Canadian Cancer Society

IT TAKES A SOCIETY

Cancer Clinical Trials Action Plan

Strengthening Canada's cancer clinical trials through shared insight and collaborative action

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Coming together with urgency and purpose

For decades, the Canadian Cancer Society (CCS) has been committed to advancing research that saves and improves lives—and clinical trials have been central to that commitment. We've proudly supported trials that have led to incredible breakthroughs, shaping cancer prevention, treatment and care at home and around the world.

We invest heavily in trials because we know they are an engine of progress. They're essential to turning research discoveries into real-world options, giving patients access to tomorrow's treatments today, and providing the evidence needed to enhance the standard of care and drive change across the cancer care system.

But CCS's role in supporting clinical trials doesn't end with funding. We also have a role to play in championing improvements to our trials ecosystem. Through our advocacy, we work with governments, decision-makers and partners across the country to strengthen policies, remove barriers and ensure people have access to the cancer care they need—including timely, equitable access to clinical trials.

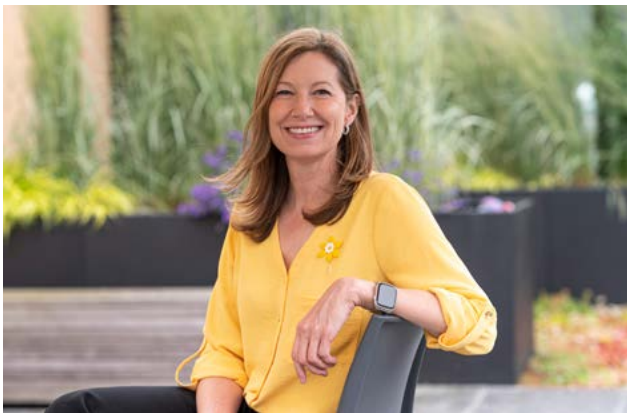
It is this dual commitment to supporting trials and advocating to improve cancer care that led CCS to convene Canada's clinical trials community to develop this Action Plan.

> We recognized the challenges facing our trials ecosystem—low participation rates, administrative and regulatory delays, geographic and financial barriers, and more—and we knew no one organization or person could solve them alone, it would take all of us working side by side.

Over the course of 7 working sessions, we facilitated a dialogue. We heard from researchers, clinicians, scientists, health research funders, representatives from the pharmaceutical industry, provincial cancer agencies, clinical trial unit leaders, and people with lived and living cancer experience who shared their expertise and perspectives. Together, we shaped a vision for a coordinated, sustainable and inclusive clinical trials ecosystem.

The urgency to improve our trials system and speed up research advancements has never been greater. Fortunately, Canada has an incredibly talented research community. Some of the brightest scientific minds are taking on cancer's toughest problems right here at home. We owe it to them, and to everyone facing cancer, to ensure research breakthroughs can benefit as many people as possible, as quickly as possible.

This plan represents a call to collective action to help us achieve this. It lays out clear, practical steps we can take today to strengthen our trials ecosystem. CCS is proud to have helped develop it, and we are committed to working with partners, supporters, and people affected by cancer to build a stronger clinical trials system in Canada.



Andrea Seale

Chief Executive Officer
Canadian Cancer Society

Innovating for impact: Transforming cancer clinical trials in Canada

Access to cancer clinical trials has never been more important. The improved outcomes that people living in Canada experience today are the result of decades of scientific discovery rigorously evaluated through clinical trials. Patients rely on these trials to determine whether new approaches to detect, diagnosis and treat cancer are safe, effective and superior to standard care.

The pace of development is now so rapid that often a clinical trial represents the best or only available treatment option for patients facing a life-threatening cancer. When trials of innovative cancer therapies occur outside of Canada, our patients have to wait, on average, two years for approval and public coverage of new therapies. For many, this timeline is not survivable.[i] Conducting trials in Canada enables patients to access promising therapies, equips clinicians with experience using these innovative treatments, and allows governments to more rapidly assess their value within our publicly-funded healthcare system.

Despite these benefits, Canada's position as a leading destination for cancer clinical trials is declining. Fragmented and under-resourced trial infrastructure, increasing diagnostic and therapeutic complexity, and significant workforce pressures impair our ability to launch and conduct trials efficiently. Health professionals lack protected time and incentives to participate in trials, while institutions face increasing regulatory, contractual, privacy, and liability concerns. Patients, particularly those in rural and remote communities, continue to experience geographic, financial, and informational barriers to participation.

At a moment of tremendous scientific opportunity to advance cancer outcomes, Canada lacks a coordinated pan-Canadian system to support equitable, efficient and high quality cancer clinical trials. To address this, the Canadian Cancer Society convened experts, health system leaders, health research funders, pharmaceutical industry representatives, clinical trial units leaders and people with lived and living experience in national forums to identify solutions. This report represents the initial step in developing and growing a comprehensive pan-Canadian clinical trials system that will improve clinical trial access and conduct to benefit all people in Canada.

i Lexchin J. Time to potential for listing of new drugs on public and private formularies in Canada: a cross-sectional study. CMAJ Open. 2022;10(4):E993-E999. doi:10.9778/cmajo.20220063

We believe that every patient diagnosed with cancer or another life-altering disease should have an opportunity to participate in a clinical trial regardless of where they live, their gender, their race and ethnicity, their age, their ability, their level of education, or their financial situation. A pan-Canadian clinical trials system will advance equity, improve outcomes, and strengthen Canada's global research competitiveness.

Cancer remains the leading cause of death in Canada. But the extraordinary pace of biomedical advances offers real hope. We can transform hope into reality by creating a pan-Canadian clinical trials system in Canada. By building a coordinated, sustainable and patient-centred national clinical trials system, we can turn that hope into tangible benefits for people across Canada. We call on governments, health system leaders, and beyond—hospital CEOs, professional associations, patient advocacy groups, research institutions and private sector partners—to implement practical, evidence informed solutions outlined in this report to ensure that Canada remains a global leader in cancer research and care, and that Canadian patients achieve the best possible outcomes.

Dr Stuart Edmonds

Dr Stuart Edmonds joined the Canadian Cancer Society (CCS) in February 2020 following the amalgamation with Prostate Cancer Canada (PCC). As Executive Vice President of Mission, he oversees the Research and Advocacy teams. Dr Edmonds spent 8 years at PCC as Vice President of Research, Health Promotion and Survivorship. He has held leadership roles at several national cancer research institutes and government agencies.

Dr Rebecca Auer

Dr Rebecca Auer is an internationally recognized leader in Surgical Oncology with a particular interest in perioperative cancer therapies. She is the Executive Vice-President of Research and Innovation at The Ottawa Hospital, CEO and Scientific Director of the Ottawa Hospital Research Institute, and co-founder of the Canadian Cholangiocarcinoma Collaborative which aims provide hope to Canadian patients with biliary tract cancers by integrating research into care. Dr Auer is dedicated to integrating research into patient treatment plans to improve the standard of care.

Dr Janet Dancey

Dr Janet Dancey is an international leader in cancer clinical trials of experimental therapeutics with special expertise in new anti-cancer drug development. She is the Scientific Director of the Canadian Cancer Clinical Trials Network, which is a pan-Canadian organization that seeks to improve the efficiency and quality of clinical trials. Dr Dancey also leads the Canadian Cancer Trials Group, Canada's largest cancer trial network with over 80 centres, 2,000 investigators and 4,000 trial staff conducting Phase I-III trials of cancer therapeutics in Canada.

Vision for a national cancer clinical trials system

Every person at risk of or living with cancer or serious illness deserves an opportunity to participate in all types of care, including research, if they choose. As a society, we have a responsibility to provide that opportunity. Embed access to clinical trials as part of care.[ii]

For each priority area outlined in our action plan, every recommendation is expected to incorporate health equity.

By 2035, every person in Canada—no matter where they live—will have timely and equitable access to cancer clinical trials through a nationally harmonized regulatory and administrative system. Patients in rural and remote communities will no longer face the burden of traveling long distances or navigating inconsistent provincial processes. Instead, interprovincial trial delivery will be the norm, bringing innovative treatments closer to home, reducing wait times, and minimizing duplication and delays.

This transformation will empower patients to participate in research that reflects their needs and realities, **doubling the percentage of Canadians enrolled in cancer clinical trials** compared to 2025 levels. It will accelerate discoveries that improve outcomes for all, while ensuring that trial participation is inclusive, accessible, and representative of Canada's diverse population.

ii There are different types of clinical trials in Canada. For an overview on the different types of trials in Canada, please visit the following link: https://cancer.ca/en/treatments/clinical-trials.

Purpose of the Cancer Clinical Trials Action Plan

The action plan is intended to support and align outreach efforts for decision-makers at all levels of government. It will be shared with research, healthcare and patient community stakeholders. The Cancer Clinical Trials Action Plan (CTAP) is designed for a general audience and aims to present information in a clear and accessible manner rather than focus on scientific or technical details. This plan represents the diverse feedback we received from various stakeholders and is not meant to serve as a timebound implementation strategy.

The Canadian Cancer Society's (CCS) role in this project is that of a convenor. We know that nothing big gets solved by one person or organization. We will continue to work with our partners, our supporters and most importantly, people affected by cancer to build a clinical trials system that is equitable and accessible for all people in Canada. Specifically, CCS will continue to convene the clinical trials community, and additional phases of implementation of the CTAP, including key performance indicators which will be developed in collaboration with community partners and shared with the broader community.

Development of the Cancer Clinical Trials Action Plan

In May 2024, CCS launched a series of sector forums to hold extensive consultations across the cancer community and beyond to address urgent issues regarding clinical trials in Canada. In total, CCS held forums with over 7 sectors, including:

- Clinical trial experts and federal health regulators
- People with lived and living experience
- Provincial cancer agencies
- Cancer research funders
- Healthcare organizations and hospitals
- Pharmaceutical industry representatives
- Clinical trial units (CTUs)

People with lived and living experience with cancer contributed to every forum. Each forum's conversations followed an agenda that included questions on the following themes:

- Implementation of best practices and standardized tools
- Legislative and regulatory opportunities
- Building capacity
- Funding

Following each forum, a "what we heard" report was prepared and shared with attendees for validation. These reports are included in Appendix B of this Action Plan. A detailed overview of all actions of the Action Plan are included in Appendix A.

Following all forums, all information was synthesized, and a thematic analysis of content from the structured interview was completed.

All forums were completed before March 2025, when the United States announced changes in health policy decisions.

CCS also partnered with the Angus Reid Institute and conducted an online survey from January 10-17, 2025. That survey explored three themes about access to cancer care, including awareness and perceptions of clinical trials. It included a randomized sample of 2,044 Canadian adults who are members of the Angus Reid Forum. The sample was weighted to represent adults nationwide according to region, gender, age, household, income and education based on the Canadian census. For comparison purposes only, a probability sample of this size carries a margin of error of ±1.5 percentage points (meaning similar results would occur 19 times out of 20).

Explore cancer.ca to learn more about clinical trials phases (cancer.ca/phasesofclinicaltrials) or the terminology (cancer.ca/glossary) used in this action plan.

While efforts were made to engage many sectors and communities, we respectfully acknowledge that we were, regrettably, unsuccessful in directly engaging Indigenous communities in our outreach efforts. CCS acknowledges and understands that, as a direct result of the ongoing outcomes of colonialism, Indigenous people in Canada face systemic racism and barriers within Canada's health systems, including unequal access to health research and clinical trials that specifically address the unmet needs and well-being of Indigenous people. We recognize that CCS has played a role in colonial structures in Canada and acknowledge the adverse and detrimental impacts that colonialism has had on Indigenous peoples in Canada. CCS recognizes it has a duty and responsibility to achieve truth and reconciliation.

We acknowledge the critical role of Indigenous people in achieving better healthcare and research outcomes for all people living in Canada. In implementing this action plan, CCS acknowledges its responsibility to provide cancer information, support and practical services that support First Nations, Inuit and Métis communities, and the need to advocate for healthy public policy and fund research that focuses on increasing health equity.

We are at an early stage in the journey of understanding how best to collaborate with and support Indigenous communities and prevent and reduce the disproportionate burden of cancer that Indigenous communities experience. Listening and learning are foundational steps. We encourage everyone in Canada to read the Truth and Reconciliation Commission of Canada: Calls to Action and reflect on its 94 calls to action, including the 7 that are specific to health and many others that address important determinants of health.[1]

Establishing the foundation for cancer clinical trials in Canada

A wide range of stakeholders—governments, hospitals, research centres, charitable organizations, clinicians, trial staff and people with lived and living experience with cancer—contribute to the processes involved in funding, approval, initiation and management of cancer clinical trials. Without a national cancer clinical trials system, these stakeholders often function within specific roles and responsibilities and cannot align with other groups to ensure efficient and effective trial conduct.

> Clinical trials of cancer interventions are even more challenging because cancer isn't merely one disease. It's more than 100 diseases, caused by cells in the body growing abnormally and spreading to other parts of the body. That means that many clinical trials test interventions for people with different, often rare types of cancers that may share a site of origin but have different biological features.

An increased focus on precision medicine further complicates cancer clinical trials. That requires new approaches to designing clinical trials that match the characteristics of an individual's cancer and personalized therapies manufactured from a person's own cells or tissue.

Barriers in cancer clinical trials in Canada are well-documented. The Canadian Cancer Research Alliance published a Report on the State of Cancer Clinical Trials in Canada in 2011.[2] Yet, many of these systemic problems continue, and the need to address them has become more urgent.

Below are common barriers in cancer clinical trials and many other therapeutic areas.

Low patient participation

Across the country, participation (also known as patient accrual) in cancer clinical trials is low. As of 2015, the last nationally centralized data showed that only 4.7% of newly diagnosed adult patients with cancer participated in clinical trials, and as low as only 1% in some provinces.[3]

Additionally, a report on recruitment for academic clinical trials in Ontario for 12 reporting cancer centres in 2017, found that on average about 7.1% of treated patients were recruited to clinical trials, though this ranged across centres between 0-18.4% of treated patients.[4] This is similar to national estimates of cancer clinical trial participation for treatment trials in the United States (7.1%).[5]

These low numbers are striking when you consider the critical role that clinical trials play in offering what is, in many cases, an option for treatment when traditional treatments have been exhausted. Many studies reveal that more people would participate in clinical trials if offered the opportunity or if trials were discussed as treatment options.

Additionally, most clinical trials are conducted with adults. Therefore, many cancer treatments are insufficiently studied for safety and effectiveness in children, which limits their use as less than one-third of children between 0 and 14 years of age, newly diagnosed with cancer in Canada were enrolled in a clinical trial.[6] Low patient participation is the leading reason clinical trials are not completed quickly or efficiently.

Lack of diverse populations

Populations in the US and Canada are frequently compared in terms of research and care. Although there is insufficient data to understand participation in Canadian clinical trials, patient participation in the US generally decreases amongst under-represented populations.[7] The lack of participant diversity is particularly concerning for cancer clinical trials because newer therapies often focus on optimizing treatments based on genomic profiles. Diverse populations often serve as an appealing incentive for clinical trial sponsors because they allow sponsors to test interventions, including therapies, on patients who may have different responses without having to do large-scale, multi-site trials around the world.[8]

Although Health Canada announced plans to resolve the disaggregated data gap in 2022, it still does not have a mechanism to systemically track, analyze and report disaggregated data on sex, age and race.[9]

Inconsistent access to information

People with cancer and their caregivers, clinicians, trial staff and healthcare teams often have little or no awareness of available clinical trials.[10] They may learn about a clinical trial through searching on their own or by relying on their healthcare team's knowledge.

Some organizations and provincial governments have tried to address this issue by creating databases where people can search for cancer clinical trials, either within their jurisdictions or based on cancer type.

Health Canada has a database of clinical trials under clinical trial applications,[11] which provides some information on human pharmaceutical and biological drugs rather than a comprehensive listing of all trials.

Many people in Canada rely on ClinicalTrials.gov, a database funded by the US federal government, for information on clinical trials in Canada. However, the ClinicalTrials.gov database does not use accessible language and its data is not regularly updated, making it difficult for people with cancer in Canada and their caregivers to find accurate information.[12]

Also hampering patient access are risk-averse interpretations of privacy and research ethics policies, which make it difficult for clinical trialists to identify and contact people who might be eligible to participate in clinical trials. Work is underway in Canada on platforms that use artificial intelligence (AI) to automatically match patients with clinical trials using their health data, reducing the time and effort it takes today. One such innovative platform is PMATCH.[13]

Delays in launching trials

There are often delays in trial initiation because of duplicative and onerous administrative processes for research ethics reviews, trial agreements, budgets and institutional reviews to assess health service impacts across multiple trial sites.[14] The ethics approval process is more complicated in multi-site clinical trials because researchers must obtain ethics approvals for each site.[14] Federally sponsored studies have recommended a standardized and coordinated approach to ethics reviews to expedite the initiation of clinical trials. [15]

Several initiatives are underway to address this issue, both in provinces (Ontario Cancer Research Ethics Board[16]) and regional networks (such as the Atlantic Clinical Trials Network[17]), and through the national approach (Accelerating Clinical Trials Canada—Accélérer les Essais Cliniques[18]). Yet, Canada is still behind countries like the United Kingdom, Australia, and South Korea, which have more coordinated and centralized regulatory and ethics review boards.

Geographic limitations

Canada's vast geography and federated healthcare system limits the capacity of clinical trial sponsors and researchers to run trials outside of major urban settings and academic centres. Regulatory and institutional support is needed.[19]

Currently, too many people with cancer cannot participate in clinical trials outside of where they live because of financial barriers. Trial sponsors typically cover the cost of the trial innovation (such as a new drug). However, patients often must pay out-of-pocket for the standard of care portion of a trial when it is not publicly funded or provided in a trial that's conducted in another province.

Rising costs for researchers and people with cancer

Clinical trials are more expensive than the general standard of care because of the additional regulatory requirements and monitoring, dedicated healthcare workforce and administrative costs involved in conducting research. Rising costs for clinical trials due to increasing regulatory, ethics and institutional requirements for trial conduct are in Canada.[20]

Some clinical trial sponsors and funders cover research-related costs for participants, such as the drug being tested and any medical procedures needed to monitor the study, while the provincial health insurance plan covers trial-related activity that is considered standard of care. Costs can be higher due to differences in the standard of care among institutions in different regions. Participants can also face out-of-pocket costs, like travelling to and from the clinical trial site, especially when the site is in a different city, region or province and territory.

For researchers and clinical trial sponsors, administrative delays in opening a clinical trial, trial complexity and a lack of core funding add to rising costs and the pressure to balance budgets. The lack of standardized costs for clinical procedures across different healthcare institutions—for example, x-rays or laboratory work—means that clinical trial costs can be highly variable when compared to costs set through provincial and territorial health insurance programs that cover the same procedures when they are provided as standard of care. In the current era of cost constraints on healthcare institutions, hospitals and clinics may see clinical trials as revenue-generating activity, putting further strain on the clinical trial infrastructure at that site.[21]

Strained healthcare workforce

The COVID-19 pandemic highlighted and worsened Canada's health human resources crisis. In 2022, Health Canada held a stakeholder symposium and established a coalition of health workers to provide the government with solutions to address health workforce.[22, 23]

In 2023, the House of Commons Parliamentary Standing Committee on Health held public consultations on this and published a report called Addressing Canada's Health Workforce Crisis.[24] The federal government has listed health human resources as a key priority in health transfer agreements between provinces and territories.[25]

While these are all significant efforts, there is insufficient recognition of the integral role that healthcare workers play in supporting clinical trials. Clinical trial staff are also healthcare workers who provide care to patients. They are nurses, physicians, pharmacists and technicians. A 2023 study, Crisis of the Clinical Trials Staff Attrition After the COVID-19 Pandemic, found that attrition among clinical trial staff worsened after the COVID-19 pandemic.[26] That has led to the loss of highly specialized practitioners with the skills required for complex therapeutic research areas, such as cancer.

Awareness and perception challenges in clinical trials

Baseline awareness of clinical trials among people in Canada is severely limited. A 2025 survey conducted in partnership with CCS and the Angus Reid Institute found that over one-third of Canadians said they knew nothing at all about clinical trials.[27] Among Canadians without a direct connection to cancer, a majority said they haven't even heard of them. Even among Canadians who were diagnosed or know a close friend or family member diagnosed, awareness is still staggeringly low, with only 11% of people personally diagnosed participating in a trial or reporting to know a lot about trials. When asked where they would go to find out more information about clinical trials, over 60% of Canadians said they would search the internet.

Given the limited familiarity with clinical trials, Canadians have conflicting views about the perceived value of participating in trials. For instance, while most view clinical trials as effective ways for people with cancer to access novel treatments, nearly 50% are unsure if they result in better treatment for patients who enroll. This contrasts with respondents with a personal cancer experience, who overwhelmingly (85%) agree that clinical trials offer paths to new treatments and better treatment for enrolled patients (50%).

> Despite the unfamiliarity with clinical trials and uncertainty about the perceived value, most Canadians say they would be willing to take part, agreeing that clinical trials offer hope for cancer patients who may have run out of other options (76% agree).

That said, women were considerably more hesitant to state that they would be willing to take part compared to men. Among women who described themselves as hesitant to take part in a trial, concerns over potential side effects, as well as a lack of trust, were cited as the main reasons for their hesitancy.

Laying the groundwork for change

Two national public health emergencies, SARS in 2003 and H1N1 in 2009-2010, brought about a renewed recognition that Canada needed to be better at translating research into clinical practice.[28, 29] Since then, several pan-Canadian initiatives have identified and tackled issues in clinical trials, often without focusing on a specific disease or therapeutic area.

The anticipated increase in cancer prevalence due to Canada's growing and aging population and a rising incidence of early-onset cancer[30] means we are facing a potential healthcare crisis with serious and ongoing impacts. This crisis has reached a critical level and deserves a serious national response across all care areas, including cancer clinical trials and innovation.

The following highlights just some of the activities that have taken place.

The progress we've made

In 2011, the Canadian Institutes of Health Research (CIHR) launched Canada's Strategy for Patient-Oriented Research (SPOR), which aims to strengthen the translation and integration of research and clinical care to improve health outcomes.[31] The strategy outlined both the common challenges in clinical trials as well as key goals.

Here are additional milestone reports:

- In 2011, the Office of the Auditor General of Canada tabled a report on the regulation of pharmaceutical drugs, including clinical trial activity. The report, Regulating Pharmaceutical Drugs—Health Canada, of the Fall 2011 Report of the Auditor General of Canada, developed 10 recommendations, which included calls for transparency by strengthening its risk-based approach to monitoring and inspecting clinical trials, timely reporting of non-compliant clinical trial sites, and enhancing public access to information on clinical trials.[32]
- In 2011, CIHR, HealthCare*CAN* (then known as the Association of Canadian Academic Healthcare Organizations), and Innovative Medicines Canada (then known as Canada's Research-Based Pharmaceutical Companies) held a Canadian Clinical Trial Summit in Ottawa to review the challenges in Canada's clinical trials system.[33] That led to the publication in 2012 of "An Action Plan to Help Attract More Clinical Trials to Canada."[34] The plan outlined 9 recommendations.
- In 2012, the Senate of Canada published a report, Canada's Clinical Trial Infrastructure: A Prescription for Improved Access to New Medicines, which identified and summarized common barriers in clinical trials and identified recommendations.[35] One of the Senate's key recommendations called for the federal government to take a leadership role in coordinating clinical trial infrastructure by creating a national framework and coordinating discussion amongst the provincial, territorial, and federal governments.
- In 2014, these activities led to the creation of the Canadian Clinical Trials Coordinating Centre, which operated until funding ended in 2019.[36]

- By 2014, Health Canada provided a final update on its response to the recommendations, including updates on public information about clinical trials (the Clinical Trials Database launched in 2013).[37] However, Canada still does not have a comprehensive, user-friendly national clinical trial directory and clinical trial registration is still not mandatory.
- In 2023, CIHR held a new round of public consultations to refresh SPOR priorities.

The cancer context

The 2011 Report on the State of Cancer Clinical Trials in Canada[2], published by the Canadian Cancer Research Alliance (and funded by the Canadian Partnership Against Cancer), put forward four areas of key recommendations:

- Create a pan-Canadian infrastructure program that supports cancer clinical trials
- Streamline the clinical regulatory environment
- Consolidate or develop reciprocity in research ethics boards
- Reduce non-value-added steps in trial development and conduct.

The report led to the creation of the Canadian Cancer Clinical Trials Network (3CTN) to establish a pan-Canadian funding and infrastructure network to support academic clinical trials.[38] Over the past decade, 3CTN has developed and implemented practices and provided funding support that has improved site participation, recruitment of people with cancer and trial efficiencies in investigator-sponsored clinical trials in Canada.

More recently, 3CTN and other trial networks, including N2 (Network of Networks) and the Canadian Cancer Trials Group, have expanded their efforts to streamline clinical trial conduct. Their initiatives include providing guidance, engaging individuals with cancer and collaborating with other stakeholders to study and implement pan-Canadian policies aimed at overcoming barriers to clinical trials. These include increasing patient participation (accrual), decentralizing trials to expand access in remote and rural settings and identifying training tools for trial.[38, 39]

Other pan-Canadian initiatives, such as the Canadian Tissue Repository Network (CTRNet), help establish national standards for sharing data and creating national standards to advance translational clinical research.[40]

The pediatric cancer community has had greater success in galvanizing political action to support pan-Canadian efforts to improve clinical trials and translational research.[41] The pediatric cancer community has effectively drawn attention to additional barriers that children with cancer experience, such as lack of clinical trials because interventions and therapies are not being tested for pediatric populations.

Overall, the cancer community has been at the forefront of streamlining clinical trials in Canada. While we have undertaken initiatives to address common barriers in clinical trials, we still encounter challenges that must be addressed through national coordination.

Renewed federal efforts

In 2019, the federal government introduced its intention to modernize clinical trials regulations.[42] The federal government provided further details on its plan for clinical trials modernization in the subsequent federal budget by launching the Biomanufacturing and Life Sciences Strategy in Budget 2021.[43] With that strategy, the federal government announced the creation of a Clinical Trials Fund that earmarked $250 million in new funding over three years.[44]

Subsequently, CIHR held public consultations on the state of clinical trials in Canada to help inform its objective of building a long-term strategy to support Canada's clinical trials ecosystem.[45]

In Winter 2023, CIHR published consultations feedback in a report, What We Heard On The Future of Clinical Trials, which reflected barriers and recommendations raised in previous pan-Canadian reviews of clinical trials in Canada.[46] CIHR also announced plans to create a long-term clinical trials strategy for Canada that would be informed by the feedback received through these consultations.[47]

In January 2023, the federal government announced the creation of Clinical Trials Funds[48] for the following streams:

- Accelerating Clinical Trials—Accélérer les Essais Cliniques, a consortium intended to create new and expand existing clinical trials networks to improve collaboration, share information and streamline processes like research ethics reviews. Led by Dr PJ Devereaux,[iii] the consortium received $39 million in federal funding for its activities spanning all therapeutic areas.[49]
- 7 training platforms, which received over $32 million in federal funding to help train scientists and researchers involved in clinical trials research.
- 22 clinical trial projects across therapeutic areas that align with the priorities of the Biomanufacturing and Life Sciences Strategy. These projects received approximately $60 million in federal funding.

In August 2024, the federal government announced its second round of clinical trials funding with an investment of $43.1 million for 14 new projects.[50] The federal government also launched a new round of public consultations on draft guidance for expanded access clinical trials.[51]

It's not known if the Clinical Trials Funds will be renewed after the current funding period ends in 2025.

iii Note: Dr PJ Devereaux attended the Ottawa forum in May 2024 and shared updates on ACT-AEC's activities.

Learning from global initiatives

Canada captures 4% of clinical trials internationally and across all therapeutic areas.[52] This percentage has stayed relatively the same over the past 15 years.[53] Approximately 30% of all clinical trials in Canada are for cancer.[54]

The challenges encountered in cancer clinical trials are not unique to Canada. However, other countries have been more proactive in tackling these issues, leading to better patient access and participation, increased operational efficiencies and stronger economic competitiveness.

The United Kingdom, United States, Australia, and France support many of the following measures through their clinical trials modernization work. Canada should strive to implement some, if not all, of these measures to improve global partnerships.

Stronger engagement with people with lived and living experience

- Create national public awareness campaigns
- Embed research in healthcare settings
- Use standard consent processes, data and technology to identify and communicate clinical trial opportunities to people living with cancer and their caregivers

Train healthcare workforce

- Offer incentives for the health workforce to participate in research
- Provide training to the health workforce on clinical trial engagement
- Work with associations, regulatory colleges and other key stakeholders on research training and engagement

Create efficient infrastructure

- Ensure centralized ethics and regulatory reviews
- Use centralized/standard master contract agreements
- Define standard of care costs that are covered in the publicly funded healthcare system versus research costs
- Require transparency in costs of clinical trial activities by healthcare institutions

Improve performance metrics and data

- Use data and digital tools to streamline processes and monitor progress
- Collect real-time data (linked to trial registration)
- Link progress to accountability frameworks and targets

There is a noticeable pattern: While national governments provide policy and funding support, successful outcomes depend on the active collaboration of other governments and institutions responsible for healthcare delivery (such as provincial, territorial or state governments) and key stakeholders that contribute to clinical trial processes, including the pharmaceutical industry and healthcare associations.

Economic and societal benefits of cancer clinical trials

Clinical trials offer numerous benefits to individuals, healthcare systems and economies. They undergo the most rigorous design, which, through randomization, improves internal validity and avoids the bias that can be hard to address in other study designs. That is why clinical trials, especially when aggregated in systematic reviews and meta-analyses, are usually the evidence of choice for clinicians and other health-system decision-makers.

Clinical trials have a tremendous impact on both clinical care and the health system, including guiding clinical decision-making, extending lives, improving quality of life and providing access to over a billion dollars' worth of medications in Canada. In addition, clinical trials can be highly efficient investments, including being a source of jobs and, potentially, substantial economic returns when one estimates the monetary value of health gains.[55, 56]

These studies have estimated economic returns from clinical trials for cancer and other conditions:

- A total of 28 US National Institute of Neurological Disorders and Stroke publicly funded Phase III Randomized Controlled Trials for neurological conditions and stroke completed before January 1, 2000 resulted in a projected benefit at 10 years of 470,339 quality-adjusted life years gained, a total economic return of $15.5 billion (a 4600% return on investment [ROI]), and an incremental cost-effectiveness ratio of $7,713 per quality-adjusted life year gained (all in 2004 USD).[57]
- Twenty-five primarily publicly funded high-impact trials in stroke, maternal/perinatal health, and intensive care in Australia and New Zealand resulted in an economic benefit of $2 billion, with an ROI of 5.8:1 (all in 2014 dollars).[56]
- Approximately four hundred industry-sponsored drug trials were conducted in Canada across all conditions and completed in 2016, with a cost of $2.1 billion dollars, most of that on medications, saving the healthcare system, individuals and insurance companies.[58]
- A total of 574 industry-sponsored clinical trials across all conditions conducted between 2012 and 2017 in Austria funded annually approximately 100 million euros worth of treatment, generated a gross production value (i.e., total cost of conducting the research) of €116.22 million per year and secured 1,215 full-time equivalent jobs.[55]
- The United States' National Cancer Institute's National Cancer Clinical Trials Network conducted 162 publicly funded trials from 1981 to 2018 with statistically significant results, which led to 14.2 million life years gained for $326 saved per life gained from 1981 to 2020.[59]

Priorities and actions for Canada's Cancer Clinical Trials Action Plan

Priority 1: Make cancer clinical trials accessible to everyone in Canada

No one should be prevented from participating in a cancer clinical trial based on who they are, where they live, their age, language, education, or their ability to pay.

Too many people with cancer never hear about clinical trials or only learn about them when other options have run out, and this needs to change. Cancer clinical trials should be an integral part of every cancer care discussion, introduced early and communicated clearly. They should be embedded as part of care, with the system obliged to provide this care.

The pediatric oncology community faces specific barriers to access, which we have included in our list of actions below in Appendix A.

Public health insurance doesn't cover clinical trial participation and associated fees for many people with cancer. That disproportionately affects people with lower incomes and those living in rural or remote areas. We can eliminate financial barriers to cancer clinical trial participation by including clinical trials in government programs and services designed to ease out-of-pocket costs of cancer, medical travel and accommodation.

While some industry and academic-supported trials cover some costs, this is not a universal or standard practice across Canada. By formally recognizing clinical trials as part of care, provinces and territories can ensure costs are covered and remove a significant barrier to participation.

Ensuring better and earlier engagement with people with lived and living experience with cancer in the development of clinical trials is necessary to identify their needs, preferences and potential barriers to participation. When people with cancer are involved in the design process, they provide insights that ensure the clinical trial addresses real-world needs and concerns.

Identifying barriers to participation makes it easier to recruit and retain participants. People with lived and living experience can play an important role on an institution's or community's research ethics board (REB) by helping identify concerns during a review of research proposals and views and experiences and those of others.[60]

Involving such individuals in the REB approval process ensures that ethical considerations are grounded in real-world patient perspectives and can lead to more relevant and compassionate research practices. Their input in reviewing study protocols, consent forms and other related materials prior to REB submission can help identify potential barriers that may not be apparent to researchers, enhancing participant recruitment, retention and overall trial accessibility.

Additionally, this requires investment in high-quality, accessible information and communication materials as part of the trial design. Such materials can aid in patient recruitment and ensure a clearer understanding of trial details for patients, caregivers and healthcare providers.

The potential of using Artificial Intelligence (AI) in cancer care is significant. AI can improve the efficiency and quality of care, increasing the odds of saving lives. To integrate AI technology into everyday care pathways, such as clinical trials, people must understand AI and the changes it can bring to the cancer community.

- → **Action 1: Integrate access to cancer clinical trials and embed clinical trials as part of care**
- → **Action 2: Include people with cancer in cancer clinical trial design, including pre-trial design**
- → **Action 3: Expand access for underserved and underrepresented communities**
- → **Action 4: Integrate artificial intelligence (AI) into cancer clinical trials**

Priority 2: Streamline regulatory and administrative processes for cancer clinical trials

Although people with lived and living experience with cancer do not have time to wait, the current regulatory system creates unnecessary delays for clinicians, researchers and industry partners, which slows down trial operations. Canada needs a single, pan-Canadian oncology ethics review system that eliminates redundant reviews at the institutional, provincial and territorial levels. This review should include experts in both pediatric and adult oncology and people with lived and living experience with cancer.

It's essential to have collaboration between federal, provincial and territorial governments to eliminate redundancies, such as multiple ethics reviews. Canada could consider adopting a model similar to the US National Review Board to streamline processes. Reducing duplicative REB reviews and enhancing agreement work are necessary changes to improve efficiencies in the clinical trials ecosystem.

By streamlining the ethics review process, we can ensure that Canada is perceived as an attractive location for investment and avoid unnecessary and costly bureaucratic delays that waste time and money. Efforts such as CanReview, which aims to establish a single research ethics review of record for multi-site clinical trials across Canada, are underway.

To enhance the efficiency and effectiveness of cancer clinical trials in Canada, it is crucial to implement master contract agreement guidelines and standardize processes across clinical trial units. This approach will ensure consistency, reduce inefficiencies and address outdated systems. By developing national guidelines and standardizing processes, including master contract agreements, clinical trial units can operate more cohesively and efficiently.

Standardization will streamline the approval process, expedite the launch of clinical trials, and ensure that all people with cancer receive timely and equitable access to trials. An example is the Ontario Universal Agreement for Clinical Trials launched by the province of Ontario, which aims to reduce inefficiencies in the clinical trials system.

We must consider a more Canadian-centered approach to cancer care and cancer research to protect people in Canada from foreign governments' policy shifts, which could lead to Canada being sidelined for new lifesaving treatments and missing out on economic stimulation.

- → **Action 1: Develop and implement a pan-Canadian oncology research ethics system**
- → **Action 2: Standardize cancer clinical trial processes across Canada**
- → **Action 3: Remove provincial and territorial barriers so people with cancer can better access cancer clinical trials**
- → **Action 4: Improve the cancer clinical trials regulatory environment**

Priority 3: Enhance public awareness about cancer clinical trials

All forums demonstrated strong support for improving communications with stakeholders across the cancer community, including patient advocacy groups, charities and clinical trial navigators, to increase awareness of cancer clinical trials. It was noted that some jurisdictions within Canada, such as Alberta, and internationally, for example, Australia, have conducted public awareness campaigns on the value of clinical trials to improve knowledge and participation among people with cancer.

Many forum participants agreed that an awareness campaign should address knowledge gaps, emphasize the importance of clinical trials in cancer treatment, offer linguistic and cultural inclusivity and reduce barriers to participation. Awareness campaigns must communicate that clinical trials are designed to address the needs of individuals at all stages of cancer, not only people with late-stage, relapsed or treatment-resistant cancers.

Finally, any awareness campaign should promote cultural sensitivity and inclusion and recognize the diverse backgrounds of people with cancer, as this will improve access to clinical trials across all communities. An awareness campaign is more effective when its messaging is aligned across sectors.

In combination with a public awareness campaign, various forum participants suggested an integrated, centralized and online clinical trials navigation system that includes a list of clinical trials across all provinces and territories.

Forum participants shared examples of clinical trial metrics that could improve evaluation and more quickly identify barriers to resolve. Examples include the number of open trials, time to activation and the number of participants recruited.

Better clinical trial data helps researchers evaluate the success of clinical trials and assess how to improve patient outcomes. Realigning perceptions, practices and incentives to support research embedded in clinical care would reestablish Canada's global leadership in clinical trial activities.

- → **Action 1: Develop a pan-Canadian campaign to raise public awareness of the benefits of cancer clinical trials for all age groups**
- → **Action 2: Improve cancer clinical trial transparency**
- → **Action 3: Enhance online tools and resources for people with cancer and their caregivers to better access information about eligible cancer clinical trials**
- → **Action 4: Strengthen sectoral partnerships**

Priority 4: Improve health workforce challenges

We consistently heard the need to address health human resource shortages. Unfortunately, staffing challenges prevent some cancer clinical trials from launching or continuing to completion. Hiring qualified staff is difficult because we lack standardized job titles within the cancer clinical trials space. Standardizing job titles and clearly defining their roles and responsibilities will help facilitate the recruitment of candidates with appropriate skills and experience.

Healthcare providers play a crucial role in delivering accessible, high-quality cancer care to Canadians through participation in cancer clinical trials, in both providing service and support roles. Within the overall healthcare system in Canada, over 80 professions are involved in delivering cancer care. When staff are overworked or stretched thin, the quality of care can suffer, negatively impacting patient outcomes. It's essential to have enough healthcare professionals to maintain high standards of care.

Forum discussion findings provide context about Canada's health human resources crisis. They also addressed broader healthcare system challenges beyond clinical trial delivery and care. By addressing staffing challenges and standardizing job titles, incentives, training programs and support systems, Canada can make progress in building a sufficient workforce to administer and run more clinical trials. That will improve the efficiency and effectiveness of cancer clinical trials and Canada's cancer care ecosystem.

- → **Action 1: Improve pan-Canadian workforce planning and include clinical trials**
- → **Action 2: Promote continued education and training about clinical trials for healthcare providers**
- → **Action 3: Improve consistency of nationwide staffing models for clinical trials**
- → **Action 4: Increase healthcare professional recruitment and retention for clinical trials**

Priority 5: Transform cancer clinical trials through integrated data collection and coordination

Data is the backbone of our cancer care system and helps governments make informed decisions for current needs and forecast future services. To close critical data gaps in Canada, we must continue to prioritize the needs of people with cancer by advancing the Pan-Canadian Cancer Data Strategy.[61] This means working alongside health administrators, researchers, academic institutions and industry partners as well as federal, provincial and territorial policymakers. We must be connected, consistent and reliable.

Participants in all forums highlighted the use of Electronic Medical Records (EMRs) as a key area for improvement. We must standardize the use of electronic data platforms and processes, such as EMRs and Clinical Trials Management Systems (CTMs), to conduct cancer clinical trials more efficiently. That includes, but is not limited to, helping identify eligible people with cancer more quickly and accurately, streamlining recruitment, ensuring a diverse and representative sample population and reducing the time and costs associated with collecting data. Making clinical trials more efficient and cost-effective and maintaining continuous access to patient health data enables better patient safety monitoring.

- → **Action 1: Improve the collection and reporting of cancer clinical trial data**
- → **Action 2: Improve the use of Electronic Medical Records and Clinical Trials Management Systems for all clinical trials**

Priority 6: Improve Canada's position as a global centre of excellence for cancer clinical trials

Canada must increase global awareness of the advantages of conducting trials in Canada. A standardized pan-Canadian tool highlighting the country's strengths and supported by consistent metrics and incentives would allow for the sector to understand Canada's leadership in the clinical trials ecosystem.

We must develop financial incentives and streamline startup times to make Canada an attractive and hospitable environment for launching clinical trials. All levels of government must recognize clinical trials as an activity that, when managed well, can attract more studies and investments from around the world.

Participants across different forums also discussed the need to accelerate Canada's drug approval pathway. Aligning our drug approval timeline with those of faster G7 countries was an ongoing discussion across sectors.

- → **Action 1: Foster Canada's leadership in clinical trials within the global market**
- → **Action 2: Improve Canada's drug approval pathway**

Priority 7: Establish robust and sustainable cancer clinical trial funding in Canada

Although many of the above actions may be less expensive ways to improve Canada's cancer clinical trials landscape, forum participants agreed that none are a substitute for increased governmental funding of clinical trials. Stable, long-term funding at federal, provincial and territorial levels supports critical infrastructure, staffing, patient education and essential services, such as labs and imaging.

A comprehensive funding approach ensures that clinical trials run smoothly and effectively and benefits people with cancer across the country.

- → **Action 1: Increase government funding for cancer clinical trials across Canada**

The way forward

Successfully implementing this pan-Canadian Cancer Clinical Trials Action Plan will be a critical step forward in improving patient outcomes.

The Canadian Cancer Society acted as the convenor in this project and will continue to perform this role. We will continue working with our partners, supporters and, most importantly, people affected by cancer to build a clinical trials system that is equitable and accessible for all people in Canada.

We will accomplish this by establishing an inclusive implementation approach that supports and drives the collective action plan across sectors and achieves measurable outcomes over the next 3 to 5 years. Through its commitment to excellence and innovation, this action plan lays the foundation for a more effective and compassionate future in cancer care.

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Appendix A

Overview of priorities and actions

This action plan outlines a set of priorities, actions, and sub-actions intended to guide discussion, to share key learnings, and inform potential strategies for strengthening clinical trials. In an effort to connect the information collected through all of the workshops, we have provided a comprehensive list of sub-actions below. CCS will continue to convene the clinical trials community, and additional phases of implementation of the CTAP.

Priority 1: Make cancer clinical trials accessible to everyone in Canada

→ Action 1: Integrate access to cancer clinical trials and embed clinical trials as part of care

a. Trials should not be limited to patients living near urban cancer centres. Establish and expand funding for lodging, transportation and financial support to reduce barriers and ensure accessibility to all trials, including those in remote areas. Funding expansion should also include pediatric-specific requirements, including travel-related support for parents and caregivers. Consider establishing psychosocial support for patients and caregivers who travel great distances from their families and communities to participate in a clinical trial.

b. Implement opt-out policies for clinical trials as part of care in hospitals. That helps identify people with cancer who are eligible to participate and ensures that clinical trials are discussed.

c. Educate healthcare providers to offer clinical trials as part of care. Eliminate potential barriers that may prevent people with cancer from accessing cancer clinical trials, including a lack of access to comprehensive biomarker testing and omics analyses.

d. Incorporate workflow processes into hospitals that identify people with cancer's eligibility for trials before their first appointment to discuss treatment options. These processes should also be embedded in ongoing discussions of routine care and apply to adult, adolescent, young adult (AYA) and pediatric populations.

e. Support a cultural shift where oncology leaders endorse clinical trials and promote their value as part of care.

→ Action 2: Include people with cancer in the design of cancer clinical trials and pre-trial design

a. Ensure earlier and better patient engagement in the development of clinical trials to identify patients' needs, preferences and potential barriers to participation.

b. Increase peer-to-peer support programs for all people with cancer and recruit community language ambassadors.

c. Involve caregivers in the clinical trial onboarding process.

d. As part of trial design, invest in high-quality, accessible information and communication materials to help recruit people with cancer and ensure patients and healthcare providers have a clear understanding of trial details. Make information and communication materials accessible to and effective for children, adolescents, young adult patients and their caregivers.

e. Make patient partnership a mandatory component of clinical trial funding applications so that the perspectives of people with cancer are respected and integrated into the design and execution of clinical trials.

f. Allocate resources to help researchers who lack experience working with patient partners on a clinical trial project team.

g. Move forms online, streamline paperwork processes and provide faster real-time responses to improve efficiency and reduce barriers for trial participants. Ensure that any process changes include support for those who are not computer literate.

h. Create a national participant recruitment strategy and a database that supports patient-trial matching efforts.

i. Integrate health equity principles into clinical trial design to ensure all people with lived and living experience with cancer have equal opportunities to participate.

→ Action 3: Expand access for underserved and underrepresented communities

a. There are currently no sites in the territories recruiting people with cancer for clinical trials, meaning residents of the territories must seek out clinical trials in other provinces. This barrier to access prevents many people from participating in clinical trials.

b. Improve access to clinical trials for transgender populations.

c. Improve access to clinical trials for ethnocultural groups.

d. Establish regional or national centres that can provide infrastructure and shared services, such as standardized labs and data management, in provinces and territories with limited capacity.

→ Action 4: Integrate artificial intelligence (AI) into cancer clinical trials

a. Continue discussing the implications of AI in research processes, including trial design, patient recruitment and access, to improve the accuracy of trial outcomes. That includes implementing AI-driven language translation applications to automate the creation of consent and other patient-facing documents, ensuring accessibility across various languages. AI should be considered as part of an overall strategy for clinical trial cycles but should not be used as a "one-size-fits-all" approach.
b. Where feasible, use AI to support matching patients to clinical trials. Consider the PMATCH model for all institutions, which uses AI to match a patient's genomic and health data against clinical trial eligibility to identify relevant trials.
c. Ensure that all clinical trial sites have the necessary technology and infrastructure to keep pace with the evolution of precision medicine.

Priority 2: Streamline regulatory and administrative processes for cancer clinical trials

→ Action 1: Develop and implement a pan-Canadian oncology research ethics system

a. Mandate a pan-Canadian oncology research ethics system as a funding condition for cancer clinical trials.
b. Eliminate replication of research ethics boards at institutional, provincial and territorial government levels and support cancer clinical trials ecosystem partners.
c. Include expertise in both pediatric and adult oncology in all roles as part of a pan-Canadian oncology research ethics system. The Ontario Cancer Research Ethics Board is a model of an integrated adult and pediatric Research Ethics Board.
d. Ensure the pan-Canadian oncology research ethics system reviews both academic- and industry-sponsored trials.

→ Action 2: Standardize cancer clinical trial processes across Canada

a. Create a national framework for coordinating cancer clinical trials, including the pediatric context.
b. Develop national guidelines and standardize processes, such as master contract agreements, for clinical trial units across Canada to ensure consistency, reduce inefficiencies and address the use of outdated systems.
c. Advance national metrics to monitor and evaluate cancer clinical trials through a pan-Canadian working group with representation from all types of clinical trial sponsors and funders (such as academic institutions, the pharmaceutical industry and charitable organizations) to improve transparency.
d. Standardize clinical trial funding models and make them transparent, including costs of tests used in clinical trial settings compared to other tests.
e. Standardize laboratory and imaging requirements in provinces and territories across all cancer clinical trials. That will enable easier comparison of results across clinical trials and sites, facilitate systemic reviews and broader conclusions, and protect patient safety.
f. Federally mandate a body similar to the Quebec and Ontario government models to streamline clinical trial regulations and processes better.
g. Review privacy concerns to support the responsible rollout of expanded access to clinical trial information.

→ Action 3: Remove provincial and territorial barriers so people with cancer have better access to cancer clinical trials

a. Support infrastructure for decentralized clinical trial delivery of adult and pediatric clinical trials and "hub-and-spoke" models that protect patient privacy, uphold ethical standards and support virtual models of care. Ensure satellite sites have the necessary resources, including staff training and a sufficient drug supply. The early success of decentralized clinical trial delivery will require dedicated investment and support from the public and private sectors, especially to establish decentralized clinical trials as standard practice that enables any person with cancer to participate in trial options closer to home.
b. Enable healthcare providers to practice across the country if they are treating people with cancer as part of a clinical trial.
c. During the initial stages, leverage existing frameworks across regions to expedite Clinical Trial Agreements and reduce costs.
d. Establish regional or national centers of excellence that can provide infrastructure and shared services, including standardized labs, data management and trial navigation, to multiple provinces and territories. That could expedite processing and trial functioning, especially in provinces with limited capacity.

→ Action 4: Improve the cancer clinical trials regulatory environment

a. Improve regulatory processes for clinical trials at Health Canada, specifically ensuring consistent reviewer feedback to improve submissions and speed up the review process.
b. Establish a federally mandated body to streamline clinical trial regulations for both adult and pediatric trials and processes.
c. Standardize consent regulation and review to ensure consistency across trial sites.
d. Establish a national regulatory framework that includes privacy and data-sharing standards.
e. Implement a Canadian commissioner for clinical trials, similar to the US Food and Drug Administration (FDA) model.
f. Improve the review and inspection processes, including training of auditor staff, conducted by Health Canada using World Health Organization guidelines. Ensure the training of auditor staff includes training for pediatric trials.

Priority 3: Enhance public awareness of cancer clinical trials

→ Action 1: Develop a pan-Canadian campaign to raise public awareness of the benefits of cancer clinical trials for all age groups

a. Develop awareness of all types of cancer clinical trials among the general public, highlighting the positive role of industry partners.
b. Dispel myths about clinical trials, emphasizing that they are designed to address the needs of all individuals at all stages of cancer, not just as a last resort.
c. Increase education and awareness of clinical trials among healthcare providers and community hospitals to better connect people with lived and living experience with available trials.
d. Initiate nationwide or provincial awareness campaigns in collaboration with cancer agencies, health authorities, patient organizations and community organizations to promote trial literacy and acceptance.

→ Action 2: Improve cancer clinical trial transparency

a. Leverage existing operating and reporting frameworks that highlight the advantages of conducting trials in Canada. This is a shared priority (see below) aimed at increasing Canada's global competitiveness and launching more clinical trials.
b. Publicize accrual information and timeliness of clinical trials.
c. Ensure that clinical trial results (both positive and negative) are shared in a timely manner and published publicly. Increase communication with patients throughout the trial to keep them informed and engaged.

→ Action 3: Enhance online tools and resources for people with cancer to better access cancer clinical trials

a. Develop an easily accessible, patient-friendly cancer clinical trial finder for people living in Canada.

b. Improve online tools and resources related to clinical trials, including webinars, to increase access to available trial details for people with cancer and support informed decision-making.

c. Make plain-language summaries of clinical trials available online to ensure that information is accessible to people with cancer, including pediatric patients and their families.

d. Support the expansion of user-friendly, centralized trial registries and patient education platforms that use plain language and integrate directly into care pathways to improve accessibility. Embed trial listings into Electronic Medical Records (EMRs) and leverage AI-driven matching tools to help connect eligible patients and clinicians quickly.

e. Centralize clinical trial navigation systems at the federal level to streamline clinicians' ability to identify eligible individuals with cancer for participation in clinical trials.

f. Develop a national database or awareness program to connect clinicians and study coordinators with industry, thereby increasing access to and awareness of clinical trials.

g. Leverage existing resources and education materials available to clinicians, researchers and people with cancer, such as those provided through N2 (Network of Networks), 3CTN (Canadian Cancer Clinical Trials Network), Clinical Trials Ontario and recent CIHR-Clinical Trials Fund investments.

→ Action 4: Strengthen sectoral partnerships

a. Encourage partnerships among industry, provinces, academic centres, patient organizations and community hospitals to improve trial access, optimize funding use and advance health innovations made in Canada.

b. Explore partnerships with corporate entities, such as the model used by Walgreens in the US, to administer drugs for people with cancer in clinical trials, thereby improving access and efficiency to low-risk trials.

c. Embed tissue sharing between industry and academia within patient consent forms.

Priority 4: Improve health workforce challenges

→ Action 1: Improve pan-Canadian workforce planning and include clinical trials

a. Ensure that staffing issues in clinical trials and health research are addressed in pan-Canadian health human resources strategies and include staff with diverse representation.

b. Integrate clinical trials education into medical school curricula, mentorship programs and ongoing professional development to create a future workforce that views trials as core to healthcare functioning and standards of practice.

c. Reduce barriers to hiring international graduates.

→ Action 2: Promote clinical trials in healthcare provider continued education and training

a. Increase the number of trained clinical research professionals in oncology research in Canada and provide them with continuous education.

b. Ensure that clinical and professional training includes competency in conducting clinical trials.

c. Promote career opportunities in clinical trials and provide staff with opportunities for continued education and professional advancement. Reintroduce awards at the Canadian Institutes of Health Research for clinical researchers who have made exceptional contributions through their work.

d. Improve the alignment of specialized clinical trials training programs nationwide, including healthcare staff and other non-medical personnel who support trials.

e. Ensure all clinical trial staff undergo comprehensive training on Indigenous health, trauma-informed care, cultural competency and cultural safety.

f. Provide training for researchers and healthcare providers to ensure they are effective and comfortable working with people with cancer who are from linguistically and culturally diverse populations.

g. Expand training programs for healthcare providers, including in clinical research organizations, to enhance their understanding of clinical trials.

h. Integrate clinical trial expertise into core staffing in healthcare settings so all providers are equipped to engage with clinical trials.

i. Provide educational materials and training for clinicians, surgeons, radiologists, pathologists and others, so that they include trial discussions from the earliest stages of a person's experience with cancer.

→ Action 3: Improve consistency of nationwide staffing models for clinical trials

a. Develop mandates, with funding support, that address understaffing, overwork and the lack of time physicians have to dedicate to clinical trial research.
b. Increase the number of clinical trial coordinators or navigators in healthcare settings.
c. Increase the number of nurse navigators and social workers and ensure those roles are eligible for funding from health research grants.
d. Standardize the names, titles, role expectations and compensation of clinical research personnel positions.
e. Increase government investment to provide stable core funding for hospitals to support departmental staff dedicated to supporting clinical trials.
f. Include core Clinical Trials Unit (CTU) staff salaries (such as CTU nurse, clinical trials assistant and pharmacist) in provincial healthcare funding for better focus on delivering trials that matter to people with cancer.
g. Create consistency across the country for the clinical trials workforce to access and leverage the expertise of pathologists and geneticists for rare cancer trials.
h. Ensure that funding and adequate compensation exist for job creation in clinical trials.
i. Create incentives for health institutions, including clinics and hospitals, to build their infrastructure and system capacity to support trial conduct.
j. Recognize the role the pharmaceutical industry plays in filling workforce planning gaps and supporting research institutions' staffing infrastructure.

→ Action 4: Increase healthcare professional recruitment and retention

a. Support the recruitment of physicians and clinician scientists by making Canada a more attractive place to design and conduct clinical trials.
b. Develop incentives for physician-scientists to lead clinical trials.
c. Create a national platform to connect retiring key investigators with up-and-coming clinicians.
d. Identify and offer incentives to retain clinical trials staff members in Canada. Support long-term retention at hospitals and academic centres through continued education and tuition remission.
e. Develop a match program between institutions and the government to help recruit and retain workers in academic trials versus industry trials.
f. Streamline the research funding process by eliminating the need for researchers to apply for multiple grants.

Priority 5: Transform cancer clinical trials through integrated data collection and coordination

→ Action 1: Improve the collection and reporting of data in cancer clinical trials

a. Implement priorities of the Pan-Canadian Cancer Data Strategy, which are to:
   - improve the efficiency, timeliness and quality of data capture and access
   - enhance linkages to current data to enable cancer data interoperability and make data for primary care, diagnostics and treatment more accessible
   - fill gaps in current data collection and make data available through linkage and analysis, including collections of patient-reported outcomes and experiences and data on race, ethnicity and other equity-focused characteristics.[62]

b. Improve the collection of race-based data to better identify gaps in access to cancer clinical trials, particularly among underserved communities. Ensure that data collection is conducted in a culturally sensitive manner and is consistent across institutions. Use data collection and analysis to better understand who is underserved due to a lack of access to clinical trials.

c. Establish defined metrics and standards to evaluate equity, diversity and inclusion efforts, as well as successes and challenges within clinical trials. Address this through collaborative input.

d. Adopt standard research agreement terms and harmonized approaches for data and sample sharing, such as those included in the released report by Accelerating Clinical Trials (ACT).[63]

e. Improve alignment on data collection between institution- and industry-led clinical trials, including reasons for screen fail, self-reported data and the publication of trial outcomes.

f. Expand and leverage data tools to streamline trial recruitment, improve trial management and reduce duplication of efforts through cross-provincial data sharing.

→ Action 2: Improve the use of Electronic Medical Records (EMRs) and Clinical Trials Management Systems (CTMs) for all clinical trials

a. Ensure EMRs include clinical research tools.

b. Standardize access to interoperable EMR tools across all institutions and jurisdictions.

c. Provide government funding to support the universal adoption of licensed EMRs by healthcare centres and CTMs by research sites.

Priority 6: Improve Canada's position as a global centre of excellence for cancer clinical trials

→ Action 1: Foster Canada's leadership in clinical trials within the global market

a. Establish a standardized pan-Canadian tool or report highlighting the advantages of conducting trials in Canada, including metrics and incentives.

b. Provide financial incentives, publicize start-up times and align performance metrics used by industry and academic trialists to attract studies, including pediatric, to Canada.

c. Review tax credits and incentives to offset the costs of clinical trials.

d. Improve government recognition of clinical trials as a key economic pillar.

→ Action 2: Improve Canada's drug approval pathway

a. Align Canada's drug approval process with those of other G7 countries by allowing simultaneous submissions of the same documentation to both the FDA and Health Canada. Consider initiatives currently underway, such as Project Orbis.[64]

Priority 7: Establish robust and sustainable cancer clinical trial funding in Canada

→ Action 1: Increase government funding for cancer clinical trials across Canada

a. Secure stable, long-term funding at federal, provincial and territorial levels to support infrastructure, staffing, patient education and essential services like labs and imaging. That ensures trials can run efficiently and equitably across the country. Stable funding for Canadian participation in international consortium trials is crucial; these trials currently account for a significant proportion of pediatric trials in Canada.

b. Provide targeted funding to embed cancer clinical trial staff and processes within impacted allied health services to reduce the barriers caused by operational challenges. Beyond dedicated clinical trial nurses and associates, this could include dedicated staff to review study protocols and perform feasibility assessments regarding impacted departments, plan and resource clinical trial-specific procedures and track trial participants and associated service delivery. It could also include sufficient personnel to meet the service demand that clinical trials impose beyond routine care.

c. Acknowledge that clinical trials are part of care and must be regulated as such, so they receive sufficient funding. This regulatory shift ensures that funding is not siphoned off from life-saving clinical trial research.

d. Create a provincial rate card to address budget inconsistencies across sites.

e. Develop a matched funding support program between the government and institutions to help academic sites recruit and retain workers and better compete with more lucrative positions that industry employers may offer.

Appendix B

"What we heard" reports

Trial experts and federal health regulators

Background

This “what we heard” report is a summary of the discussions that occurred during our two-day forum in Ottawa from May 22-23, 2024. All attendees of the forum are included below.

The path forward: Our proposed solutions

We have proposed four broad solutions that can contribute to founding a national clinical trials system in Canada. These proposed solutions come from discussions at the Ottawa forum on cancer clinical trials. We expect the solutions to evolve as the Canadian Cancer Society holds more forums and open consultations within the cancer community.

We believe that solutions must take clear action and focus on three levels:

- Federal
- Provincial/territorial
- Institutional

Although government decision-makers are best positioned to drive these activities, there is a shared responsibility to contribute towards building a national clinical trials system. That includes institutions, industry partners, associations and non-governmental clinical trial funders who can implement the proposed solutions within their areas of influence.

Funding considerations

We have deliberately chosen not to focus on funding within our set of preliminary solutions. While we acknowledge that comprehensive funding for clinical trials and health research is essential, we believe that funding alone cannot solve Canada's clinical trials challenges. We need immediate action on barriers that can be eliminated through policies, national standards, best practices and regulatory and legislative procedures.

Nevertheless, we strongly urge decision-makers to recognize that the successful implementation of these solutions will require long-term, stable funding rather than time-limited funding.

> "Everyone facing cancer or serious illness deserves the chance to participate in research if they choose to. But too many people never hear about clinical trials, or only learn about them when it's too late. Access to clinical trials should be part of care from day one, not a last resort when options run out or an afterthought."
>
> — Dr Stuart Edmonds, Executive Vice President, Mission, Research and Advocacy at the Canadian Cancer Society

Federal focus

For this report, we specifically choose to focus on federal actions for two reasons:

1. We invited federal decision-makers from Health Canada and CIHR to participate in the Ottawa forum. We also shared our preliminary solutions with parliamentarians at a meeting of the All-Party Cancer Caucus.
2. We need stronger federal leadership to drive the action that will create a national clinical trial system. We saw the success of federal leadership in the United Kingdom and Australia as they underwent clinical trial modernization.

We strongly urge provincial, territorial and institutional decision-makers to support and recognize their roles in implementing these solutions. We look forward to upcoming forums and ongoing consultations to receive feedback from stakeholders across the cancer community and beyond.

Proposed solutions

Solution #1: Better patient access to innovative care

Forum discussion

Participants with patient and clinician perspectives observed that the inter-jurisdictional challenges inherent in our federated healthcare system affected their ability to navigate clinical trials. They spoke about the difficulty people with cancer had affording out-of-pocket costs when they needed to travel to clinical sites and/or pay for cancer services not covered by provincial or territorial health insurance programs or trial sponsors. Participants said that people with cancer should be able to access genomic testing of cancer, which is often a requirement to assess eligibility for clinical trials that test precision medicine.

Clinician participants shared their concern about being unable to optimally treat patients they only met through virtual clinical trial sites (from decentralized trial models) and in clinical trials with multiple sites across Canada.

Participants expressed concern that strict interpretations of provincial/territorial privacy legislation limited their ability to share information about clinical trials with people with cancer who were outside their circle of care. Some participants shared challenges they encountered when attempting to implement opt-out policies at their institutions.

Federal action

We propose developing federal legislation and policies for clinical trials that address the following:

- Formally recognize clinical trials as the standard of care.
- Implement automatic opt-out policies regarding information sharing so that people with cancer can be more proactively informed about clinical trials for which they may be eligible.
- Review privacy concerns to support the responsible rollout of expanded access to clinical trial information.
- Enable physicians to practice across the country when treating cancer patients as part of a clinical trial.

Solution #2: Comprehensive resources for health professionals and trial sponsors

Forum discussion

Participants expressed frustration over the lack of transparency regarding the costs of tests used in clinical trial research settings compared to standard-of-care tests, as well as what constitutes standard-of-care management. The lack of transparency makes managing tight trial budgets difficult, which is a growing concern as cancer clinical trials become increasingly complex and expensive.

While institutions seek to generate revenues from clinical trial participation, their assessment and charges for trial activities affect participation and feasibility due to delays in the review process and increased trial costs. That affects publicly funded trials disproportionately and without consideration for cost savings in drug and pathology testing.[65, 66, 67]

Participants noted the success of centralized ethics review boards and template master contract agreements in other jurisdictions that have undergone clinical trial modernization, such as the UK and Australia. Those efforts have reduced the unnecessary administrative burden of otherwise duplicative processes.

Many participants advocated for scaling up a "hub-and-spoke" model[iv] of decentralized clinical trials infrastructure, which pan-Canadian cancer networks like 3CTN and CCTG have piloted, particularly regarding the lessons learned from national health emergencies, such as COVID-19, that led to extensive shutdowns of non-essential clinical research.

Participants also shared examples of clinical trial metrics that could improve evaluation and more quickly identify barriers that need to be resolved. Examples of metrics include the number of trials that have opened, the time to activation and the number of participants recruited. Better clinical trial data helps researchers evaluate the success of clinical trials and assess how to improve patient outcomes.

Realigning perceptions, practices and incentives to support research embedded in clinical care would re-establish Canada's global leadership in clinical trial activities.

iv Note: A 'hub-and-spoke' model refers to a set-up with a single distribution centre that can deliver to connected satellite locations.

Federal action

- Integrate best practices with health institution accreditation requirements.
- Develop policies to support master contract agreement templates that clinical trial funders (including government, charities and private sources) should agree to use.
- Implement a national ethics review board and mandate its use as a condition of federal funding for clinical trials.
- Support infrastructure for decentralized trial delivery and "hub-and-spoke" models.
- Further develop national metrics to monitor and evaluate clinical trials through a pan-Canadian working group with representation from clinical trial sponsors and funders, including academic institutions, the pharmaceutical industry and charitable organizations.

Solution #3: Stronger health system capacity

Forum discussion

Participants stated that clinicians and staff are often focused on clinical care and have limited capacity due to the overburdened nature of our healthcare system. Constraints on time, capability and the need for specialized skillsets create barriers for professional staff who could enter work in the trials ecosystem.

At the same time, participants stated there is typically a strong interest in clinical trial work because staff who participate express satisfaction in being able to improve health outcomes for people with cancer and in achieving professional and academic recognition.

Participants suggested that clinical trial staff would benefit from additional training, support, resources and institutional support through their professional associations and regulatory colleges.

Federal action

- Ensure that staffing issues in clinical trials and health research are reflected in pan-Canadian health human resources strategies.
- Establish national best practices and standards for compensation related to research procedures and patient services provided through clinical trials.
- Ensure that competency in trial conduct is included in both clinical and professional training.

Solution #4: Greater public awareness about clinical trial benefits

Forum discussion

Patient participants expressed that they deserved the right to know about clinical trials and research relevant to their illness and cancer care needs. They stated that while clinical trials are not a guaranteed line of treatment, they should have the right to access a clinical trial if one becomes available and they meet eligibility criteria.

Participants believed that information needs to be accurate, patient-friendly and often tailored to the individual. Participants stated that clinical settings providing cancer care or healthcare services should provide trustworthy information about clinical trials and research.

The Canadian Cancer Society noted we are currently developing a new national cancer clinical trials directory. The directory's goal is to help people with cancer and their families find accurate, up-to-date information about clinical trials in an easy-to-use platform with navigational support. This work is ongoing.

There was strong support for improved communication in collaboration with stakeholders across the cancer community, including patient advocacy groups, charities and clinical trial navigators, as well as a broader range of communication streams, such as in clinics, online through trusted sources and individual outreach. It was noted that some jurisdictions within Canada, such as Alberta, and internationally, for instance, Australia, have conducted public awareness campaigns on the value of clinical trials to enhance patient knowledge and participation.

Federal action

- Develop a pan-Canadian campaign to raise public awareness of the benefits of clinical trials for people with cancer, researchers, the healthcare workforce and the general public.
- Expand the pan-Canadian clinical trials training platforms to deliver ongoing specialized clinical trials training for healthcare staff and other non-medical staff who support clinical trials.

Acknowledgments

The Canadian Cancer Society had the honour of partnering with Dr Rebecca Auer and Dr Janet Dancey, who co-chaired our inaugural stakeholder forum on modernizing cancer clinical trials in Canada. Dr Auer and Dr Dancey—who had each shared their vision for systemic changes for clinical trials in editorials—brought together approximately 40 experts, federal regulators, and patient partners to identify practical solutions towards the creation of a national clinical trials system in Canada.

"More people can have good information about clinical trials, good information about these new interventions that might help them at this most important time in their life than ever before.

All we need to do is to basically update our regulations, update our approaches, update the ways we design and run trials, update the ways that we ask and the type of information that we collect from patients to accelerate these advancements, to demonstrate their benefits and to lead to their adoption into our healthcare system to benefit all of us."

— Dr Janet Dancey

People with lived and living experience

Background

The objective of this forum was to gather feedback from a pan-Canadian group of people with lived and living experience with cancer and caregivers on the challenges of cancer clinical trials for both adult and pediatric populations.

The workshop, which hosted 25 people with lived and living experience with cancer and caregivers from across Canada, was held in person in Toronto on November 13, 2024. The selection criteria for participants were that they either had experience as a patient or caregiver in a clinical trial or were a patient partner in the development and delivery of clinical trials.

The themes identified in this report are the result of a pre-workshop survey and the workshop itself. The categories listed below are the result of grouping issues and solutions identified and presented in order of importance. Patients and caregivers were asked to choose their top priority, and patient partners had two choices.

The identified solutions can be considered for implementation by several audiences, including federal and provincial governments, health authorities, trial sponsors, trial funders and Clinical Trial Units.

The path forward: Our proposed solutions

Solution Category #1: Awareness and outreach

All solutions listed in this section are suggested as actions complementary to what is currently happening. They are not meant to have duplicative outcomes.

- **Implement an effective awareness campaign**: Launch a nationwide awareness campaign to improve awareness of clinical trials for all people with lived and living experience with cancer across Canada. The campaign should focus on addressing knowledge gaps, emphasizing the importance of clinical trials in cancer treatment, and reducing barriers to participation. It must be linguistically and culturally inclusive. Ensure that any awareness campaign clearly expresses that clinical trials are not limited to people with late-stage, relapsed or refractory cancers but are designed to address the needs of individuals at all stages of cancer. Finally, any awareness campaigns should promote cultural sensitivity and inclusion and recognize the diverse backgrounds of people with cancer, which will improve access to clinical trials across all communities.

- **Enhance online tools and resources**: There is a need for a patient-friendly, easily accessible clinical trial finder for people living in Canada. Improve online tools and resources related to clinical trials to increase patient access to available trial details and support informed decision-making. Make plain-language summaries of all clinical trials available online to ensure information is clear and accessible to people with cancer and their families.
- **Expand patient peer support programs**: Peer support refers to the emotional and practical assistance provided by two people who share a common experience. Increase patient peer-to-peer support programs for all individuals with cancer and recruit community language ambassadors who promote the values of global citizenship and cultural understanding through language education and engagement. Their role is crucial in creating inclusive environments that celebrate diverse languages and cultures. That will help address cultural concerns about research.
- **Include caregivers in patient onboarding**: Involve caregivers in the clinical trial onboarding process, as they often help people with cancer understand and navigate the trial process and can collaborate with trial navigators to disseminate key information.
- **Update federal guidelines**: Revise and modernize federal guidelines to incorporate approved wording for public-facing clinical trial materials.

Solution Category #2: Access and decentralization

- **Integrate clinical trials into standard care**: Advocate for clinical trials to be a standard part of cancer care while recognizing that not every patient will be eligible and that medical treatment evolves as scientific understanding progresses.
- **Utilize government funding for clinical trials**: Advocate for provincial and territorial governments to allocate sufficient funding for clinical trials, recognizing them as a vital component of universal healthcare access. Integrate lodging, transportation and financial support with clinical trial participation to reduce barriers and ensure accessibility for all people with cancer.
- **Improve data collection and analysis**: Enhance data collection to understand better who is underserved by a lack of access to clinical trials, why some people with cancer are not enrolled and the specific challenges patients face when participating in trials.
- **Train more healthcare providers**: Train additional healthcare providers and staff involved in clinical trials, such as clinical research associates, to support these trials, thereby increasing access and availability, particularly in rural communities.
- **Support decentralized clinical trials**: Utilize virtual care teams to facilitate a decentralized model for clinical trials, allowing for broader participation and greater flexibility for patients. Decentralized trials aim to provide care as close as possible to an individual's home. That can include services delivered at satellite hospitals and other local facilities, not only through virtual care. Governments should provide specific funding criteria to support clinical trials in remote areas, including incentives for trials in urban centers and funding to help rural people with cancer access trials in urban locations.
- **Leverage corporate partnerships for drug administration**: Explore partnerships with corporate entities, such as the model used by Walgreens in the US, to administer clinical trial drugs to people with cancer, improving access and efficiency.
- **Standardize agreements to expedite trials**: Establish standardized agreements across all settings involved in delivering a clinical trial to streamline the approval process and accelerate the launch of clinical trials.

Solution Category #3: Funding and administration

- **Provide funding for core clinical trials unit staffing**: Many clinical trial units (CTUs) operate as profit centres, resulting in decisions being made based on how much a trial sponsor pays them versus the right trials for people with cancer. Including core CTU staff salaries (such as for CTU nurses, clinical trials assistants and pharmacists) in provincial healthcare funding will mean less focus on being a profit centre and more attention on delivering trials that matter to people with cancer.
- **Standardize clinical trial processes across Canada**: Develop national guidelines and standardize processes, such as master contract agreements, for CTUs across Canada to ensure consistency, reduce inefficiencies and address the use of outdated systems. Standards of care in hospitals could include workflow processes that identify a patient's eligibility for a trial before their first appointment to discuss treatment options.
- **Streamline ethics review boards**: Create one Ethics Review Board at a national level and eliminate replication of that work at institutional and provincial levels. That could include the creation of a National Ethics Review Board to streamline ethical reviews and should include expertise in both pediatric and adult oncology.
- **Increase training for healthcare providers**: Expand training programs for healthcare providers, including clinical research organizations, to improve their understanding of clinical trials. Ensure that clinical trial expertise is integrated into core staffing in healthcare settings, so all providers are equipped to engage with clinical trials.
- **Strengthen resources in smaller centres**: Equip smaller healthcare centers with the necessary human and equipment resources to support clinical trials, ensuring that all people with cancer, including those in smaller or more remote areas, have equal access to trial opportunities.
- **Simplify the research funding process**: Streamline the research funding process by eliminating the need for researchers to apply for multiple grants.

Solution Category #4: Trial design and development, timelines and accrual

- **Engage people with cancer early in clinical trial development**: Ensure earlier and better patient engagement when developing clinical trials to identify people with lived and living with cancer and their needs, preferences, and potential barriers to participation. Invest in recruitment strategies that enable more individuals with lived and living experience with cancer to participate in clinical trials, ensuring trials are completed promptly and reports are provided quickly to determine the effectiveness of treatments. That requires investing in high-quality, accessible information and communication materials as part of a trial's design to aid in recruitment and ensure a clear understanding of trial details for both people with lived and living experience with cancer and healthcare providers. Forum participants suggested that trials should be designed with transparent processes and provide clear explanations about why specific trials succeed or fail to improve learning and inform future trial designs.
- **Require patient input for trial funding**: Make patient partnership a mandatory component of trial funding applications to ensure that patient perspectives are respected and integrated into the design and execution of clinical trials.

- **Support researchers in patient engagement**: Allocate resources to help researchers who lack experience working with patient partners as team members on a clinical trial project. Additionally, provide training for researchers and healthcare providers to ensure they are comfortable and effective working with linguistically and culturally diverse populations with lived and living experience.
- **Incorporate artificial intelligence (AI) and real-world data in trial design**: Integrate AI and real-world evidence into clinical trial design to enhance data collection, analysis and the accuracy of trial outcomes. That includes implementing AI-driven language translation applications to automate consent and other patient-facing documents, ensuring accessibility across languages. AI should be considered part of an overall strategy for clinical trial cycles.
- **Streamline paperwork and improve access**: Move more forms online, streamline paperwork processes, and provide quicker real-time responses to improve efficiency and reduce barriers for trial participants. Ensure any process changes include support for those who are not computer-literate.
- **Embed health equity in trial design**: Integrate health equity principles into clinical trial design to ensure all people with lived and living experience with cancer, regardless of background, have equal opportunities to participate.
- **Ensure new treatment for all trial participants**: Make every effort to remove the use of placebos in clinical trials. Randomized and blind clinical trials are critically important, especially for collecting information to support drug approval if the treatment is successful. However, randomized clinical trials may not be appropriate for all treatments, especially personalized and targeted therapies (for example, CAR T-cell therapy). Randomized and blind clinical trials were designed in 1946 when there was no access to real-world data or AI. Explore modern methods of creating a control arm by using real-world data and AI to ensure appropriate data for drug approval.
- **Align drug approval pathways with G7 countries**: Align Canada's drug approval process with those of other G7 countries by allowing simultaneous submissions of the same documentation to both the FDA and Health Canada. That will expedite approval so that drugs proven to work in trials can be timely and accessible to Canadian people with cancer. Compared to trials for novel cancer treatments in the US and many European countries, Canada currently lags behind. That means Canadians must travel to other countries for novel or experimental treatments (trials). Many drugs considered standard of care in other countries are still experimental in Canada. We need a strategy to align Canadian drug approval processes based on successful trial results in that country. We need an overarching research and clinical trial strategy and criteria to ensure funding and research are focused in the right areas. One suggested solution was to conduct a cancer research gap analysis at the national level, inventory and prioritize identified items for study, and research funding competitions, creating a focus on and incentive to bridge the gaps and bring investigational treatments to Canadian people with cancer. That will put Canada on a more equal footing in research.
- **Improve trial communication and transparency**: Ensure that clinical trial results, both positive and negative, are shared promptly and increase communication with trial participants to keep them informed and engaged.

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"Among all the voices in the cancer clinical trials ecosystem, the patient and caregiver perspective is the only one grounded in lived experience—the perspective of those who must try to navigate not only their disease, but also the research intended to bring them hope. The CCS Patient and Caregiver Forum we facilitated gave voice to the realities, challenges, and aspirations of those who use clinical trials, not just study or deliver them.

It is by listening to these "end users" that we can truly identify and use the gaps they experienced to craft solutions that are not only innovative, but efficient, meaningful and human-centred. Thank you CCS, for recognizing that to build a better future for cancer trials in Canada, the system that delivers them must be co-designed with the very people they aim to serve."

— Judy Needham and Antonia Palmer, co-chairs of the patient and caregiver forum

Provincial cancer agencies

Background

CCS partnered with the Canadian Association of Provincial Cancer Agencies (CAPCA) to engage clinical experts, cancer program leads and trial leads from across the country. These stakeholders provided firsthand insights into the operational, regulatory, and infrastructure barriers that prevent timely and equitable access to cancer clinical trials.

CAPCA and CCS hosted three forums with experts throughout October and December 2024. Below is a summary of key themes and opportunities participants identified to address challenges in Canada's current clinical trial ecosystem and its associated regulatory frameworks.

Best practices and standardized tools

- **Recognize trials as care**: Clinical trials are often treated as "research" or an "add-on," rather than a core component of care. Government and health authorities need to recognize trials as a legitimate part of the standard of care continuum with associated financial, infrastructure and policy support. In addition to education and training for clinical staff, it was also recommended that trial information be embedded into clinical pathways, including pre- and post-surgical visits, so people with cancer can learn about trials and have them be part of routine discussions.
- **Develop harmonization and efficiency of trials**: Multiple layers of administration, duplicative ethics reviews, and inconsistent standard operating procedures across provinces and institutions make clinical trial initiation and management cumbersome. Developing standardized master contracts, ethics approvals and data-sharing agreements at the national level was identified as a solution to reduce duplicative efforts and streamline trial activation. That could involve developing standard agreement templates, consolidating ethics approvals under one centralized body and standardizing laboratory and imaging requirements. Encouraging inter-jurisdictional and inter-departmental collaboration to leverage existing expertise, reduce silos and ensure people with lived and living experience with cancer have consistent access to trials, regardless of their location, was also encouraged.
- **Enhance patient and clinician navigation tools**: Far too often, people with cancer are unaware or unable to identify available trials, and some clinicians shared that they have trouble identifying eligible participants. Existing tools, such as clinicaltrials.gov, can be confusing and do not use patient-friendly language. Creating user-friendly, centralized trial registries and patient education platforms that use plain language and integrate directly into care pathways would improve accessibility. In addition, embedding trial listings into Electronic Medical Records (EMRs) and utilizing AI-driven matching tools can help connect eligible patients and clinicians quickly.

- **Create awareness campaigns**: Public awareness initiatives, including social media, targeted advertising, and patient education resources, can help demystify clinical trials for individuals with cancer and their caregivers, while also fostering a broader conversation about their role in cancer care. National or provincial awareness campaigns to promote trial literacy and acceptance, in collaboration with cancer agencies, health authorities and patient groups, were encouraged.

Legislative and regulatory opportunities

- **Have clear and consistent national guidelines**: Every new trial requires ethics approval at each participating centre. Some participants shared that the ethics approval processes can prolong a trial's start-up time and impact the limited health human resources available. Additionally, differing provincial and territorial regulations and interpretations create barriers to cross-border trial access. Establishing national, centralized ethics and regulatory frameworks, including privacy and data-sharing standards, could accelerate trial activation and ensure that people with cancer in different provinces have equal access to trials.
- **Enhance policies that support trials**: In some jurisdictions, standard healthcare coverage, such as travel and laboratory tests, does not extend to participants in clinical trials. That can create significant financial burdens on people with cancer or discourage trial enrollment altogether. (You can find additional information about the financial burden of people with lived and living experience with cancer in this report's Foreword.) We encourage recognizing trials as part of healthcare and seeking legislative and regulatory amendments to ensure participation costs are covered through both government programs and healthcare funding, so that all people with cancer, regardless of where they live, can benefit from innovative therapies.
- **Encourage virtual and decentralized trials**: Virtual and decentralized trial models can reach people with cancer in rural or remote areas, expanding participation and creating health equity. Creating and/or adopting national guidelines for virtual and decentralized trials that protect patient privacy and uphold ethical standards will facilitate broader trial participation.

Building capacity

- **Increase workforce development and training**: Expanding the pool of trained clinical research professionals and providing them with continuous education ensures stability in trial operations. Currently, there are few health human resources, such as research nurses, coordinators and administrative support staff, who are dedicated to clinical trials. Inadequate succession planning hinders the efficiency of trials, especially in already stretched healthcare environments that are competing to deliver basic standards of care. Integrating clinical trials education into medical school curricula, mentorship programs and ongoing professional development creates a future workforce that views trials as core to healthcare functioning and standards of practice. In addition, education materials and training should be provided to clinicians, surgeons, radiologists, pathologists and others so they can integrate trial discussions from the earliest stages of the patient's journey.

- **Enhance infrastructure capacity**: Some provinces lack dedicated research hospitals and integrated lab or imaging services, which often results in clinical trial requests taking secondary priority to standard-of-care testing, imaging, and health human resources. Sending specimens out of province and competing for limited diagnostic imaging resources delays trial processes. Establishing regional or national centers of excellence that provide infrastructure and shared services, such as standardized labs, data management and trial navigation, to multiple provinces and territories could expedite processing and trial functioning, especially in provinces with limited capacity.
- **Leverage data and technology**: Without robust metrics and data tools, it's challenging to benchmark performance, identify patient cohorts for trials and set meaningful targets for trial enrollment as a marker of high-quality care. Clinical trial clinicians and staff often spend excessive time on paperwork and coordination rather than focusing on patient recruitment and support. Integrating EMR and AI-driven patient matching can streamline trial recruitment and improve trial management. Cross-provincial data sharing can further enable this work and reduce duplication. Useful tools, such as EPIC and Varian, exist in this space and could be expanded.
- **Encourage cultural change through leadership**: Effective leadership can significantly influence an organization's culture. By explicitly recognizing and promoting clinical trials as the standard of care, integrating them into strategic planning and promoting their value, leaders can increase trial uptake and ensure that trials are not viewed as merely "extra work."

Funding and incentivizing levers

- **Secure long-term, stable funding**: Trials rely on ad-hoc funding, which prevents sustainable trial activity. Securing stable, long-term funding at the federal, provincial and territorial levels that supports infrastructure, staffing, patient education and essential services, such as labs and imaging, ensures that trials can run efficiently and equitably across the country.
- **Create strong business cases**: Governments and health system leaders may not fully understand the economic and care-quality benefits of running trials, often viewing them as "research" rather than integral to standard care. Demonstrating outcomes, such as improved patient survival, economic returns from attracting trial sponsors or faster access to innovative treatments, is essential in attracting and stewarding investment. Standardized trial-related terminology, metrics, and reporting to clearly communicate trial value to policymakers, funders and the public will be important.

Cancer research funders: Canadian Cancer Research Alliance

Background

This forum with the Board of Directors of the Canadian Cancer Research Alliance, part of the CCS forums, was held during a Board meeting in December 2024.

The path forward: Our proposed solutions

Solution Area #1: Standards and best practices

The board was asked what all levels of government can do to support the use of standards and best practices to operationalize cancer clinical trials more efficiently in Canada, and the following discussion ensued:

- The Canadian Institutes of Health Research (CIHR) was commended for providing funding for the national consortium Accelerating Clinical Trials (ACT). The two primary ACT focuses have been 1) to expedite progress toward a single national Research Ethics Review Board (REB) and 2) to create more efficient grant and contract processes.
- Initially, ACT did not include oncology clinical trials; however, this has evolved, and oncology is now included.
- Participants noted that ACT's two priorities have had varying levels of success. For example, there is willingness across research sites to improve processes and make grants and contracts more efficient. However, the proposal of a national REB has met challenges. Participants shared that there are deeply entrenched attitudinal barriers to a shift to a single national REB.
- Participants felt that the solution to the problem of establishing a national REB would be a "top-down" approach, which requires Canada to have a centralized REB. There are examples of this:
  - The National Institutes of Health successfully transitioned to a centralized model.
  - The province of Quebec is demonstrating leadership with a model for pediatric clinical research.
  - It was noted that affiliated hospitals in Toronto have implemented a "boards of record" process as a mechanism to expedite review.
  - Finally, Clinical Trials Ontario is exploring a centralized REB model for the province.

- Participants felt that provincial and territorial legislation is also a barrier to streamlining reviews. However, they noted that if a centralized REB was required for funding, all affiliated parties would be motivated to make legislative changes.
- The role of the president of CIHR was identified as an important agent for change.

Solution Area #2: Legislative and regulatory amendments

Participants discussed what legislative and regulatory amendments could be put in place to improve equitable access to the standard of care provided through cancer trials, and the following discussion was captured:

- Data was identified as a crucial need, with a mandate to track the representativeness of Canadians within trials. While this is enabled for standard of care, it is not the case for clinical trials.
- The Canadian Remote Access Framework for Clinical Trials (CRAFT) and pathways to permit cross-border access to clinical trials were identified as important.[68]
- Participants discussed a significant barrier being that oncologists do not inform people with cancer about clinical trials, even those happening within their own centres. That barrier elicited much discussion about the potential roles of nurse navigators and social workers, although participants noted that health research funders do not typically fund grant proposals for trial navigators.
- Several hospitals are currently considering a proposal to reduce regulatory burden by implementing an automatic opt-in process during patient registration. Trial matching would occur before seeing the oncologist. Participants recognized that a culture change at a site would be needed for this to be successful.
- Participants proposed that an opt-out process may also work, whereby permission to contact programs across the country is secured.
- A participant mentioned that there has been a 50% decrease in clinical trials over the past 10 years and that, from an industry perspective, Canada ranks at the bottom in terms of efficiency.
- It was suggested that improving patient matching to therapy (PMATCH) may be a good model for all institutions to consider.[69] This model uses AI to match a patient's genomic and health data with clinical trial eligibility requirements, identifying relevant trials, and the results are automatically sent to the oncologist. That project increased patient accrual at Princess Margaret Cancer Centre from 15% to 50%. A successful rollout across the country may help people with cancer who otherwise have to receive treatment in the United States.
- Participants recognized that the lack of a unified, patient-friendly Canadian clinical trials portal is a gap in access. The portal U-Link, in the pediatric space, provides summaries of early phase trials and identifies funding sources for children with cancer to travel to trials outside of their home area.[70]
- Finally, the participants acknowledged the importance of improving patient education about clinical trials. For example, participants mentioned that online webinars could be used to help people with cancer better understand what clinical trials are and how to use and navigate trial finders.

Solution Area #3: Clinical trial workforce and infrastructure optimization

On the question of how to optimize the clinical trial workforce and strengthen clinical trial infrastructure, the following discussion happened:

- Trials are increasingly happening at community hospitals, which do not have dedicated resources.
- Challenges arise when protocols require tests and services from allied providers, beyond the clinical trials' nurses.
- Inefficiencies created by an artificial division between nurses delivering standard of care and those engaged in clinical trials were identified. The participants hypothesized that if administrative and structural issues related to clinical trials can be addressed, all health human resources could be utilized.
- Clinical trials should be reframed as an integral part of the standard of care. All affiliated parties ("the system") need to buy into this concept so the onus is shifted away from people with cancer.

Solution Area #4: Funding incentives

While this solution area was not covered in the meeting, the following feedback was provided in writing as part of a validation exercise:

Use existing funding commitments and agreements for cancer trials to:

- educate patients about clinical trials in Canada
- develop mechanisms to run clinical trials at or near a patient's cancer centre
- promote tools that match people with cancer to clinical trials.

Clinical trials infrastructure funding can reduce barriers caused by operational challenges by addressing the resourcing pressures that clinical trials impose on our health system and service lines, such as increased demand for medical imaging, laboratory services and pathology services. Targeted funding can help embed clinical trial staff and processes within impacted allied health services.

Needed clinical trial infrastructure, beyond dedicated clinical trial nurses and associates, includes:

- dedicated staff to review study protocols and perform feasibility assessments with impacted departments
- planning and resourcing for clinical trial-specific procedures
- tracking trial participants and associated service delivery
- enough personnel to meet the service demand imposed by clinical trials (beyond routine care).

Health research funders: HealthCare*CAN*

Background

The Canadian Cancer Society engaged members of HealthCare*CAN* for a virtual forum in February 2025. Stakeholders provided firsthand insights into operational, regulatory and infrastructure barriers that prevent timely and equitable access to cancer clinical trials. This feedback is intended to inform the overall report and should not be attributed to any one site, institution or person.

The path forward: Our proposed solutions

Solution Area #1: Best practices and standardized tools

When asked what all levels of government can do to support the use of standards and best practices to operate cancer clinical trials more efficiently in Canada, we captured the following discussion:

- **Regulate clinical trials so they are considered part of patient care**: Attending members of HealthCare*CAN* emphasized the importance of considering clinical trials part of the standard of care for people with cancer. The regulatory separation of clinical trials from clinical care has meant that many institutions forgo making every possible treatment option available for a patient. That deprives people with cancer who, if clinical trials were seen as care, could see their lives extended or perhaps even saved due to innovative therapies being used in clinical trial research.
- **Optimize clinical trial navigation tools**: Centralizing clinical trial navigation systems at the federal level would streamline clinicians' ability to identify eligible people with cancer to participate in clinical trials and better enable them to find appropriate trials. Furthermore, having consistent access to health records would greatly benefit clinicians. Clinical trial researchers and staff often spend an excessive amount of time on paperwork and coordination, rather than focusing on patient recruitment and treatment. Integrating Electronic Management Records (EMRs) would ensure that incompatible EMR systems and paper-based records aren't overlooked, potentially allowing people with cancer better access to the care they need.

- **Improve jurisdictional barriers to launching and participating in clinical trials**: Different provinces have different Research Ethics Boards (REB). Having a national REB, as opposed to the current provincial model, would simplify the requirements for clinicians to launch clinical trials. Currently, many find the process cumbersome due to over-complexity that stems from regional variations in standards. Uncertainty about healthcare coverage can prevent people with cancer from participating in clinical trials due to financial constraints. In some jurisdictions, standard healthcare coverage, such as travel and laboratory tests, does not include participation in clinical trials, making it difficult for patients from these provinces to participate. Recognizing clinical trials as part of covered medical interventions that are standard care would enable people with cancer to benefit from clinical trials regardless of their income or location.
- Efforts by provinces to boost interprovincial trade, due to Canada's current strained relationship with the United States, provide an opportunity to streamline clinical trial infrastructure, which hinders access to interprovincial care.

Solution Area #2: Legislative and regulatory opportunities

Participants discussed legislative and regulatory amendments that could be put in place to improve equitable access to the standard of care provided by cancer trials in Canada. The following discussion took place:

- **Simplify and standardize the regulatory environment**: Participants identified challenges in the regulatory process for clinical trials at Health Canada. Some noted administrative burdens, bureaucratic delays and inconsistencies in feedback from different reviewers, which created ambiguity about approval requirements and impacted the overall efficiency of the trial approval process. For more complex studies, the approval process was said to be the most challenging aspect. That highlights the importance of streamlining regulatory and review processes to support innovation in Canada.
- **Expand access for rural and remote communities**: All jurisdictions are not equal when it comes to cancer care. Many people in Canada do not live in densely populated areas with cancer clinical trial units. The territories have no clinical trials at all, and residents must seek necessary medical interventions through trials in other provinces, such as Alberta. This barrier to access prevents many individuals from participating in and receiving treatment from clinical trials.

Solution Area #3: Building capacity

Regarding how to optimize the clinical trial workforce and strengthen clinical trial infrastructure, participants discussed the following:

- **Recruit more clinical trial professionals**: To run more clinical trials in Canada, we need to ensure there is a sufficient workforce to administer them. Unfortunately, there are staffing challenges that prevent clinical trials from being initiated and/or completed. Hiring additional staff is made difficult by a lack of standardized job titles within the clinical trial space. Those who set up clinical trials struggle to hire individuals with the requisite level of experience because it's unclear what their experience entails. That is due to differences in titles, which do not reflect seniority or areas of responsibility.
- **Incentivize physician-scientists to lead clinical trials**: Currently, the incentives for dedicating a career to clinical trial research, as opposed to clinical care, are insufficient and do not attract enough candidates. To address this, one should examine researchers' salaries and compare them to those of other, closely related careers. One participant suggested reintroducing CIHR's presentation of awards to clinical researchers who make exceptional contributions through their work.
- **Allow virtual visits for clinical trials**: While some clinical trial appointments must be conducted in person, many can be done online, which improves accessibility for those in regions with few or no clinical trial units and potentially saves costs. Virtual appointments between clinical researchers and people with cancer have been successfully introduced in some jurisdictions, such as Australia.

Solution Area #4: Funding and cost efficiency

A discussion of funding incentives included the following discussion:

- **Increase budgets and streamline funding sources**: To ensure that clinical trials receive sufficient funding, we must acknowledge that they are part of the standard of care and should be regulated accordingly. That regulatory shift will ensure that funding is not siphoned off from life-saving clinical trial research. When one funding source isn't enough, we should collaborate to streamline funding from multiple sources and ensure adequate support.
- **Increase transparency between clinical trial researchers**: To avoid duplicating efforts, we should improve transparency among clinical trial researchers. By identifying similarities between different trials, we can create opportunities for cost-efficient collaboration.

Life sciences industry

Background

A forum with pharmaceutical industry partners was held in person in Toronto in January 2025. This feedback is intended to help inform the overall report and is not attributable to any one person or organization.

The path forward: Our proposed solutions

Solution Area #1: Standards and best practices

When asked what all levels of government can do to support using standards and best practices to operationalize cancer clinical trials in Canada more efficiently, the following discussion was captured:

Standardization of contracts, budgets and agreements

- Reducing bureaucracy and streamlining the approval process are crucial. The federal government should consider a National Research Ethics Board that encompasses both academic and industry-led trials, rather than relying on localized review.
- It's challenging to establish a uniform standard of submission across all institutions and provinces because each institution has its own methods for assigning contracts, which are often dictated by Standard Operating Procedures. Mandating a provincial master process document and standardized processes for cancer clinical trials in Canada is a possible solution.
- Innovative Medicines Canada could bring together stakeholders and agree on guidelines that help expand the scope of trials. For example, master contract agreements would streamline processes that could take hours instead of months.
- Pharmaceutical companies must comply with both global and Canadian systems and regulations.
- As technology evolves in precision medicine, operationalizing precision oncology trials at a site involves communicating with labs to ensure they have the necessary infrastructure to detect the biomarker under investigation. We need a more consistent way to access and leverage the expertise of pathologists and geneticists for rare cancer trials.

Provincial/territorial differences and opportunities for collaboration

- Differences in drug reimbursement, lab services and doctor availability across provinces and territories dictate patient journeys.
- Strong collaboration between centers across provinces could help streamline contracting and improve patient access to trials. It's essential to overcome challenges in interprovincial and territorial collaboration. A legal umbrella could help mitigate issues and ensure collaboration.
- A national database or awareness program that connects clinicians and studies coordinators with industry could increase access and awareness of clinical trials.
- Further centralization should be balanced to avoid equity issues for those who cannot access major sites.
- A cooperative approach within a region can save costs at the initial stages. The Atlantic Clinical Trials Network, for example, which aims to speed up approval times, found that time zone differences are a factor in slowing down processes. That highlighted the need for a framework to solve such bottlenecks.[17]

Canada as a global destination for clinical trials

- Increasing inflation, rising costs, bureaucracy, COVID-19 impacts and a lack of resources are significant challenges for trials attempting to launch in Canada. Ontario's Leadership Table at Clinical Trials Ontario aims for a 45-day turnaround time. Participants cited the leadership of both the provinces of Quebec and Ontario multiple times during the forum. For example, Quebec's government finance department recognizes the value of clinical trials and encourages institutions to get on board. The Government of Ontario is adopting best practices from Catalis (Quebec) and Clinical Trials Ontario processes.
- It was suggested that a federally mandated body would better streamline clinical trial regulations and processes.
- There is growing global awareness that Canada is not fertile ground for clinical trials. A standardized tool or report, with metrics and incentives, that highlights the advantages of conducting trials in Canada is needed.
- Incentivized financials could attract studies to Canada and publicize the Canadian environment. Participants discussed publicizing start-up times, which in turn could incentivize quicker processes. Performance metrics used by industry and clinicians/institutions need to align.

Clinical trials workforce

- The clinical research workforce is overworked, understaffed and often reluctant to work at sites, which adds to timelines and inefficiencies. Clinicians need dedicated research time from their institutions. Government mandates could support this.
- As key investigators lose capacity or retire, a national platform is needed to connect them with up-and-coming clinicians. Nurse practitioners and others could support clinical trials.
- Sensitization and education opportunities for physicians could help them understand and support clinical trials.
- Read more details about opportunities to improve the clinical trials workforce in Solution Area #3.

Solution Area #2: Legislative and regulatory amendments

Participants discussed legislative and regulatory amendments that could be implemented to improve equitable access to the standard of care provided through cancer trials in Canada. The following discussion took place:

Opportunity to streamline the Health Canada process

- Health Canada does not have a commissioner for clinical trials, as the FDA does.
- Health Canada needs a strong mandate to improve clinical trial regulations, and more timely responses from Health Canada are needed, particularly to facilitate with industry to review rejected studies and improve submissions.
- Clinical trials are an economic opportunity for all levels of government. It was noted that the Ontario government has identified the life sciences sector as a significant economic pillar.
- The challenge of not having a national ethics review board was discussed.
- Legislation on the promotion of clinical trials could be improved.

Biomarkers

- The conversation turned to biomarkers. Biomarker-driven cancer trials often do not include non-actionable biomarkers during standard care, which can add time for additional testing. There is an opportunity to improve biomarker accessibility for people with cancer.
- Earlier biomarker profiling needs to be done across the country.

Clinical trial data

- Publication of trial outcomes, both positive and negative, is inconsistent across organizations. Additionally, information for individuals who screen "failed" is not collected, although this data is important. We should be documenting reasons that people with cancer don't make it to enrollment.
- Self-reporting could help democratize clinical trials, but there is not enough alignment on data collection.
- EMRs are inconsistent in documenting demographic data, and healthcare providers need training to request this information appropriately.

Patient access and awareness

- Transgender populations struggle to access clinical trials, and we need connections with these populations. We need outreach with organizations already connected to specific populations.
- We need education on offering clinical trials as standard care, including complete biomarker testing. Equitable access means everyone has the same conversations with their oncologist at the same time in treatment.
- Lack of data and smaller community sizes are challenges. It was noted that these groups can help facilitate conversations. Self-reporting demographics, such as race and ethnicity, vary by institution but could make it easier for clinicians to identify patients for clinical trials. As for patient-caregiver interactions, trainers should teach how to ask demographic questions sensitively.
- The FDA incorporated diversity into its mandate last year, and Health Canada is working on a similar initiative. Unity Health/Princess Margaret Hospital has an Equity, Diversity and Inclusion initiative, but the implementation varies by institution. Requests for information must be presented in a culturally safe manner.

Decentralized trials

- Decentralized trials, particularly those involving low-risk operations, may necessitate modified regulations.
- Adverse events should be managed in the community.
- A hybrid model could reduce risk for both parties, with telehealth support being more accepted by physicians.
- Satellite sites face logistical and financial challenges, including training, resources and drug supply.

Solution Area #3: Clinical trial workforce and infrastructure optimization

Regarding how to optimize a clinical trial workforce and strengthen clinical trial infrastructure, the following discussion was captured:

Solutions for healthcare workforce planning

- Participants noted that the number of staff working on a specific trial depends on the funding received for that study.
- There should be consistency in role expectations for clinical trials staff.
- Overall, participants felt that there is a healthcare workforce planning crisis, with challenges including, but not limited to, barriers faced by international graduates.
- A clinical trials coordinator or navigator role was identified and discussed. If other similar roles existed, they could potentially bring greater awareness to clinical trials currently underway at different sites.

- As with other health workforce challenges, participants felt there is a need to ensure adequate funding for job creation and compensation for clinical trials. Other countries, such as Spain and Australia, have invested in trial infrastructure and have a more advanced system than Canada.
- Participants discussed the need to invest in engaging local community members to support clinical trials in rural and remote areas.
- Some participants shared that industry partners sometimes pay to fill workforce planning gaps and support the institute's staffing infrastructure.
- The participants discussed how clinical trial investigators sometimes feel discouraged due to inconsistent standards set by Health Canada inspectors, and stated that the current bureaucratic environment does not encourage increasing the workforce for clinical trials. Audits could be simplified to eliminate some of the discrepancies among trial inspectors. World Health Organization guidelines could be used to improve the auditing process.
- An opportunity discussed at the meeting was the development of Quality Improvement Grants, specifically, grants aimed at increasing efficiencies in physicians' clinical programs.

Solutions for technology

- Institutions using outdated or high-security systems experience slow document exchange, which lengthens processes. Some sites still require printed binders of information. Participants noted that this is an opportunity to create change, such as through shared portals.
- Technological solutions, such as AI, are tailored to industry partners, and internal discussions are underway on how to use this technology.

Solution Area #4: Funding incentives

The following discussion about funding incentives was captured:

Global funding modes opportunities

- The group identified Australia and the US as countries with effective global funding models that could serve as examples to be replicated in Canada.
- There is a need to advocate streamlined budgets across multiple sites in Canada by aligning on certain procedures, master contracts and budget negotiations.
- Clinical Trials Ontario is currently leading some of the more innovative streamlined approaches to clinical trials, and their models could be replicated in other parts of the country.

Streamline clinical trials regulations

- Participants shared that contract inconsistencies are an ongoing issue facing the sector, and improvements are needed to improve contract timeliness. An example is Expanded Access Programs, where delays of up to 3 months can result in a patient passing away before the contract is completed.
- Clinical Trials Ontario addresses contract inefficiencies and is a leading example nationwide. Its Universal Agreement for Clinical Trials is a standardized clinical trials agreement developed by Clinical Trials Ontario.[71] It serves as a starting point for clinical trials between institutions and sponsors. By creating the Universal Agreement, Ontario aims to accelerate trial set-up timelines, improve access to clinical trials and support faster delivery of research outcomes and patient treatments.
- Another example given was Nova Scotia Health Authority's approach of having one contract and one budget, which leads to expedited start-up and a centralized approach. This model was highlighted as a great model for outreach.
- It was noted that CCS has a potential role in helping spread awareness about clinical trials and reducing cycle wait times.

Proposed budget solutions

- Some participants suggested creating a provincial rate card to address budget inconsistencies across sites.
- There are currently budget inconsistencies across different sites in a region, with some costs listed by item and others by hour, which leads to inefficiencies and discrepancies in how study budgets are presented across sites.
- Participants noted the challenge of patients' travel expenses and stated there is a role for different levels of government to cover these expenses. Currently, industry partners often cover these costs for people with cancer.

Clinical trial units

Background

This forum was held virtually in February 2025, with Canadian Cancer Clinical Trials Network (3CTN) members and patient partners. The feedback captured below is intended to help inform the overall report and is not attributable to any one site or person.

The path forward: Our proposed solutions

The forum agenda probed for gaps and opportunities to improve the Canadian cancer clinical trials ecosystem in the following areas:

- Standards and best practices
- Legislative and regulatory amendments
- Clinical trial workforce and infrastructure optimization
- Funding incentives

Many of the participants' issues and proposed solutions crossed over topic areas, so responses were merged and organized according to the following themes:

Awareness of cancer clinical trials

- There is a need for system-wide recognition that access to clinical trial options is a best-practice standard of cancer care. A grassroots awareness campaign, supported by government funding, is needed to overcome the negative stigmas associated with clinical trials. It will also help deliver a better understanding of their benefits, increasing receptiveness among the general public. Aligned messaging supported by provincial agencies and other stakeholders would enhance its effectiveness.
- Better education and awareness of clinical trials among the general public, healthcare providers and allied health staff to foster discussions of available trial opportunities throughout a patient's cancer journey. A greater understanding and openness to trial options will lead to improved patient outcomes, better trial performance and realization of study objectives with significant health and economic impacts for Canada.
- We can better leverage and support awareness of existing best practice resources and educational materials available for clinicians, researchers and people with cancer, such as those provided by N2 (Network of Networks) and 3CTN (Canadian Cancer Clinical Trials Network), as well as recent CIHR Clinical Trials Fund investments.

Standardization of cancer clinical trials

- Limiting conventional trials to relatively few sites significantly limits accessibility and results in high direct and indirect costs related to required travel for eligible patients to participate. Clinical trial access should not be limited to national cancer centers.
- The government should establish a standard for access to cancer trials across all provinces and territories to ensure people with cancer have equal opportunities to participate. System-wide, we need to recognize that access to clinical trial options is a best-practice standard of cancer care.
- Clinical trial activation and rapid access to care:
    - Universal adoption of a single, national research ethics review process remains a priority. Reducing repetitive REB reviews will significantly contribute to better efficiencies in clinical trial activation. The evaluation, optimization and scaling of initiatives such as CanReview or REBx are already underway.[72, 73]
    - The adoption of standard research agreement terms and harmonized approaches for data and sample sharing, such as those included in the Governing Data and Samples Sharing Agreement, released by ACT, are expediting the review process.[63] Sharing work and resources and collaborating with initiatives arising from CIHR-CT fund investments and others outside the cancer space can help accelerate improvements in Canada's clinical trials environment.

Patient support and regional inequities in access to cancer trials

- Building on the conversation about access and awareness, some participants cited the financial burden for people with cancer and proposed that added mechanisms are needed to reimburse out-of-pocket expenses for accessing clinical trial centers. At times, the complexity of the process can discourage people with cancer and providers from contending with the impacts of their illnesses. People with cancer can face significant financial and other costs associated with travel and time needed to participate in trials. That can be particularly burdensome for trials that are only outside of a province or territory, where financial costs may reach tens of thousands of dollars and are not covered by provincial or territorial health plans.
- Trial sponsors often reimburse travel costs; however, this is not a standardized practice. Some site institutions cover all patients' costs, but coverage needs to be more consistent and comprehensive.
- Provincial and territorial boundaries should not hinder people with cancer from accessing the best clinical trial options. There are significant inequities in standards of cancer care and trial participation opportunities in Canada. More could be done to address provincial and territorial barriers, which deter enrollment and add to the high cost of trials. Trials that close due to failed accrual have a greater cost for people with cancer and the public, who do not benefit from research results or care offered for enrolled patients. Capturing and quantifying the benefits of improved trial accrual rates would make a solid business case for continued investment.
- In recent years, significant progress has been made in implementing decentralized trial conduct through the Canadian Remote Access Framework for Clinical Trials (CRAFT) approach.[68] Early success requires dedicated investment and collaboration from the public and private sectors to establish decentralized clinical trials as a standard practice, enabling any patient to participate in trial options closer to home, regardless of their location.

Inequity in access to cancer clinical trials

- It's crucial to develop culturally sensitive navigation programs for cancer care. These programs should match people with cancer to appropriate care.
- Canada does not currently collect race data; however, initiatives like 3CTN are starting to standardize the collection of race-based data. This data is essential for identifying inequities in trial access and developing action plans to address them.

Improving funding and infrastructure support for clinical trial sites

- The government could help standardize and ensure adequate funding support and build capacity across provinces for some clinical trial activities. For example, CAR-T studies may have varying levels of provincial support.
- Adequate funding and reimbursement structures are needed for dedicated research personnel and should align with those existing for clinical operations to recognize clinical trial conduct as part of standard care.
- Clinical trial units in Canada often operate on a profit center model, with revenues being minimally required to cover operating costs. The government must understand that existing investments in conducting academic trials are insufficient to cover institutional costs. Sustained public investment that supports Canada's operating capacity for conducting pediatric and adult cancer clinical trials is required.
- Government funding is needed to support the universal adoption of licensed EMRs by healthcare centres and CTMs by research sites. The use of EMR and CTMs solutions is essential for ensuring clinical trial efficiency, capacity and the highest standards of care, but is not yet standard practice across Canada.
- The government needs to acknowledge and commit to filling identified gaps in clinical trial infrastructure and support. There is a pressing need to review outcomes from 3-year investments by CIHR, provincial cancer organizations, sponsors and networks that can inform an aligned, pan-Canadian strategy for creating greater clinical trials capacity, improved efficiencies and system-level supports. An example is the need for complete transparency about reported outcomes of CIHR-CTF investments ending this year, including systemic achievements, persistent gaps and opportunities for those from the cancer trial community to be included as key participants in scaling and sustainability going forward.
- We need to reduce the number of approvals Principal Investigators (PIs) must go through to secure funding for a trial.
- Sites work with multiple sponsors and Clinical Research Organizations (CROs) to conduct cancer clinical trials. This results in having to accommodate multiple data platforms and processes, which can increase the administrative burden of conducting a trial. Support and clarity could be helpful to streamline this process.
- Partnerships between centres, provinces, territories, the private sector and the public sector are essential. Working together, rather than in silos, would make funding more effective and extend its reach.

Partnership opportunities for cancer clinical trials

- We need to embed tissue sharing between industry and academia in patient consent forms. Utilizing master agreements between provinces, territories and institutions could facilitate this process. Patient involvement is crucial for success. Consent to share collected biospecimen samples between entities ensures that samples may be used appropriately to enable, facilitate and accelerate collaborative research.
- There's an opportunity for the government to engage with industry and form partnerships. Those partnerships could help break down silos and provide funding for institutions.
- Industry companies fill gaps and provide funding, and their role should be recognized and integrated.

Clinical research workforce at cancer clinical trial sites

- There is a crisis in the clinical trials workforce across Canada's cancer centre network. Academic salaries cannot compete with industry salaries, leading to perpetual challenges of attrition and retention of trials staff. Identifying and offering incentives to retain staff is crucial to sustaining the capacity and effectiveness of this country's academic cancer research enterprise.
- Standardizing the names of Clinical Research Personnel positions could prevent individuals from being dissuaded from applying and moving between roles and organizations.
- We need more clinical trial navigators in cancer care settings to help people with cancer and their providers access trial opportunities and support those enrolled in a study.
- We also need sustained investments in the core operations of clinical trials. A matched funding support program between the government and institutions could help academic sites recruit and retain workers and better compete with comparable but more lucrative positions offered by industry employers.
- The government can support the recruitment of physicians and scientists by making Canada an attractive place to conduct clinical trials. That would bring additional talent to the country and leverage the diverse population for cancer trials.
- There is currently a heavy reliance on philanthropy to support core staff, which is not sustainable as not all clinical trials are profitable.
- More tuition remission for continued education can make hospitals and academic centres more attractive to talent and help with long-term retention.
- Better systemic alignment of clinical research and trial training programs, such as N2 courses, CIHR CT Fund CTPs, and academic institutions and professional associations, should be a priority for identifying training gaps and reducing duplication.

List of participants

On behalf of the diverse stakeholders and co-chairs who led forums and other efforts to engage people with varied perspectives, the Canadian Cancer Society would like to thank the approximately 140 people and 50 organizations engaged in the development of the Cancer Clinical Trials Action Plan.

Members of the Canadian Cancer Research Alliance: https://www.ccra-acrc.ca/about-us/members

Members of the Canadian Association of Provincial Cancer Agencies: https://capca.ca/about-us/members-and-partners

Approximately 25 members of HealthCare*CAN*'s vice presidents of health research committee participated in an exclusive consultation: https://www.healthcarecan.ca/membership/our-vice-presidents-of-health-research/

In February 2025, 3CTN led a virtual forum of over 30 Clinical Trial Unit patient partners, representing 22 organizations: https://3ctn.ca/for-patients/patient-representative-community/

On November 20, 2024, CCS consulted with volunteer advocates in the Advocacy Constituency Team (ACT) Lead program, and we thank those who provided input at that meeting, as well as those who provided written input: Prisha Adya, Justin Brown, Sharon Dennis, John Fredericks, Paramjot Gogia, Kelly Graham-Miele, and Matthew LaRose.

Trial experts and federal health regulators

Attendees of two-day forum in Ottawa, May 22-23, 2024

Aisha Lofters
Clinician Scientist and Associate Professor, University of Toronto

Alethea Kewayosh
Director, Indigenous Cancer Control Unit, Ontario Health

Amit Oza
Head of Division of Medical Oncology and Hematology, University Health Network

Amy Clark
Patient partner

Andrea Seale
CEO, Canadian Cancer Society

Anthony Fields
Emeritus, University of Alberta (medical oncologist)

Christine Williams
Executive Director, Advancing Childhood Cancer Experiences, Science and Survivorship

Craig Earle
CEO, Canadian Partnership Against Cancer

David K. Lee
Chief Regulatory Officer, Health Canada

Haydn Bechthold
Patient partner

Janet Dancey
Chair, Canadian Cancer Trials Group

Jennifer Cox
Lawyer and Legal Counsel and Manager in Research Contracts, Ottawa Hospital Research Institute

John Mark
Patient partner

Judy Bray
Vice President of Research, Canadian Cancer Society

Kathy Brodeur-Robb
Executive Director, C17 Council

Kathy Soltys
Director, Office of Clinical Trials, Health Canada

Kim Chi
Vice President and Chief Medical Officer, BC Cancer

Kostas Trakas
CEO, Exactis Innovation

Lucie D'Amours
Director General, Consortium de recherche en oncologie clinique du Québec (Q-CROC)

Margot Burnell
President-elect, Canadian Medical Association & Chief of Staff in Saint John area, Horizon Health Network

Mary Gospodarowciz
Radiation Oncologist, Consultant, Princess Margaret Cancer Centre

Megan Bettle
Executive Director for Clinical Trials, Canadian Institutes of Health Research

Michelle Rand
Senior Manager, Indigenous Cancer Care Unit at Ontario Health

Natascha Kozlowski
Executive Director, Ontario Cancer Research Ethics Board

PJ Devereaux
Head, Accelerating Clinical Trials Consortium (ACT); McMaster University

Ravi Ramjeesingh
Medical Oncologist, Nova Scotia Cancer Centre. Medical Director of the Atlantic Cancer Clinical Research Unit (ACCRU)

Rebecca Auer
Research Director and Surgeon-Scientist, Ottawa Hospital Research Institute

Rebecca Deyell
Clinical Investigator, BC Children's Hospital

Rosalyn Juergens
Medical Oncologist & Associate Professor, McMaster University

Scott Gavura
Director of Provincial Drug Reimbursement Programs, Ontario Health

Stephanie Michaud
President and CEO, BioCanRX

Stephen Sundquist
Executive Director, Canadian Cancer Clinical Trials Network

Stuart Edmonds
Executive Vice President of Mission, Research and Advocacy, Canadian Cancer Society

Stuart Peacock
Co-Director, Canadian Centre for Applied Research in Cancer Control (ARCC), BC Cancer, and Simon Fraser University

People with lived and living experience

Patient and caregiver workshop in Toronto, November 13, 2024

Amy Clark
Patient

Antonia Palmer
Caregiver

Bill Richardson
Patient

Bob Taylor
Patient

Camille Leahy
Patient

Carol Gordon
Patient

Catherine Wells
Patient

Don Wood
Caregiver

Erwin Wanderer
Patient

Géraldine Jippé
Patient

Helena Sonea
Director, Advocacy, Canadian Cancer Society

Isabelle Dalcourt
Caregiver

John Mark
Patient

Judy Needham
Patient

Karen Haas
Caregiver

Kathy Smith
Patient, Caregiver

Lisa Mina
Caregiver

Martina Wood
Patient

Munaza Jamil
Caregiver

Ruth Ackerman
Patient

Sally Nystrom
Patient

Stephanie Bazinet
Canadian Cancer Society

Stephen Piazza
Director of Public Engagement, Advocacy, Canadian Cancer Society

Stuart Edmonds
Executive Vice President of Mission, Research and Advocacy, Canadian Cancer Society

Suzanne Bays
Caregiver

Suzanne Wood
Patient

Tracy Torchetti
Vice President, Cancer Information and Policy, Canadian Cancer Society

Life sciences industry

Forum with pharmaceutical industry partners held in Toronto, January 2025

Carle Ryckman
Bristol Myers Squibb

Daniella Viera
AstraZeneca

Fadie Jebtrail
Daiichi Sankyo

Heidi Biagi
Pfizer

Jacqueline Dobson
Innovative Medicines Canada

John Mark
Patient Partner

Josh Silverton
Bayer

Lorraine Hudson
AstraZeneca

Marie-Christine Phan
Pfizer

Michele Caveen
Amgen

Monisha Nundy
Bayer

Munaza Jamil
Patient Partner

Nathalie Dutli
Bristol Myers Squibb

Paulo Covizzi
Amgen

Sarah Douglas
Daiichi Sankyo

Stephanie Hamzo
Johnson and Johnson Innovative Medicine

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