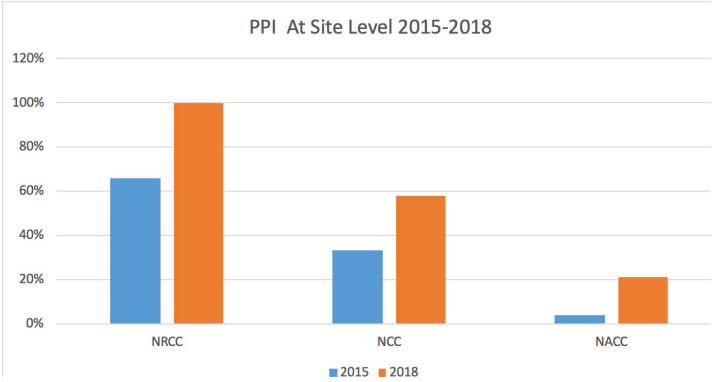
Remembering Robbie Stewart

(Lay Representative Advisory Committee member who passed in 2017)

PPI is often an overlooked component in clinical trials, but it represents a great opportunity to drive improvement for all clinical trial stakeholders in Canada"

Adoption of PPI

Adoption of PPI in different regions across Canada has been broad. Successful implementation of PPI strategies has occurred at 23 of the Network sites. PPI is dependent on many variables and looks very different from one cancer clinical trial centre to another. Factors such as population, size of site and perceived value, just to name a few, can affect the outcome of success. One factor that ties together the "concept" of successful PPI is that 3CTN ensured very high percentage of trial centres across Canada now have some level of PPI embedded within their organization.



Judy Needham honoured at the Canadian Cancer Research Conference (January 2018)

Judy Needham, a member of the 3CTN Lay Representative Advisory Committee is a recipient of the 2017 Canadian Cancer Research Alliance biennial awards which recognize significant contributions to cancer research in Canada. The award ceremony took place on November 6, 2017 at the Canadian Cancer Research Conference (CCRC) in Vancouver. Judy received the award for "Exceptional Leadership in Patient Involvement in Cancer Research". This award recognizes Judy's passionate and long-standing commitment to improving outcomes for cancer patients. Judy did this through the development of tools and direct engagement of patients in the development of clinical trial questions, protocols and patient materials to ensure that the patient perspective is integrated throughout the research lifecycle.

EDGE: A Collaborative Information System for the Network and Sites

The Canadian Cancer Clinical Trials Network (3CTN) success is dependent on a robust and flexible clinical trials management system (CTMS) with utility for managing and reporting trial metrics of value to both the central Coordinating Centre and Network sites. The best solution was to establish a CTMS to track the metrics and research activities on a common platform that would address the following needs:

1. portfolio management - to support the identification and communication of portfolio trials to patients and the public
2. a data repository to enable analysis and aggregate reporting of collective data derived from participating site reports across Canada without imposing an added burden to the cancer centres
3. a site trial management tool for centralized, comprehensive tracking of clinical trial activities, staffing, milestones, metrics, and finances in an organized fashion
4. a virtual platform for site communications and collaboration in sharing best practices

3CTN selected the EDGE system, which was developed in the United Kingdom by the University of Southampton and University Hospitals Southampton National Health Service Foundation Trust. Recognizing some sites have their own in-house CTMS, EDGE adoption was not mandated but instead provided through the CC as a supported option for those centres that expressed the need, interest, capacity and readiness for adopting a system.

The 3CTN CC has developed comprehensive implementation support to interested sites including: live demonstrations of the system, project planning, data structure setup, customized Admin User Manual, lead Admin user training and front-line access to facilitate the roll-out at the site level. The 3CTN CC also hosts monthly teleconferences to promote best practices, resolve user issues and to determine how EDGE can best be used and standardized to benefit all sites across the country.

We use EDGE to track all recruitment activities, assign studies, analyze staff workload, share recruitment reports and trial listings, track ethics submissions and approval, upload regulatory documents and centralized files, track basic finance information, among many other uses. If it's clinical trials related, it's in EDGE.

- Bianca Bier, Juravinski Cancer Centre, Hamilton Health Sciences

The success of early EDGE adopters like the Ottawa Hospital Cancer Program and BC Cancer has encouraged more sites to consider the benefits of using a CTMS. Over the last three years, 16 cancer member sites are now using EDGE (5-BC, 2-Alberta, 1-Manitoba, 8- Ontario,), four sites under setup (3-Quebec and 1-Ontario) and several other sites expressing interest in implementing over the next four years.

EDGE provides us with a wealth of knowledge to know which trials are accruing and which are not and why not.

- Richard McClelland, London Regional Cancer Centre

Cancer centres are using a CTMS to effectively track important trial milestones, regulatory processes, recruitment, reporting and finances. EDGE users have said they are especially pleased with its powerful reporting capabilities, which allows them to follow trends in research activities over time. Using a Network-customized and web-based application like EDGE leads to better performance management and collaboration capabilities within the cancer clinical trial network community across the country. Drawing from its successes, 3CTN is committed to continue to support more cancer centres in adopting EDGE as part of its Strategic Plan for 2018-22.

3CTN Portfolio Patient Recruitment Network Target Achieved: Strong Finish to Year Four

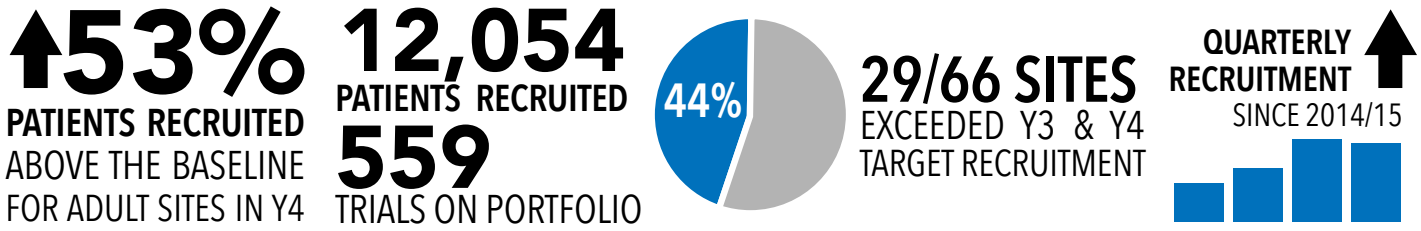
Since its creation in 2014, one of 3CTN's key objectives has been to improve patient access and recruitment to Portfolio trials by 50 percent above the pre-3CTN baseline within four years. In just three years, 3CTN reversed the decline in academic cancer clinical trial recruitment, and implemented other performance improvements across the Network through specific initiatives and workshops and the combined efforts of 3CTN members. However, this success was not assured. At the time of 3CTN's launch, a 50 percent growth target in four years was considered an aspirational Network "target", given changes in the trial environment, with few large randomized trials and more trials in rare cancer populations. At the 3CTN Scientific Advisory Board (SAB) 18-month review, recruitment, which had fallen in the first year, was observed to be on the rise, but still trending behind the Network target.

To address the SAB's recommendation to further focus on improving recruitment, the Coordinating Centre implemented a number of targeted initiatives to specifically identify and address barriers to cancer trials' accrual. These initiatives included the creation of a recruitment best practices manual, the identification and adoption of recruitment tools, including a Recruitment Corrective Action Plan and Lessons Learned Template, holding annual recruitment workshops and creating new communication messages such as the "feature trials" item in 3CTN newsletters and the monthly Portfolio Watch. These communications were implemented to encourage the participating sites to recruit patients to newly added portfolio trials, and highlights of top/low recruiting trials.

"With the collaboration of 3CTN, the CHUM, already considered one of the largest patient recruiters, has succeeded in increasing its number of academic clinical studies in oncology up to 140%"

Centre Hospitalier de l'Université de Montréal

By the end of the third year, recruitment had significantly improved: every region reported increases in recruitment over Year 1 and, more sites met their quarterly recruitment targets. Patient recruitment had increased at Network sites by 150 percent compared to pre-3CTN baseline, well exceeding the Year 3 target of 137.5 percent. The improvement in recruitment continued into Year 4 despite some high recruiting trials closing. By the end of Year 4, 3CTN members met the Network target for patient recruitment: 4118 patients were recruited to the portfolio trials, with 29 sites meeting their annual target in Year 4.



More than 35 sites received top up per case funding, with more than $1.8 million distributed in each of Years 3 and 4.

	Year 1	Year 2	Year 3	Year 4
Number of PCF-eligible Patients	32	459	1497	1509
PCF amount total	$ 49,000	$ 581,000	$1,838,695	$1,857,325

"3CTN has helped our department rally resources and network both internally and externally to expand our trial portfolio and promote recruitment. These efforts have resulted in our site exceeding the target of 50 per cent increase in Y4. We are proud of our achievements and proud to be involved in 3CTN!"

Bianca Bier, Network Coordinator and Brenda Kowaleski, Clinical Trial Manager, Juravinski Cancer Centre, Hamilton Health Sciences

What's next

Moving forward, the focus for 2018-2022 will be on addressing the variable performance within certain regions and at 3CTN sites. Key new initiatives will be tailored to individual sites' needs for improvement. 3CTN site engagement remains high and it is anticipated that improvement in performance will continue with sustained high accrual across the network.

Recruitment to 3CTN Portfolio Trials Year 3 and Year 4

Network Site	Type	Pre-3CTN Baseline	Y3 Total	% of baseline	Y4 Total	% of baseline
London Regional Cancer Program	NCC	186	187	101%	169	91%
Grand River Regional Cancer Centre	NACC	20	43	215%	32	160%
Windsor Regional Hospital	NACC	14	63	450%	32	229%
Juravinski Cancer Centre	NCC	181	247	136%	454	251%
Niagara Health System	NACC	17	13	76%	23	135%
Cambridge Memorial Hospital	NACC	11	5	45%	4	36%
St.Joseph Healthcare Hamilton	NACC	21	54	257%	74	352%
Sunnybrook Research Institute	NCC	141	398	282%	363	257%
North York General Hospital	NACC	1	8	800%	11	1100%
Michael Garron Hospital (Toronto East General Hospital)	NACC	2	1	50%	7	350%
Humber River Hospital	NACC	1	1	100%	9	900%
Princess Margaret Cancer Centre	NCC	396	533	135%	473	119%
Northeast Cancer Centre - Health Sciences North	NACC	24	12	50%	9	38%
Trillium Health Partners	NACC	27	51	189%	10	37%
Thunder Bay Regional Health Sciences Centre	NACC	26	46	177%	16	62%
Southlake Regional Health Centre	NACC	10	75	750%	26	260%
Royal Victoria Hospital	NACC	8	58	725%	23	288%
St. Michael's Hospital	NACC	19	27	142%	2	11%
William Osler Health System	NACC	1	29	2900%	13	1300%
Markham Stouffville Hospital	NACC	1	28	2800%	9	900%
Mount Sinai Hospital	NACC	21	40	190%	7	33%
The Ottawa Hospital Cancer Centre	NCC	132	396	300%	500	379%
Kingston General Hospital	NACC	41	122	298%	84	205%
Lakeridge Health	NACC	22	70	318%	18	82%
CancerCare Manitoba	NCC	99	102	103%	90	91%
Saint John Regional Hospital	NACC	37	22	59%	11	30%
Dr. Everett Chalmers Hospital	NACC	1	5	500%	9	900%
Dr. Léon-Richard Oncology Centre	NACC	9	3	33%	3	33%
Nova Scotia Health Authority	NCC	39	52	133%	45	115%
PEI Cancer Treatment Centre	NACC	8	2	25%	0	0%
Nova Scotia Health Authority, Hematology	NACC	7	16	229%	12	171%
Eastern Regional Health Authority (NFL)	NCC	15	12	80%	8	53%
BC Cancer Agency - Vancouver Centre	NCC	106	152	143%	127	120%
Abbotsford Centre	NACC	16	14	88%	22	138%
Centre for the North, Prince George	NACC	1	4	400%	8	800%
Sindi Ahluwalia Hawkins Centre for the Southern Interior	NACC	38	30	79%	28	74%
Vancouver Island Centre	NACC	26	69	265%	64	246%
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal(CIUSSS CODIM)	NCC	87	159	183%	141	162%
CISSS de l'Outaouais	NACC	3	4	133%	32	1067%
CHU de Québec – Université Laval	NCC	180	144	80%	236	131%
CISSS du Bas-Saint-Laurent(CISSS-BSL)	NACC	4	4	100%	7	175%
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke (CIUSSS-Estrie-CHUS)	NACC	46	70	152%	55	120%
Centre Hospitalier de l'Université de Montréal (CHUM)	NCC	153	123	80%	149	97%
CIUSSS de la Mauricie-et-du-Centre-du-Québec (CIUSSS MCQ)	NACC	8	17	213%	13	163%
CISSS de Laval	NACC	4	12	300%	11	275%
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	NACC	3	4	133%	16	533%
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	NACC	60	51	85%	49	82%
Tom Baker Cancer Centre	NCC	76	125	164%	154	203%
Cross Cancer Institute	NCC	102	137	134%	99	97%
C17 (national pediatric total)	NRCC	347	355	102%	361	104%
The Hospital for Sick Children	NACC	91	89	98%	69	76%
CHU Sainte-Justine, peds	NACC	42	44	105%	40	95%
BC Children's Hospital	NACC	34	41	121%	31	91%
Montreal Children's Hospital	NACC	24	14	58%	20	83%
Alberta Children's Hospital	NACC	21	10	48%	14	67%
McMaster/Hamilton Health Sciences Centre	NACC	14	19	136%	28	200%
Children's Hospital of Eastern Ontario	NACC	20	35	175%	31	155%
Children's Hospital, London Health Sciences Centre	NACC	12	26	217%	9	75%
Stollery Children's Hospital	NACC	11	26	236%	33	300%
IWK Health Centre	NACC	20	16	80%	40	200%
CHU de Quebec, peds	NACC	17	7	41%	17	100%
CancerCare Manitoba,peds	NACC	18	14	78%	17	94%
Saskatoon Cancer Centre	NACC	6	5	83%	4	67%
Janeway Child Health Centre	NACC	4	4	100%	4	100%
Kingston General Hospital	NACC	9	5	56%	4	44%
Allan Blair Cancer Centre, peds	NACC	4	0	0%	0	0%
CHU de Sherbrooke, peds	NACC	1	0	0%	0	0%
Total (N=66 in Y3&4, 65 in Y2 & 53 sites for Y1)		**2798**	**4195**	**150%**	**4118**	**147%**
Adult Patient Sites (N=49 for Y3&4, 48 for Y2, and 36 for Y1)		**2451**	**3840**	**157%**	**3757**	**153%**
Ped sites (N=17) total		**347**	**355**	**102%**	**361**	**104%**
Total # of sites met target				**29**		**29**

3CTN Coordinating Centre Achievements in Four Years (2014-2018)

The Coordinating Centre (CC) is a site responsible for organizing and managing activities and logistics for all collaborative components of the Network. Key responsibilities include: overall data and financial management, monitoring progress against objectives and communication among sites, funders, members and major stakeholders. Over the past four years, 3CTN CC executed all of its responsibilities and it has been responsive to its stakeholders, inspiring support and allowing 3CTN to achieve numerous successes, which have transformed the academic cancer clinical trial environment in Canada.

Outlined below are activities within key performance categories achieved in 2014-2018.

Network Governance and Sustainability:

- Executed contractual agreements with 18 funding partners and/or collaborators;
- Formed three Governance Committees: The Scientific Advisory Board, the Steering Committee and the Strategic Council. The Committees have successfully provided high level oversight and advice on strategic directions and priorities and ensured operationalization of all program activities;
- Coordinated the Scientific Advisory Board's evaluations at 18 and 36 months of the 3CTN program, as well as the responses to SAB recommendations.

Network Implementation:

- Established 49 agreements with 59 institutes through formal Request for Applications peer review, and approval process. Member sites span across 10 provinces, including: Six Network Regional Coordinating Centres (NRCCs), 14 Network Cancer Centres (NCCs) and 52 Network Affiliated Cancer Centres (NACCs), comprising adult and pediatric centres.

Network Performance:

Implemented activities to increase patient recruitment to academic trials, including:

- Formed the Performance Strategy Team to evaluate the Network's performance, identified problems and proposed the development of new initiatives and tools to improve a) the efficiency and quality of trial activities, b) the competencies of clinical trial staff through education, training and mentoring and c) methods to achieve greater patient access to trials;
- Developed and published the 3CTN Recruitment Best Practices Inventory for Network sites;
- Organized recruitment workshops to improve sites' understanding and implementation of recruitment best practices;
- Launched the "Ask Me" clinical trial education and awareness campaign across network sites;
- Created and rolled out new recruitment tools;
- Established a regular Recruitment Discussion Forum for Network sites;
- Developed metrics for tracking trial-specific tasks and timelines for cross-site comparison.

Supported activities to report trial metrics across the Network:

- Set up EDGE Clinical Trial Management System (CTMS) for the CC and member sites;
- Facilitated adoption of EDGE CTMS for 16 Network sites executing agreements to implement EDGE and provided support for implementation through:
  - The creation of site roll out package and training program;
  - Hiring and training of EDGE super-users to provide site support.

Developed the Trial Portfolio to support conduct of trials addressing questions important to cancer patients, researchers and the Canadian Health System:

- Formed the Portfolio Committee to provide scientific oversight, consistent and transparent application of the Portfolio criteria to ensure inclusion of trials that drive improvements in Canadian cancer care;
- Created and provided operational support for key processes for new trial application submission and assessment with the Portfolio Committee;
- Developed the trial complexity weighting system (TCWS), used to determine payments associated with accrual to Portfolio trials;
- Developed and implemented a communication plan to ensure sites' awareness of new trials added to the Portfolio;
- Reviewed 226 trials, of which 185 were approved since 2015, and with a median time from application to approval of six days. As of April 1, 2018, the Portfolio contains 185 active recruiting trials.

Collaborated to improve the Canadian cancer research environment:

- With Jazz Pharmaceuticals, supported a workshop to develop an Adolescents and Young Adult clinical trial in Acute Lymphocytic Leukemia;
- Facilitated a request for applications for prostate cancer clinical research supported by a $500,000 grant from Janssen Canada. Funding was awarded to Dr. Kim Chi, BC Cancer Agency to support precision medicine basket trial in prostate cancer;
- With the Canadian Tissue Repository Network (CTRNet), launched a biobanking education program for Network sites, to increase access to high-quality biospecimens, through standardization of biobanking processes. To date, 63 per cent of all Network sites have completed CTRNet registration.

Network Communication:

Developed and executed a comprehensive Network communication strategy including:

- Created the 3CTN Website and regular 3CTN website updates;
- Developed and distributed monthly e-newsletters to more than 400 stakeholders;
- Organized quarterly conference call for site managers, to provide opportunity for regional updates addressing local challenges;
- Hosted 74 Scientific meetings, public events/outreach workshops and courses, attended by 814 participants;
- Responsible for 38 presentations made at conferences and 86 articles posted in newspapers and/or on social media/internet.
- Coordinated four Annual Stakeholders' Meetings over the four years with each having over 60 attendees from across Canada.

Network Research

- Collaborated with the Canadian Centre for Applied Research in Cancer Control (ARCC), on two research projects to help inform 3CTN on what steps to take to improve the academic trial environment in Canada. These projects will be completed in 2018;
- Supported the formation and operation of three Clinical Trial Study Groups (melanoma, breast, and genitourinary), to identify key research priorities. These priorities were provided to the research community for their consideration for new trial proposals.

Patient and Public Involvement:

- Formed the Lay Representative Advisory Committee to focus on providing meaningful feedback, insight, expertise and support to the Network in terms of active solicitation of lay involvement in the development and evaluation of 3CTN activities;
- Consulted and collaborated with the Lay Representative Advisory Committee (LRAC) to ensure the incorporation of PPI across the Network and all 3CTN Committees;
- Published the 3CTN Guide to PPI for site staff and Lay Representatives;
- Published the Framework of Community Representation on Health Research Committees.

3CTN Regional and Site Achievements

Between 2014-2018, the Network built a strong foundation to address challenges to conducting ACCTs arising at 3CTN sites both across and within regions that share provincial health care and cancer delivery systems.

Supported by the Coordinating Centre, the regions strengthened communications and interactions among sites, streamlined their operational processes, participated in important recruitment initiatives such as the "Ask Me" Campaign, increased recruitment and implemented innovative PPI strategies.

Launch of the Ask Me Campaign at the 3CTN Recruitment Workshop March 2016

Meetings, Recruitment Workshops, as well as the Scientific Advisory Board (SAB) 18 and 36-month reviews, sites have reported on significant improvements made in aligning multi-centre trials' conduct, shared uptake of best practices and have informed the broader community of the value of trials and the Network. Significant improvement in regional communication, collaboration and human resource capacity among cancer trial centers has, in turn, improved the quality and performance of trial activities both within regions as well as benefited others across the country through knowledge exchange.

Today, regulatory and GCP compliance has been accomplished and maintained with SOP (Standard Operating Procedure) adoption at 100 per cent of 3CTN sites and larger centres are sharing knowledge and personnel with smaller centres to increase clinical trial activities. This has resulted in turnarounds in recruitment to academic clinical trials in all regions presented in this report.

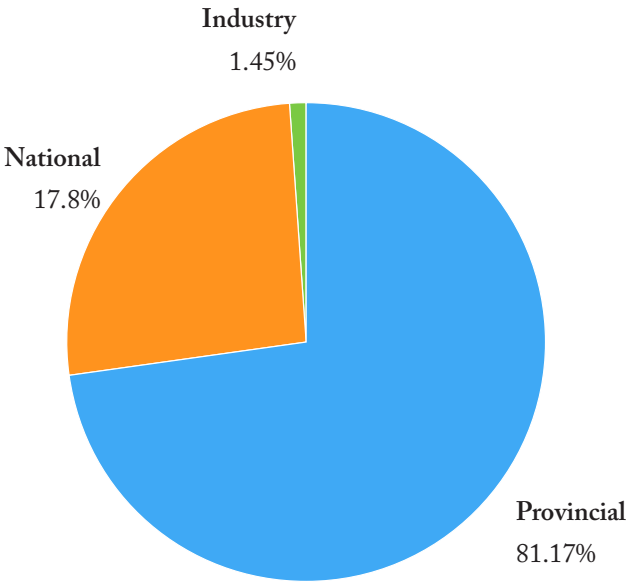
Accomplishments Highlights	BC	Alberta	Manitoba	Ontario	Quebec	Atlantic Canada	C17
Established NCC (number)	1	2	1	5	3	2	-
Established NACC (number)	4	-	-	19	7	5	17
Increased recruitment accrual (% above baseline)	33%	42%	-	79%	29%	-	104%
Accrual to 3CTN target (% achieved)	89%	95%	61%	120%	116%	51%	NA
Developed & adopted enhanced regional organization & communications	✓	✓	✓	✓	✓	✓	✓
Implemented PPI representation for the region	✓	-	-	✓	✓	✓	✓
Implemented organized efforts to raise patient & public awareness of trials	✓	✓	✓	✓	-	-	✓
Implemented EDGE CTMS software	✓	✓	✓	✓	✓	-	-
Completed CTRNet registration at sites	✓	✓	✓	✓	✓	✓	✓

Revenue and expenses for fiscal years 2014-2018

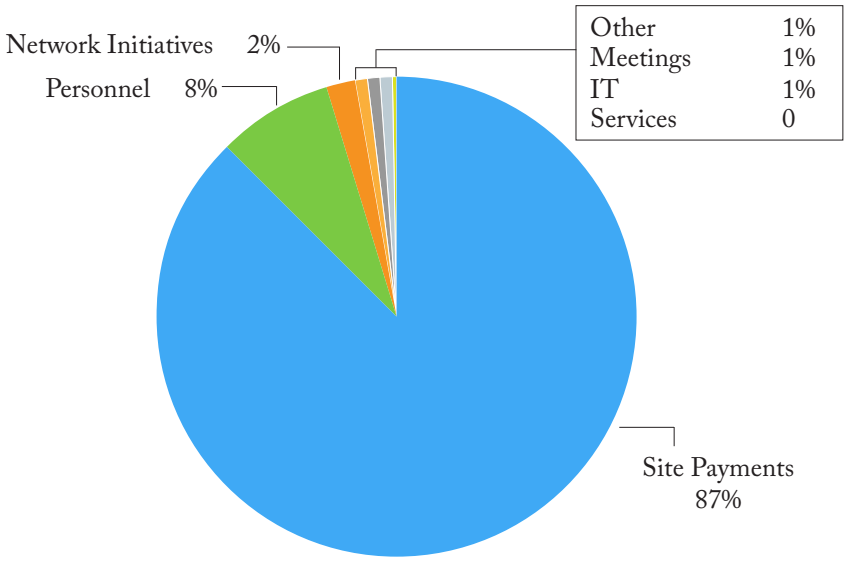
Period ending March 31, 2018		Amount in CDN $
Revenue		
National		5,900,000.00
Provincial		16,393,679.79
Other		225,600.17
Total	**$**	**22,519,279.96**
Expenses		
Site Payments		18,483,545.14
Personnel		1,641,143.60
Network Initiatives		368,302.81
Other		204,459.49
Meetings		190,970.78
IT		181,640.57
Services		1,311.63
Total	**$**	**21,071,374.02**

Note: Excess of revenue over expenses carried forward to Y5 (18-19) for Per-Case Funding, which cleared in Y5, Q1.

Revenues



Expenses



Funding partners

Alberta Cancer Foundation

BC Cancer Foundation

CancerCare Manitoba
ActionCancerManitoba

New Brunswick Health Research Foundation
Fondation de la recherche en santé du Nouveau-Brunswick

Nova Scotia Health Research Foundation

OICR
Ontario Institute for Cancer Research

Canadian Partnership Against Cancer
Partenariat canadien contre le cancer

Canadian Breast Cancer Foundation
Fondation canadienne du cancer du sein

Janssen
Pharmaceutical Companies of Johnson & Johnson

Q-CROC

Fonds de recherche Santé Québec

Direction Générale de Cancérologie

Eastern Health
Newfoundland & Labrador

QEII Health Sciences Centre Foundation

Collaborators

Canadian Cancer Trials Group
Groupe canadien des essais sur le cancer

OICR
Ontario Institute for Cancer Research

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

3CTN Steering and Executive (*) Committee

Ian Tannock (Chair)*, MD
Emeritus Professor of Medical Oncology
Princess Margaret Cancer Centre

Janet Dancey*, MD
Scientific Director,
3CTN

Bernie Eigl*, MD
Provincial Director, Systemic Therapy Clinical Trials,
BC Cancer Agency

Annette Cyr*
Lay Representative and Chair,
Melanoma Network of Canada

Craig Earl*
Vice President, Cancer Control
Canadian Partnership Against Cancer

Gerald Batist*, MD
Scientific Director,
Q-Clinical Research Organization in Cancer (Q-CROC)

Kathryn Dyck, BA
Manager, Clinical Trials Unit,
CancerCare Manitoba

Joseph Pater, M.Sc., MD
Emeritus Professor,
Queen's University

Leonard Minuk, MD
Medical Oncology and Hematology
CancerCare Manitoba

Jim Pankovich, M.Sc., MBA
Vice President, Clinical Operations & Drug Development
Qu Biologics

Daniel Rayson, MD
Professor of Medicine, Medical Oncology,
Dalhousie University

James Whitlock, MD
Division Head, Hematology/ Oncology,
The Hospital for Sick Children

Glenn Bauman, MD
Radiation Oncology
London Regional Cancer Program

Fred Saad, MD
Chief of Urologic Oncology
University of Montreal Health Centre

Patricia Tang, MD
Clinical Assistant Professor, Departments of Oncology
Tom Baker Cancer Centre

Karen Arts
Executive Director,
3CTN

Lam Pho
Director, Information Technology,
3CTN

Since its inception, the Steering Committee has been responsible for overseeing 3CTN's original implementation as well as supporting its scientific and operational management functions throughout the original 2014-2018 business plan. For the 2018-2022, the responsibilities of the Steering Committee will transition to the newly formed Management Committee, which will continue to provide 3CTN organizational guidance by overseeing processes for implementing scientific and operational objectives, ensuring achievement of deliverables and assisting in evaluating the progress of program activities.

3CTN Scientific Advisory Board

Peter Selby, MD, DSc. (Chair)
Professor of Cancer Medicine, University of Leeds,
President of the Association of Cancer Physicians

Gavin Stuart, MD
Dean, Faculty of Medicine and Vice Provost Health
University of British Columbia

Kathy Pritchard – Jones, MD
Chief Medical Officer
London Cancer

John Mackey, MD
Medical Oncologist,
Cross Cancer Institute

Martin Schechter, MD
Professor, Faculty of Medicine
University of British Columbia

Patrick Sullivan
Lay Representative

Karen Arts
Executive Director, 3CTN

Janet Dancey
Scientific Director, 3CTN

3CTN's Scientific Advisory Board has been responsible for providing recommendations to 3CTN on strategic priorities for trials and activities, and for evaluating the progress of 3CTN. Over the coming 2018-2022 business cycle, the Scientific Advisory Board will continue its responsibilities to suggest changes in the scope or direction of 3CTN research priorities and focus of clinical activities, as well as advising on relevant changes in regulations, health policy and/or overall trends in health care, science and technology related to Canadian cancer trials conduct.

3CTN Strategic Council

Robert Phillips, PhD
Professor Emeritus, Dept. of Medical Biophysics,
University of Toronto

Anthony Fields, MD
Professor Emeritus, Dept. of Oncology,
University of Alberta

Lynn Guerreiro, MHSc
Assistant Deputy Minister, Negotiations and Accountability
Management Division, Ministry of Health and Long-Term Care

Elizabeth Eisenhauer, MD
Professor Emerita, Department of Oncology,
Queen's University

Karen Arts
Executive Director,
3CTN

Janet Dancey, MD
Scientific Director,
3CTN

The Strategic Council has been responsible for supporting the development of 3CTN's strategy, to ensure alignment with key stakeholder priorities as well as ensuring effective engagement of Canadian stakeholder groups. For the 2018-2022 business plan, the responsibilities of the Strategic Council will be undertaken by the 3CTN Funders Oversight Committee, which will provide advice on strategic direction, priorities and sustainability planning for the Network.

3CTN Coordinating Center

From left to right:
Front row: Saher Lalani, Rebecca Xu, Sarah Luttrell,
Back row: Suzana Kovacevic, Dr. Janet Dancey, Stephen Sundquist, James Schoales,

Not shown:
Lam Pho

Janet Dancey, MD
Scientific Director

Stephen Sundquist
Executive Director

Lam Pho
Director, Information Technology

Suzana Kovacevic
Project Manager

Rebecca Xu
Portfolio and Informatics Specialist

Saher Lalani
Project Financial Analyst

James Schoales
Portfolio Metrics Coordinator

Sarah Luttrell
Administrative Assistant

Canadian
Cancer Clinical
Trials Network

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