Canadian Cancer Clinical Trials Network

IMPROVING ACCESS TO ACADEMIC CANCER CLINICAL TRIALS

ANNUAL REPORT 2021-2022

Executive Opening Statement

The Canadian Cancer Clinical Trials Network's (3CTN) annual report for 2021–2022 highlights achievements in the final year of the Network's strategic plan for 2018–2022 and summarizes outcomes against its strategic objectives and unique challenges affecting cancer trials conduct throughout the past four years.



Janet Dancey Scientific Director



Stephen Sundquist Executive Director

Since the Network's formation, member cancer centres have realized yearly overall increases in patient accrual to academic cancer clinical trials (ACCTs). The past year was no exception despite exceptional challenges throughout the COVID-19 pandemic. 3CTN members and stakeholder partners embraced adaptive approaches to resume trial activities particularly those that enabled remote patient visits and sponsor interactions.

The response to COVID will support innovative approaches to trial conduct in the post-COVID period. Uptake of the 3CTN-led Canadian Remote Access Framework for Clinical Trials (CRAFT) by adult and pediatric centres is one of 3CTN's strategic initiatives to create more equitable access to trial options for all Canadian patients.

3CTN's mission is to support conduct of new Portfolio trials of high scientific interest and potential clinical impact as successful trials lead to improved outcomes for patients. To support the new strategic plan and renewal of funding, the Network undertook a comprehensive review of ACCT Portfolio performance over the 2018–2022, reviewed its achievements and lessons-learned and consulted its broad stakeholder community. The rich, high-quality dataset characterizes trial activations and accrual at each centre, within regions and nationally showed improvements in accrual and other trial metrics at many sites and highlighted areas for additional improvement. Considerable progress was made addressing strategic priorities for access, recruitment, patient engagement and lessons learned. These results guided a consultation process involving our sites, funders, and oversight committees to develop meaningful priorities, requirements and innovative approaches to support postpandemic ACCT conduct within 3CTN's new five-year strategic plan. Activities will be supported by an evolved performance incentive funding model that will reflect new benchmarks for the coming period with aim to focus on trial initiation and trial performance activities at cancer centres across all regions of the country.

3CTN remains uniquely positioned to help navigate challenges and promote continued improvements to the Canadian ACCT environment. 3CTN members and partners remain dedicated to promoting scientific excellence in research, leveraging achievements and knowledge to improve trial conduct, optimizing patient and public involvement and leading initiatives centred on improving cancer patient's access to the novel interventions offered through high-performing academic clinical trials.



Gerry Batist Associate Scientific Director



Bernie Eigl Associate Scientific Director

Janet Dancey

Scientific Director

Gerry Batist Associate Scientific Director Stephen Sundquist Executive Director

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Introduction

During 3CTN's 2018–2022 strategic plan, more than 21,500 cancer patients received innovative treatments and interventions through participation in the 3CTN Portfolio trials.

Recruitment across Network cancer centre sites was 130 per cent above pre-3CTN baseline levels (average accrual, 2011-2013) and surpassed a target 75 per cent increase for 2021-2022. In total, about 33 per cent of adult 3CTN sites met or exceeded their recruitment target for the current four-year period, which is a remarkable achievement and also highlights persistent variations in accrual seen across the Network. Addressing this variation will remain a 3CTN priority.

We have realized major achievements in improving trial access:

 Nine C17 pediatric cancer centres rejoined 3CTN, co-developed trial performance measures and a unique incentive funding model that reflects the priorities for trials involving children, adolescents and young adults with cancer.

2. The 3CTN-led Canadian Remote Access Framework for Clinical Trials (CRAFT) was published and the proof of concept pilot was launched. The pilot is evaluating an array of clinical trials, decentralized trial delivery approaches and regions implemented at three **3CTN** Cancer Centres, each leading a hub-and-spoke/ trial cluster. The CRAFT publication and implementation pilot has drawn strong interest from 3CTN stakeholders and those outside of oncology. Such interest reflects the unprecedented receptiveness from patient and researcher communities to remote care and decentralized trial delivery.

Substantial progress was made toward achieving Network ACCT quality and performance goals. Achievements include:

- Setting new trial activation benchmarks using 3CTN derived data
- Expanded adoption of a clinical trial management system by more centres to streamline local site operations, facilitate collaboration and additional efficiencies for multi-centre trials
- Furthering PPI and engagement by sites to ensure patient values and preferences are reflected in clinical research activities

Despite the successes of the last four years, there remain unprecedented challenges to trial unit operations and resources. 3CTN plans to provide improved informatics resources for members and work with industry and other partners on initiatives to support sites' research capacity and improve performance post-COVID.

We invite you to review the achievements detailed in this report as examples of how 3CTN demonstrates a high return on investment by supporting Canada's ACCT ecosystem and trials that are testing promising new screening and therapeutic options for all cancer patients.

Improving trial access for rural and remote communities in Newfoundland and Labrador

In June 2022, Eastern Health launched its first Clinical Research Satellite Site in Grand Falls–Windsor, a first in the province and the region for decentralized clinical trial delivery using the Canadian Remote Access Framework for Clinical Trials (CRAFT).

In Newfoundland and Labrador, gaining access to available clinical trials can be particularly challenging for many cancer patients given its predominately rural population distribution. Participation previously necessitated travel to Dr. H. Bliss Murphy Cancer Centre in St. John's. That's beginning to change. In June 2022, Eastern Health launched its first Clinical Research Satellite Site in Grand

Clinical Research Satellite Site in C Falls-Windsor, a first in the province for decentralized clinical trial delivery using the Canadian Remote Access Framework for Clinical Trials (CRAFT). Through CRAFT, Eastern Health aims to broaden access to innovative treatment options through trials for eligible cancer patients, regardless of where they live. "Decentralized clinical trials provide tremendous benefits for patients," says Dr. John Thoms, Radiation Oncologist and Physician Director of Clinical Trials at the Dr. H. Bliss Murphy Cancer Centre. "By eliminating the need to travel to a primary health-care facility in the city, we are able to give more patients in rural and remote areas the opportunity to participate in research that is changing the landscape of cancer treatment."



The new facility will initially serve as a satellite site for the PRIME Phase 3 clinical trial studying the use of metformin in prostate cancer patients and is a result of a partnership with the Town of Grand Falls-Windsor's Excite Corporation, in cooperation with Central Health. Area patients requiring regular study assessments otherwise would have to regularly commit to making the 425 kilometre drive to the Dr. H. Bliss Cancer Centre from Grand Falls-Windsor.

Patients who qualify for this trial will attend the Grand Falls-Windsor clinic for physical assessments, bloodwork, and other follow-up care, eliminating the need to travel to St. John's while maintaining access to the study physician via telehealth appointments. Involving the Grand Falls-Windsor site in this decentralized clinical trial approach will make it possible for more patients from central Newfoundland to be enrolled.



Satellite site, Grand Falls-Windsor

personally, is the stress relief from the expense of travel, as well as worry about moose and weather during the long drive. My wife and children were always concerned about me travelling on the Trans-Canada Highway," says the first trial patient to use this Satellite Site clinic. "With the availability of the satellite clinic. all of that stress

"The biggest impact on me

is lifted. Plus, making involvement more enticing for patients from a greater geographic portion of our province can help to boost cancer research. It's great news from all aspects."

Eastern Health is one of three CRAFT proof-of-concept sites in Canada and is funded with the support of the Canadian Cancer Clinical Trials Network, through collaboration and financial support from the Canadian Partnership Against Cancer Corporation and Health Canada.

Accelerating the activation of high priority trials at pediatric cancer centres

In partnership with C17 Council, 3CTN designed an incentive for pediatric cancer centres to accelerate the opening of high priority trials within 90 days, expediting access to innovative therapies for children with cancer.

In April 2020, 3CTN partnered with C17 Council to design a process for incentivizing the rapid activation of selected clinical trials with the potential to answer important questions, generate new critical knowledge and accelerate access to promising treatment options for pediatric cancer patients. These high priority trials are identified by pediatric oncology leaders and researchers from across Canada following an established assessment criteria and earmarked as such within the 3CTN Portfolio database. Member cancer centre sites that open the trial within 90 days are then eligible for designated incentive funding.

One of these high priority trials is the Effect of Metformin on Behaviour and the Brain in Children Treated for a Brain Tumour (Met Med Can) trial developed by Canadian researchers



"When your child is diagnosed with cancer, as a parent, you are more vulnerable and helpless than you will ever be. You hope everything that can be possible to treat your child is being done and that your child's journey is making a positive impact on the advancement of future treatments. That is why it is so important that clinical trials are opened urgently for Canadian kids."

Maura

Parent advocate for cancer research.

and opened in Canada and Australia. It is a randomized, double-blinded, placebo-controlled Phase III trial of metformin for cognitive recovery and white matter growth in pediatric medulloblastoma patients. The study aim is to improve the memory ability of children and adolescents who survive medulloblastoma, a brain tumour that requires aggressive therapy, resulting in brain injury and cognitive impairment. Of the 11 3CTN pediatric member centres participating in the "This trial is potentially a game changer for improving the quality of life of these vulnerable children. If we find that metformin helps recovery of memory skills – this would be the first evidence of reversing the significant learning problems experienced by children and adolescents who survive medulloblastoma," says Dr. Don Mabbott, Program Head and Senior Scientist, Neurosciences and Mental Health, Hospital for Sick Children, who leads the trial. "The fact that we were able to open the trial in 11 sites within

90 days was outstanding."

In alignment with its goals, 3CTN will continue to develop and offer support for our pediatric cancer centres in providing equitable, rapid access to academic clinical trials for more patients that can help researchers answer important questions

sooner, leading to better outcomes and quality of life for children with cancer.

From 2021-2022, sites were able to activate high priority trials within 90 days

94%* of the time with an average of 11 sites opening each trial. *Y8 trials

trial, all centres opened the trial within 90 days, a resounding success when compared to the current median time of 370 days for a Portfolio trial.

3CTN Performance Metrics, 2021-2022

		Recruitment to Portfolio Trials				3CTN Objectives	
Network Site	Turne	Pre-3CTN Baseline	Total # Recruited	% of Baseline	% to Annual	Patient Rep Recruitment	CTRNet
Alberta	Туре	Daseline	Recruited	baseline	Target	Recruitment	Registration
Cross Cancer Institute	NCC	102	118	116%	66%	(
Tom Baker Cancer Centre	NCC	76	166	218%	125%	✓ ✓	
British Columbia	Nee	70	100	21070	12370	↓	
BC Cancer – Vancouver	NCC	106	175	165%	94%		/
BC Cancer – Abbotsford	NACC	100	2	13%	7%		✓ ✓
BC Cancer – Prince George	NACC	1	21	2100%	1200%	✓	v √
BC Cancer – Kelowna	NACC	38	35	92%	53%	v	v √
BC Cancer – Victoria	NACC	26	42	162%	92%		 ✓
Manitoba	10,000			10270	0270		•
CancerCare Manitoba	NCC	99	59	60%	34%	\checkmark	✓
Western Manitoba Cancer Centre	NACC	1	1	100%	57%	v	v
Nova Scotia		· ·	· ·		51,0		
Nova Scotia Health Authority	NCC	39	NA	NA	NA		✓
Newfoundland			101				v
Eastern Regional Health Authority	NCC	15	10	67%	38%		✓
Ontario				0170			•
		10.0	050	2520/	2022(
London Health Sciences Centre	NCC	186	656	353%	202%		✓
Grand River Regional Cancer Centre	NACC	20	23	115%	66%		✓
Windsor Regional Cancer Centre	NACC	14	3	21%	12%		✓
Juravinski Cancer Centre	NCC	181	190	105%	60%	✓	✓
Cambridge Memorial Hospital	NACC NACC	11 21	11 87	100% 414%	57% 237%		\checkmark
St. Joseph's Healthcare Hamilton	NACC	17	23	135%	77%	✓	
Walker Family Cancer Centre Sunnybrook Health Sciences Centre	NACC	141	671	476%	272%		<u>√</u>
Humber River Hospital	NACC	141	2	200%	114%		✓ ✓
Michael Garron Hospital	NACC	2	0	0%	0%		v
Princess Margaret Cancer Centre	NCC	396	338	85%	49%	✓	✓
Markham Stouffville Hospital	NACC	1	0	0%	0%		
Mount Sinai Hospital	NACC	21	543	2586%	1478%	✓ ✓	√
Northeast Cancer Centre	NACC	24	2	8%	5%	v √	v √
North York General Hospital	NACC	1	10	1000%	571%	v	v √
Royal Victoria Regional Health Centre	NACC	8	44	550%	314%	√	v √
Southlake Regional Health Centre	NACC	19	13	130%	74%	•	 ✓
St. Michael's Hospital	NACC	10	9	47%	27%		v √
Thunder Bay Regional Health Sciences Centre	NACC	26	39	150%	86%	√	v √
Trillium Health Partners - Credit Valley Hospital	NACC	27	10	37%	21%	v	√
William Osler Health System	NACC	1	3	300%	171%	 ✓	 _
The Ottawa Hospital Cancer Centre	NCC	132	771	584%	334%	✓	√
Cancer Centre of Southeastern Ontario at Kingston General Hospital	NACC	41	52	127%	72%		\checkmark
R.S. McLaughlin Durham Regional Cancer Centre	NACC	22	7	32%	18%	\checkmark	\checkmark

3CTN Performance Metrics, 2021-2022

Network Site	Туре	Recruitment to Portfolio Trials				3CTN Objectives	
		Pre-3CTN Baseline	Total # Recruited	% of Baseline	% to Annual Target	Patient Rep Recruitment	CTRNet Registration
Quebec							
CIUSSS du Centre-Ouest-de-l'Île-de-Montréal (CIUSSS CODIM)	NACC	87	156	179%	102%		\checkmark
CISSS de l'Outaouais	NACC	3	0	0%	0%		
CHU de Québec – Université Laval	NACC	180	456	253%	145%	\checkmark	\checkmark
CIUSSS de l'Estrie – Centre hospitalier universitaire de Sherbrooke	NACC	46	57	124%	71%		\checkmark
Centre Hospitalier de l'Université de Montréal (CHUM)	NACC	153	139	91%	52%		\checkmark
CIUSSS du Nord-de-l'Île-de-Montréal (CIUSSS NDIM)	NACC	3	980	32667%	18667%		
CIUSSS de l'Est-de-l'Île-de-Montréal (CIUSSS-EDIM)	NACC	60	10	17%	10%	\checkmark	\checkmark
CIUSSS de l'Ouest-de-l'Île-de-Montréal (CIUSSS ODIM)	NACC	1	0	0%	0%		
Pediatrics							
Alberta Children's Hospital	NACC	21	14	67%	NA		
BC Children's Hospital	NACC	34	24	71%	NA	\checkmark	\checkmark
CancerCare Manitoba - Pediatrics	NACC	18	6	33%	NA		\checkmark
Centre hospitalier universitaire de Sainte-Justine	NACC	42	54	129%	NA		\checkmark
Children's Hospital - London Health Sciences Centre	NACC	12	5	42%	NA		\checkmark
Children's Hospital of Eastern Ontario	NACC	20	16	80%	NA		
CHU de Québec-Université Laval / Centre Mère-Enfant Soleil	NACC	17	26	153%	NA		
IWK Health Centre	NACC	20	11	55%	NA	\checkmark	\checkmark
Janeway Children's Health and Rehabilitation Centre	NACC	4	2	50%	NA		
Jim Pattison Children's Hospital	NACC	6	3	50%	NA	\checkmark	
McMaster Children's Hospital – Hamilton Health Sciences Centre	NACC	14	24	171%	NA		
Montreal Children's Hospital	NACC	24	20	83%	NA		
Stollery Children's Hospital	NACC	11	23	209%	NA	\checkmark	\checkmark
The Hospital for Sick Children	NACC	91	73	80%	NA		
Total (N=57)		2709	6235	230%	132%	(22) 39%	(41) 72%
Adult Patient Sites (N=43)		2375	5934	250%	143%		
Pediatric Sites (N=14)		334	301	90%			
Number of sites achieving Y8 accrual target					14		

Network Achievements for 2021-2022

Alberta

Accrual to target 91% | 3 Patient partners

- Implemented a new Clinical Trials
 Management System (CTMS) that will result in improved trial efficiency.
- Engaged Patient Advisors in the implementation of a new electronic medical record (EMR) system. Patients can now be contacted via MyChart for potentially eligible trials.
- Training courses to address biosafety in clinical trials for staff members is under development.

British Columbia

Accrual to target 84% | 3 Patient partners

- Linked the new clinical trials website to the CTMS to provide an updated list of open trials for patients.
- Implemented a new Phase 1 room to allow patients on Phase 1 clinical trials to rest post-treatment.

Manitoba

Accrual to target 34% | 1 Patient partner

- Launched a new business unit model to allow greater physician engagement and more access to trials for patients.
- Held daily virtual events during International Clinical Trials Week and engaged Patient Representative to participate in events.

Newfoundland

Accrual to target 38% | 1 Patient partner

- Launched and implemented Clinical Trials Management System – EDGE.
- Listed all open trials on Eastern Health website for patients and stakeholders.

Nova Scotia

1 Patient partner

- Developed a Clinical Trials Working Group (CTWG) to address trial start-up, feasibility and patient population for recruitment.
- Added a Patient Representative to the CTWG to provide feedback on potential upcoming trials.

Ontario

Accrual to target 151% | 17 Patient partners

- Developed clinical trial resources to support patients, families and friends.
- Implemented initiatives to improve trial selection and trial activation processes.
- Developed quality improvement initiatives to standardize processes and empower individuals to solve problems and integrate quality improvement into day-to-day work.
- Collaborated with other Network sites on best practices for audits.

Network Achievements for 2021-2022

Quebec

Accrual to target 193% | 5 Patient partners

- Developed and launched Clinical Trials Navigator pilot project, a first of its kind in the province.
- Redesigned and relaunched a new version of OncoQuébec, an online resource for sourcing available cancer clinical trials within the province of Quebec, based on user feedback.

Pediatrics

14 Patient partners

- C17 launched and promoted U-Link, a resource to improve access to clinical trials among the pediatric cancer sites.
- Three High Priority Trials (HPT) were identified and prioritized for trial activation. 94 per cent of participating sites activated HPTs within 90 days.

3CTN Network

- 2022-2027 Strategic Plan development and approval
- Network sites' application, review, alignment and approval processes required for renewal.
- 3CTN Portfolio trial information and reporting has also been transformed through the development and roll out of a dynamic reporting interface, making it possible for the first time for stakeholders to independently have access to current trial information at a national, regional or individual cancer centre level.

Publications:

- CRAFT—A Proposed Framework for Decentralized Clinical Trials Participation in Canada
- The Impact of COVID-19 on Academic Cancer Clinical Trials in Canada and the Initial Response from Cancer Centers
- Addressing the Barriers to Clinical Trials Accrual in Community Cancer Centres Using a National Clinical Trials Navigator: A Cross-Sectional Analysis

Portfolio Application Overview



Featured Portfolio Trials Y8 (April 2021 - March 2022)

(CCTG) CAPTUR/PM.1| NCT03297606

Canadian Profiling and Targeted Agent Utilization Trial (CAPTUR): A Phase II Basket Trial Current sites: 9 | Disease: Solid Tumor Y8 Total recruitment: 82

(CCTG) PR.20 | NCT03784755

A Randomized Phase III Trial of Local Ablative Therapy For Hormone Sensitive Oligometastatic Prostate Cancer (PLATON) Current sites: 17 | Disease: Prostate Y8 Total recruitment: 106

(BCC) BRLALEAST NCT03917082

LA LEAST- Luminal A, Limited Endocrine Adjuvant Systemic Therapy. A Trial of Abbreviated Hormone Therapy for Low Risk Hormone Receptor Positive, HER2 Negative Early Breast Cancer Current sites: 7 | Disease: Breast Y8 Total recruitment: 84

(COG) AALL1731 | NCT03914625

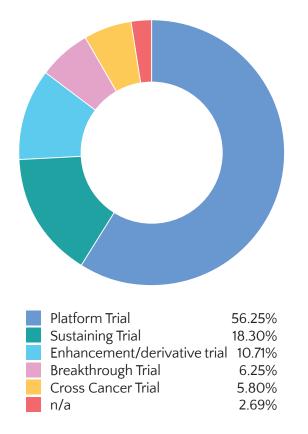
Phase 3 Trial Investigating Blinatumomab (IND# 117467, NSC# 765986) in Combination with Chemotherapy in Patients with Newly Diagnosed Standard Risk or Down Syndrome B-Lymphoblastic Leukemia (B-ALL) and the Treatment of Patients with Localized B-Lymphoblastic Lymphoma (B-LLy) **Current sites: 14 | Disease: Lymphoma Y8 Total recruitment: 114**

(CHUM) 20.208 / PATRON | NCT04557501

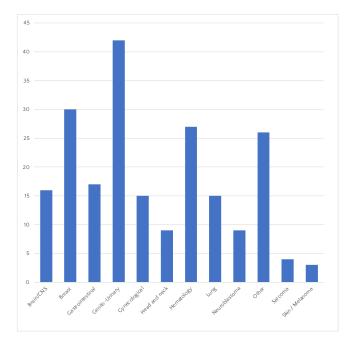
PSMA PET/CT Guided Intensification of Therapy in Patients at Risk of Advanced Prostate Cancer **Current sites: 8 | Disease: Prostate Y8 Total recruitment: 136**

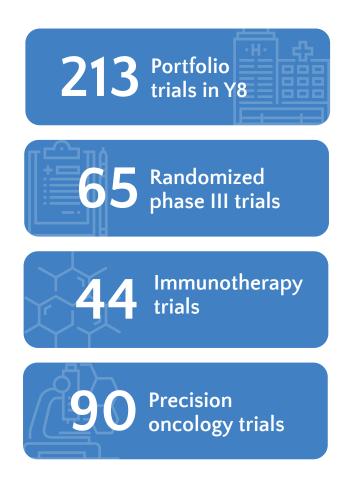
Clinical trials portfolio

Potential Impact on Patient Population

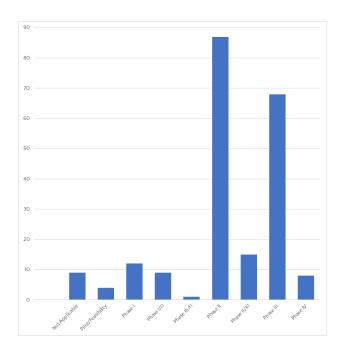


Number of clinical trials by disease site





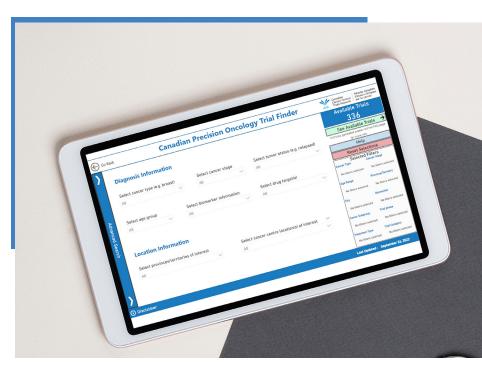
Number of clinical trials by trial phase



Mapping Canada's cancer trial landscape: The Canadian Precision Oncology Trial Finder

3CTN has developed The Canadian Precision Oncology Trial Finder, a comprehensive visual representation of all cancer clinical trials active across Canada with a precision medicine focus.

The Trial Finder was developed to improve access to clinical trials and go beyond existing resources and assist cancer patients, their caregivers, as well as the research community in searching for active trials according to specific biomarkers or genetic variants of interest. Existing registry data frequently lacks this information. The Trial Finder will go beyond existing registries and search tools by addressing these current data



limitations. Patients will be able to find active recruiting trials with the help of customizable filters and locate trials conducted within specific cancer sites across Canada. Researchers, sponsors and advocacy groups can also benefit from accessing a customizable display of the current trial landscape to better identify gaps in trial availability and inform future opportunities.



3CTN worked alongside Jill Hamer-Wilson, Patient Partner and cancer research advocate, to ensure a patientcentered approach was at the forefront of the project throughout the design, testing, implementation and evaluation phases. In addition, the Trial Finder was refined through multi-stakeholder feedback on the utility, content and ease of navigation.

Future work will focus on raising awareness of the Trial Finder within the cancer community and to continue to optimize the maintenance process for new trials through collaborations with stakeholders. The Canadian Precision Oncology Trial



"Clinical trials can mean years of high-quality life for people affected by cancer. The Canadian Precision Oncology Trial Finder helps people easily identify and gain access to clinical trials that are the best match for them,"

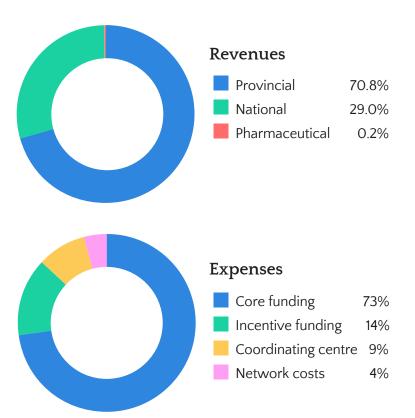
Jill Hamer-Wilson

Finder was developed with funding from Bayer HealthCare Pharmaceuticals Inc., through the Precision Oncology Patient Innovation Award.

Revenue and Expenses for Fiscal Year 2021-2022

Revenues

	\$ Amount in CDN
Provincial	4,065,483.00
National	1,663,833.67
Pharmaceutical	10,405.20
	\$ 5,739,721.87



Expenses

	\$ Amount in CDN
Core funding	3,861,949.51
Incentive funding	763,720.86
Coordinating centre	502,307.28
Network costs	190,852.58
	\$ 5,318,830.23
Net (Revenue less expenses)	\$ 420,891.64

Funding Partners



Scientific Advisory Board

David Cameron, MD (Chair) Chair, Breast International Group

Gavin Stuart, MD Professor, Division of Gynecologic Oncology, University of British Columbia

Rachel Syme, PhD Assistant Director, Institute of Cancer Research, Canadian Institutes of Health Research

Patrick Sullivan Patient Representative, 3CTN Judy Needham Patient Representative, 3CTN

Stephen Sundquist Executive Director, 3CTN

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Funders Oversight Committee

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

Ian Tannock, MD Emeritus Professor of Medical Oncology Princess Margaret Cancer Centre

Christy Holtby Vice President, Philanthropy, Alberta Cancer Foundation

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

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Kathryn Dyck Manager, Clinical Trials Unit, CancerCare Manitoba

Christine Williams, PhD

Executive Vice President and Head of Implementation Science, Ontario Institute for Cancer Research

Antonia Palmer Patient Representative, 3CTN

Stephen Sundquist Executive Director, 3CTN

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Janet Dancey*, MD Scientific Director, 3CTN

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

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

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Joel Gingerich, MD Medical Director, Community Oncology, CancerCare Manitoba **Jim Pankovich** Vice President, Clinical Operations & Drug Development, Qu Biologics

Jim Whitlock, MD Division Head, Haematology/Oncology, The Hospital for Sick Children

Arik Drucker, MD Medical Oncologist, Nova Scotia Cancer Centre

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Saher Lalani Project Financial Analyst

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