Canadian
Cancer Clinical
Trials Network

Supporting Conduct, Improving Outcomes and Demonstrating Impact of Canadian Academic Cancer Trials

2018/19

ANNUAL REPORT

Executive Opening Statement

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

On behalf of the Canadian Cancer Clinical Trials Network's (3CTN) members, funders, collaborators and stakeholders, we are proud to present our annual report for the 2018-2019 fiscal year, which reflects the accomplishments achieved in the first year of the Network's current strategic plan.

This year we launched our renewed strategic plan for 2018-2022, incorporating objectives and activities for participating cancer centres and affiliated centres from regions across the country. We implemented a restructured governance framework and an adapted communications model to align with set objectives and activities developed to best address operating capacity and evolutionary changes in the clinical trials environment.

We are pleased to note that the year-over-year trend of increased patient accrual to Canadian academic clinical trials observed since 3CTN's creation has continued again this year. 3CTN is also proud to continue its leadership in establishing a comprehensive model for embedding Patient and Public Involvement (PPI) in the planning and conduct of cancer trials. Highlights of achievements over the past year include collaborative development and implementation of newly-defined measures for trial initiation, expanded use of clinical trials management systems and a novel framework for defining impact of 3CTN Portfolio trials.

During their six-month review following the renewal, 3CTN's Scientific Advisory Board (SAB) acknowledged the successful implementation of the new strategic plan with the consensus that Network's adapted organizational model is well poised to transition and build on achievements realized from 3CTN's initial four-year plan. Maintaining a priority focus on academic cancer clinical trials, Portfolio and work undertaken to delineate trials with greater impact were recognized as imperative for sustaining the major advancements seen to date.

Central to 3CTN's continued success will be to place a priority on research opportunities and initiatives that are as inclusive of as many regions and populations as possible. For example, work in the coming years will include efforts to create more equitable access to trial options for all patient populations – those living greater distances from cancer centres as well as to further develop the 3CTN Portfolio to include innovative measures and data to better capture and help address the specific needs of paediatric and adolescent and young adult (AYA) populations. The SAB's report also emphasized the essential need for a robust and diversified funding model that adequately supports core activities and is augmented by performance incentive and project-based funding from both existing sources and new partnerships.

We trust 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. We extend sincerest thanks to all who's commitment to advancing trial performance standards, patient involvement and accrual enables a greater number of cancer screening and treatment options being made available through high quality clinical trials. By leveraging achievements and successfully addressing noted priorities, 3CTN contributions can be expected to continue to improve the Canadian cancer clinical trials landscape and yield better outcomes for Canadian cancer patients.

Changing the ACCT Landscape

The Canadian Cancer Clinical Trials Network (3CTN) seeks to ensure that Canada remains a recognized global leader in academic cancer clinical trials (ACCT) through 2018-2022 by building on the successful achievement of our 2014-2018 strategic plan objectives.

Networking Canada's cancer centres and partner institutions helps overcome local and systemic challenges to initiation and efficient multi-centre trial conduct. Central access to up-to- date Portfolio of trials, shared resources and study management tools means site teams are able to focus on trial conduct activities as well as draw on a wealth of research community experience when undertaking continuous improvement, development initiatives or optimizing performance.

3CTN priorities for 2018-2022:

- Continue to improve patient awareness, access and accrual to open trials across all sites;
- Enhance patient and public involvement in trial design, engagement and conduct;
- Improve performance, focusing on trial initiation timelines, recruitment projections and quality initiatives;
- Further optimize the 3CTN ACCT Portfolio by creating additional trial opportunities for cancer centres and demonstrate trials' impact.

While initial 3CTN strategic objectives focused on establishing the foundational framework of the Network, present focus is on improving patient involvement, trial performance and providing tailored support for sites' core competency development to support achievement of accrual targets.

The continued success of the Network depends on maintaining and further developing some key enablers:

- Engaged, transparent governance and management;
- Enhanced collaboration, communications and reporting to stakeholders;
- Efficient, dynamic operating framework and processes that serve an evolving Network and changing trial environment;
- Strategic partnerships to address challenges;
- Diversified funding sources to ensure sustainability.

Across Canada and with 3CTN's leadership support, trialists, research staff and patients have accomplished measurable improvements in ACCTs. This year, 4172 Canadians have received innovative treatments or interventions through participation on 3CTN Portfolio trials, raising Network-wide recruitment to 74% over pre-3CTN (2011-2013) baseline levels and greatly surpassing the target objective for a 55% increase.

While the 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 operating challenges as well as to address regional variations in accrual. Strategies include development of a framework that better supports trial access for a sizeable proportion of Canadian cancer patients for whom physical distance from the nearest cancer centre presents a barrier to participation in a clinical trial.

We can take pride in the substantial progress made towards improved quality and performance of trial activities:

- All Network cancer centres have achieved regulatory compliance for implementing GCP SOPs
- Over half of centres have now adopted a clinical trial management systems (CTMS)
- Close to 80% have registered with the Canadian Tissue Repository Network (CTRNet) outlining practices for biospecimen management

While creating connections between Canada's cancer research organizations is important, it is also widely-recognized as integral to engage and collaborate with cancer patients, advocacy groups and charities. Patient and Public Involvement (PPI) within 3CTN is evolving beyond its governance framework to incorporating the patient voice in guiding research planning and conduct of research at each Network centre. A section of this report is devoted to sharing more detail and progress related to these and other exciting PPI initiatives.

Through increased access to promising new detection and treatment options arising from ACCTs, 3CTN's overarching aim continues to focus on demonstrating return on investment for our funders and ultimately, achieving better outcomes for cancer patients across the country.

"After a year of contributing to 3CTN's work, I have come to appreciate how the Network contributes to the Canadian cancer clinical trial environment. Patient representatives play an important role in clinical trials, and it is crucial to have national leadership which focalises our voice so we can effectively contribute to the overall clinical trial process." **- JF. Denault, 3CTN Patient Rep Advisory Committee**

3CTN Trial Portfolio: Measuring Impact

The 3CTN Portfolio is made up of academic cancer clinical trials (ACCTs) that meet a pre-defined criteria for research quality and applicability for the Network. These criteria are transparent and include externally peer-reviewed, multi-centre, academically sponsored, independently funded, interventional oncology trials. To provide a specific and translatable description of Portfolio trial types and measure their impact for stakeholders, a comprehensive framework for cancer trial categorization was adapted from a model by Dilts et al[1] and developed this year. The framework was assessed and validated with support of the 3CTN Portfolio Committee to ensure categories and definitions were robust, distinct and covered the range of trials.

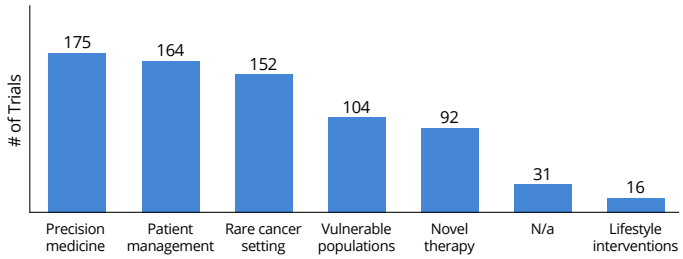
The categories were then applied to all Portfolio trials and the process was operationalized to classify new trials as they are added to the 3CTN Portfolio. Additionally, completed trials are assessed for outcomes based on published results and stated primary outcomes. This approach now allows 3CTN to enhance Portfolio performance monitoring and outcomes reporting, begin to analyze trends in the ACCT landscape and communicate Network impact, identified research gaps and opportunities to stakeholders. Furthermore, this framework can be combined with other trial metrics and serve as a model to be adapted and applied beyond ACCTs.

[1] Dilts DM, Cheng SK. The importance of doing trials right while doing the right trials. Clin Cancer Res. 2012;18(1):3–5. doi:10.1158/1078-0432.CCR-11-2586

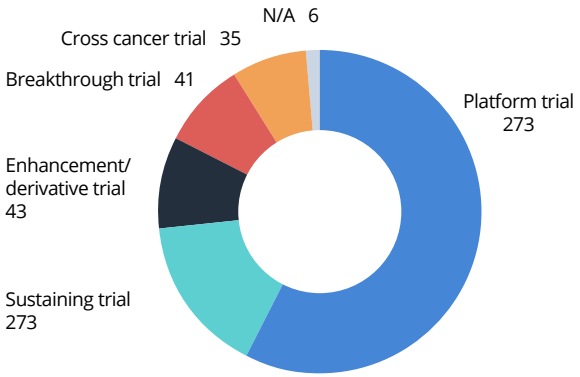
Impact Domain	Impact Category
Trial Areas of Special Interest	Novel Therapy
	Rare Cancer Setting
	Patient Management
	Vulnerable Populations
	Lifestyle Interventions
	Precision Medicine
Potential Impact on Patient Population	Breakthrough Trial
	Platform Trial
	Enhancement/ Derivative Trial
	Sustaining Trial
	Cross Cancer Trial
Innovation	Incremental
	Paradigm Shifting
Study Results	Positive/Negative

Impact Assessment Results for 3CTN Portfolio Trials from 2014-2019 (N=445)

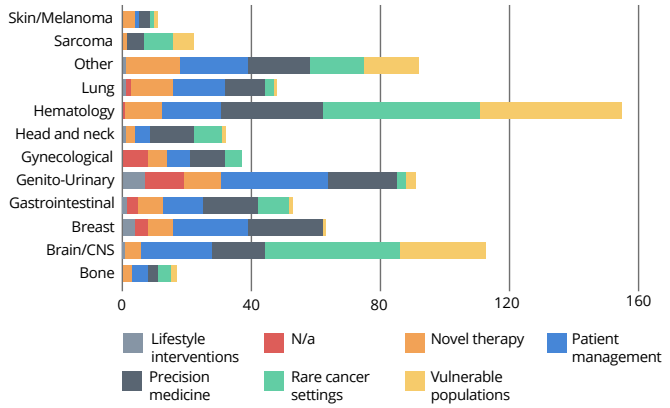
Trial areas of special interest



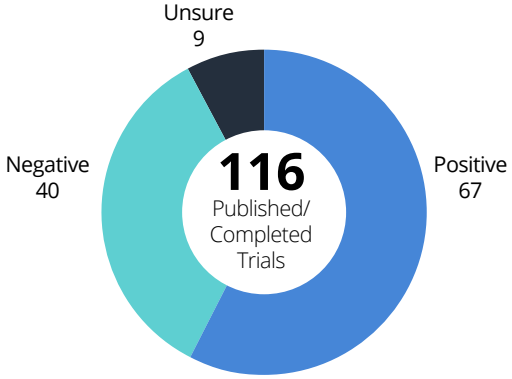
Potential impact on patient population



Trial areas of special interest by disease site

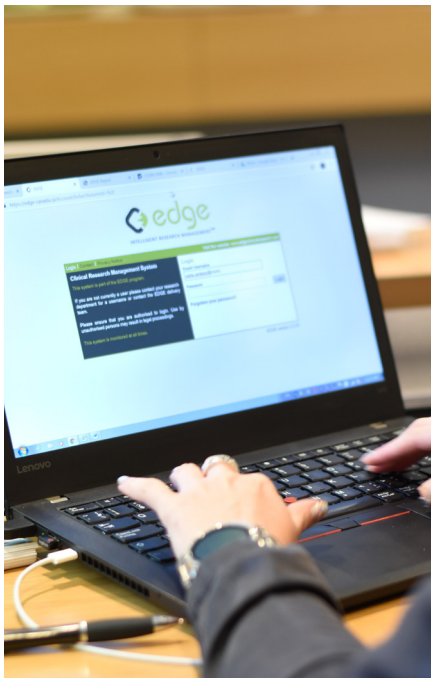


Study results



To learn more about the 3CTN Portfolio and Impact criteria definitions please visit the 3CTN Portfolio Website: https://3ctn.ca/page/portfolio

3CTN Continues to Expand IT Systems Supports for Trial Management



There is strong demand among cancer centers for a clinical trial management system (CTMS) to manage and track trial activities. 3CTN supports the adoption of EDGE, a cloud-based CTMS, and it has been successfully adopted by the 3CTN Coordinating Centre and 18 cancer centres across the Network.

In 2018, the Coordinating Centre assisted with data migration from multiple servers across Canada to one server, hosted by Q9 located in Brampton, Ontario. This required pre-migration planning, data standardization and post-migration data review and clean-up to avoid any disruption to 3CTN reporting processes. All EDGE Canada users are now connected, leading to less duplication, more standardization and increased collaboration.

In addition, the Coordinating Centre has continued to support Network implementation, provided Lead Administrator User training to six organizations and delivered eight information sessions to interested sites. This has resulted in three cancer centres successfully implementing EDGE in the past year, including Montreal Children's Hospital. "Before using EDGE, we had many issues in communicating and disseminating vital information with project collaborators and multi-disciplinary teams," said Stephanie Badour, Clinical Research Unit Manager of Montreal Children's Hospital. "Now we are able to input and view research data and reports in real time and we have created reports in the system that are meaningful for our site."

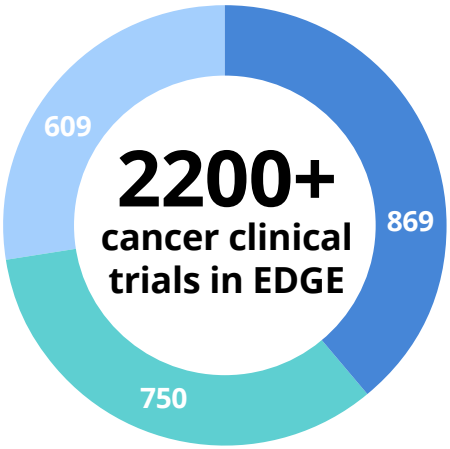
3CTN will continue to promote EDGE adoption as part of its objectives to improve trial efficiency across the Network.

"Since we've added our local activation checklist to EDGE, there is no need to manually transfer data, saving us a lot of time and reducing the chance of transcription errors. We are able to collect a lot more data than we previously did, which allows us to run all kinds of reports looking more closely at each step of our local activation process" **- Elizabeth Lylyk, Resource Coordinator, Ethics & Regulatory Affairs, CancerCare Manitoba**

CTMS: By the numbers

127% increase in sites using a CTMS

EDGE: By the numbers



18/24 of Network sites use EDGE

26,000 patients recorded in EDGE

72% of sites using a CTMS use EDGE

edge

3CTN Performance Metrics Year 5

		Recruitment to Portfolio Trials				3CTN Objectives		
Network Site	Type	Pre-3CTN Baseline	Total # Recruited	% of Baseline	% to Target	Patient Rep Recruited	Ask Me Campaign	CTRNet Registration
Ontario								
London Health Sciences Centre	NCC	186	248	133%	86%	in process	×	✓
Grand River Regional Cancer Centre	NACC	20	32	160%	103%	✓	×	✓
Windsor Regional Cancer Centre	NACC	14	16	114%	74%	in process	×	✓
Hamilton Health Sciences, Juravinski Cancer Centre	NCC	181	345	191%	123%	✓	✓	✓
Cambridge Memorial Hospital	NACC	11	5	45%	29%	✓	✓	✓
St. Joseph's Healthcare Hamilton	NACC	21	40	190%	123%	in process	×	×
Walker Family Cancer Centre, Niagara Health System	NACC	17	37	218%	140%	in process	×	✓
Sunnybrook Health Sciences Centre, Sunnybrook Research Institute	NCC	141	651	462%	298%	✓	✓	✓
Humber River Hospital	NACC	1	7a	700%	452%	in process	✓	✓
Michael Garron Hospital	NACC	2	2	100%	65%	in process	×	×
Princess Margaret Cancer Centre	NCC	396	720	182%	117%	in process	×	✓
Markham Stouffville Hospital	NACC	1	2	200%	129%	in process	✓	✓
Mount Sinai Hospital	NACC	21	12	57%	37%	in process	✓	✓
Northeast Cancer Centre - Health Sciences North	NACC	24	18	75%	48%	in process	✓	✓
North York General Hospital	NACC	1	9	900%	581%	in process	✓	✓
Royal Victoria Regional Health Centre	NACC	8	9	113%	73%	✓	✓	✓
Southlake Regional Health Centre	NACC	10	68	680%	439%	✓	✓	✓
St. Michael's Hospital	NACC	19	1	5%	3%	in process	×	✓
Thunder Bay Regional Health Sciences Centre	NACC	26	25	96%	62%	✓	✓	✓
Trillium Health Partners	NACC	27	12	44%	29%	✓	×	✓
William Osler Health System	NACC	1	0	0%	0%	in process	×	✓
The Ottawa Hospital Cancer Centre	NCC	132	850	644%	415%	in process	✓	✓
Cancer Centre of Southeastern Ontario at Kingston General Hospital	NACC	41	72	176%	113%	in process	✓	✓
Lakeridge Health, RSM Durham Regional Cancer Centre	NACC	22	15	68%	44%	✓	×	✓
Manitoba								
CancerCare Manitoba	NCC	99	98	99%	64%	✓	✓	✓
Prairie Mountain Health	NACC	1	1	100%	65%	✓	✓	×
British Columbia								
BC Cancer Agency - Vancouver Centre	NCC	106	107	101%	65%	in process	×	✓
Abbotsford Centre	NACC	16	22	138%	89%	✓	×	✓
Centre for the North, Prince George	NACC	1	9	900%	581%	✓	×	✓
Sindi Ahluwalia Hawkins Centre for the Southern Interior	NACC	38	38	100%	65%	in process	×	✓
Vancouver Island Centre	NACC	26	69	265%	171%	in process	×	✓
Alberta								
Alberta Health Services, Cross Cancer Institute	NCC	102	103	101%	65%	✓	×	×
Alberta Health Services, Tom Baker Cancer Centre	NCC	76	139	183%	118%	✓	×	×
Quebec								
CISSS de l'Outaouais	NACC	3	1	33%	22%	in process	✓	×
CHU de Québec – Université Laval	NACC	180	99	55%	35%	in process	✓	✓
CIUSSS de l'Estrie - (CIUSSS-Estrie-CHUS)	NACC	46	18	39%	25%	✓	✓	✓
Centre Hospitalier de l'Université de Montréal (CHUM)	NACC	153	112	73%	47%	in process	✓	✓
CIUSSS du Nord-de-l'Île-de-Montréal(CIUSSS NDIM)	NACC	3	8	267%	172%	in process	✓	×
CIUSSS de l'Est-de-l'Île-de-Montréal(CIUSSS-EDIM)	NACC	60	23	38%	25%	in process	✓	✓
Nova Scotia								
Nova Scotia Health Authority	NCC	39	42	108%	69%	✓	×	✓
Newfoundland								
Eastern Regional Health Authority	NCC	15	15	100%	65%	✓	×	✓
Pediatrics								
CancerCare Manitoba - Pediatrics	NACC	18	4	22%	22%	✓	✓	✓
CHU de Quebec - Pediatrics	NACC	17	22	129%	129%	in process	✓	×
Centre hospitalier universitaire de Sainte-Justine Pediatrics	NACC	42	38	90%	90%	in process	✓	✓
Montreal Children's Hospital	NACC	24	8	33%	33%	in process	✓	×
Janeway Child Health Centre	NACC	4	0	0%	0%	✓	×	×
Total (N=46)		**2392**	**4172**	**174%**		**(20) 43%**	**(25) 54%**	**(36) 78%**
Adult Patient Sites (N=41)		**2287**	**4100**	**179%**	**116%**			
Ped Sites (N=5)		**105**	**72**	**69%**				
Number of sites achieving Y5 accural target					**16**			

Network Site Achievements

Newfoundland
- **Accrual to Y5 target = 65%**
- Recruited 1 Patient Rep
- Set up ongoing maintenance of the Clinical Trials Flowsheets and trial tracking system

Nova Scotia
- **Accrual to Y5 target = 69%**
- Recruited 1 Patient Rep
- PPI on Portfolio Review Committee
- Evaluation of open trials process – study performance metrics evaluation

Quebec
- **Accrual to Y5 target = 38%**
- Recruited 1 Patient Rep
- Initiated Pre-screening & Permission to Contact implementation at sites;
- Re-launched Ask Me Campaign at all sites during International Clinical Trials Week in May

Ontario
- **Accrual to Y5 target = 156%**
- Recruited 11 Patient Reps
- Launched Clinical Trials Navigator Program
- Public outreach events to raise CTs awareness
- Streamlined trial activation processes

Alberta
- **Accrual to Y5 Target = 88%**
- Recruited 3 Patient Reps and engaged them in activities
- Developed formal process for conducting post-mortem

Manitoba
- **Accrual to Y5 target = 64%**
- Recruited 1 Patient Rep
- Created process to identify and remediate unforeseen CT budget expenses
- Mentorship for the NACC
- Developed Patient Satisfaction Survey

British Columbia
- **Accrual to Y5 Target = 85%**
- Recruited 1 Patient Rep
- Streamlined process for referral of trials between centres
- Streamlined QA processes and tools

"...3CTN has been a fantastic breath of fresh air by bringing back enthusiasm to performing trials. It has enabled the REaCT Program to expand our portfolio of pragmatic trials across Canada and offer the opportunity for trial participation to thousands of patients. We have already seen significant trial results that have benefited patients both across Canada and globally." **– Mark Clemons, MBBS MSc MD, Professor of Medicine, University of Ottawa**

3CTN Achievements

Renewal activities

46 Network sites

8 Funders

6 Collaborators

Recruitment

74% Increase in patients recruited above pre-3CTN baseline

223 Portfolio trials supported

4172 Patients recruited

Portfolio Management

48 Portfolio applications reviewed

79% Application Approval

Median application processing time <24hrs

"I am extremely honoured and fortunate to be a Patient Advisor. This work is rewarding and meaningful. I do not feel that I was diagnosed with cancer in order to experience suffering. I DO feel that I have a cancer diagnosis for the opportunity to use my experience to improve the lives of others. As a Patient Advisor having a voice is truly a blessing" **– Diane Huband, 3CTN Patient Representative**

Patient and Public Involvement Expansion Progress

Enabling Meaningful Patient Contributions

One key aspect of 3CTN's 2018-2022 Strategic Plan is to reach a standard level of Patient and Public Involvement (PPI) activities at 100 per cent of Network sites by the end of 2022.

Patient Representatives can contribute a crucial perspective to clinical trials by providing feedback, insight, expertise and support towards trial activities and initiatives. Key to increasing PPI across the Network in the last year has been to support individual sites as they begin recruiting Patient Representatives and engaging them in everyday site activities that fit their needs. In an effort to address the challenges of identifying Patient Representatives at the site level and then selecting activities for their meaningful participation, 3CTN, with input from the Patient Representative Advisory Council (PRAC), developed practical and useful Patient Representative Orientation Package toolkit. Consisting of a Patient Representative job description template, a role responsibilities matrix, as well as an orientation checklist the tool is designed to help sites define Patient Representative opportunities during recruitment and co-develop responsibilities during onboarding as well as on an ongoing basis. Each resource can be tailored to reflect both the clinical trial team's priorities as well as the patient partner's capacity, skillsets and interests.

For the purpose of sharing PPI best practices, accessing learning and development opportunities, and addressing any challenges in implementing PPI locally, the Coordinating Centre, together with the PRAC, undertook a further step to establish the Patient Representative Community of Practice (PRCoP), made up of all local Patient Representatives within 3CTN. Quarterly meetings have been organized to connect members and bolster engagement and communication, helping Patient Representatives benefit from the support, experience and mentorship offered both by peers and other PRAC members in attendance. The PRCoP is growing rapidly, with 21 members from across Canada currently on board and many other centers recruiting.

"Being a Patient Representative for 3CTN has been a very rewarding experience. Not only do I get to collaborate and work with great staff but I also get to be part of a Volunteer Network where everyone shares the same values and passion for giving back" - **Don Wood, 3CTN Patient Representative**

Many Patient Representatives assisted their sites in events that were organized during the week of International Clinical Trials Day in May 2019.

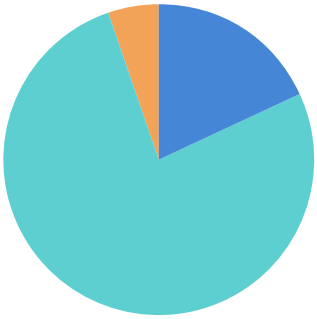
"My hope is that patients are better educated and better advised to the clinical trial treatments that offer them best chance of defeating the disease. I'm proud to work alongside all members of the Network, and the PRAC to help brighten the future for those that reach out for all the support they can get. With the countless people at the cancer centers across Canada working so hard on behalf of the patients, we see victories every day, victories that were thought of as impossible a few short years ago" - **Fred Clark, Chair of the PRAC**

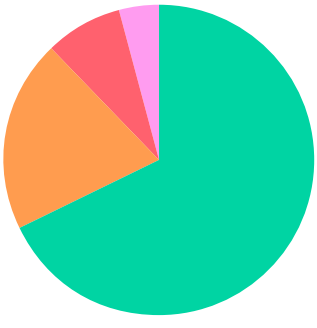
2nd row L to R: Scott Gammer, Fred Clarke, Suzana Kovacevic
1st row: Erwin Wanderer, Judy Needham, Gretta Hutton, Louise Gagne

Revenue and Expenses for Fiscal Year 2018-2019

Period ending March 31, 2019	Amount in CDN $
Revenue	
National	1,000,000.00
Provincial	4,197,133.00
Other	291,500.00
Total	5,488,633.00
Expenses	
Site Core Funding	4,158,155.45
Per Case Funding*	1,238,170.00
Coordinating Centre	492,248.45
Network Costs	224,882.21
Total	6,113,456.11
NET: Revenue Less Expenses	**(624,823.11)**

Note: *PCF amount reflects funds distributed for Y4 (17-18) and accounted for in Y5-Q1 (18-19)





Funding Partners

Collaborators

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Professor of Cancer Medicine, University of Leeds,
President of the Association of Cancer Physicians

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Janet Dancey, MD
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Theresa Radwell
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Scientific Director,
Q-Clinical Research Organization in Cancer (Q-CROC)

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

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Antonia Palmer
Patient Representative

Farah McCrate, PhD
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Diana Kato
Manager, Operations

Suzana Kovacevic
Manager, Projects

Saher Lalani
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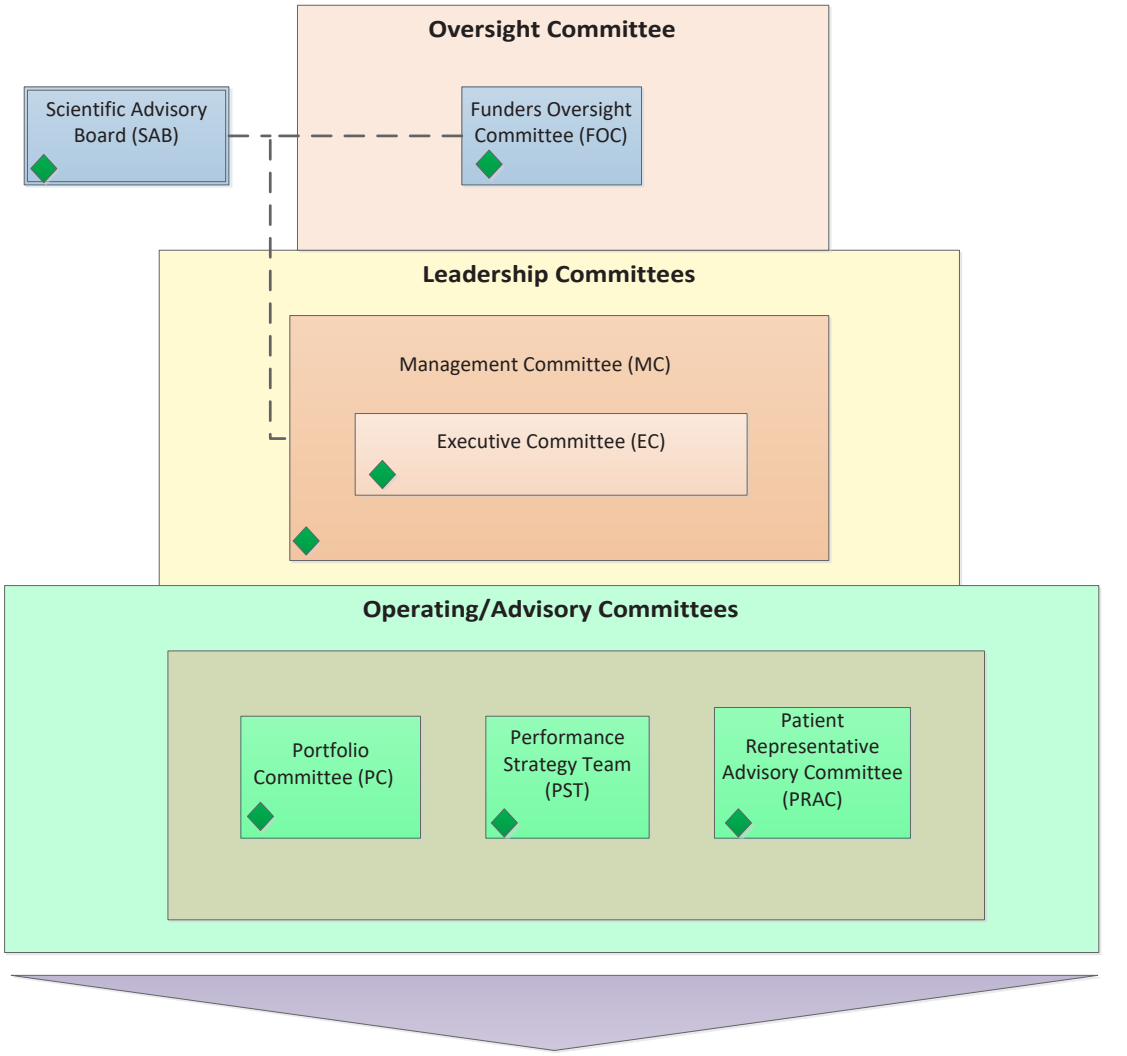
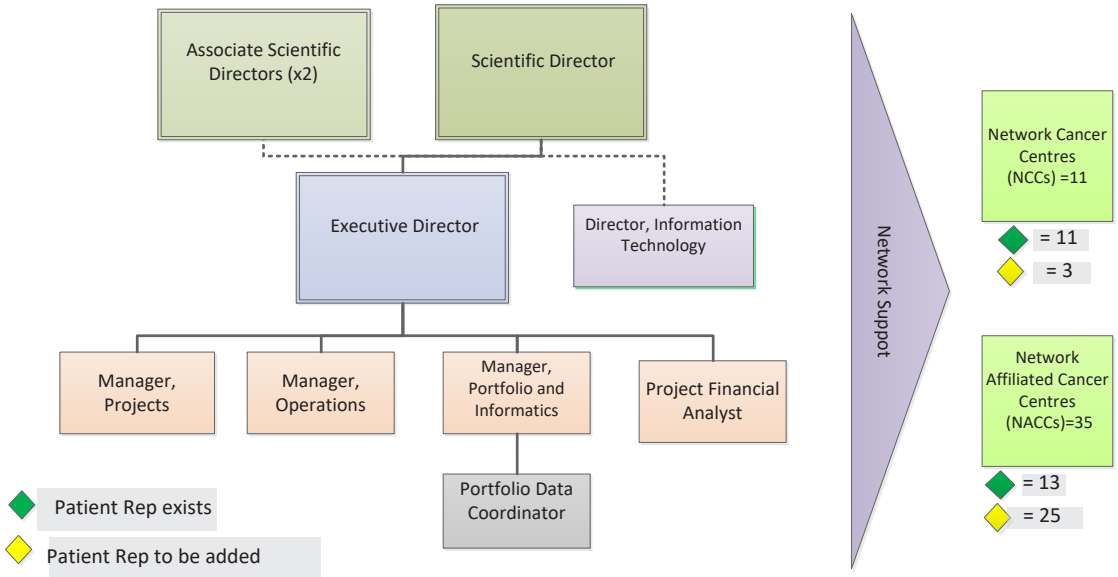
Rebecca Xu
Manager, Portfolio and Informatics

James Schoales
Portfolio Data Coordinator

3CTN GOVERNANCE & ORGANIZATIONAL STRUCTURE



Coordinating Centre Organizational Chart



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