STRATEGIC PLANNING REPORT

A PAN-CANADIAN CLINICAL TRIAL STRATEGY

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Revised January 18, 2018

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Executive Summary

The Canadian Clinical Trials Coordinating Centre (CCTCC) was established in 2014 in response to emerging global challenges to Canada's clinical trial competitiveness. The CCTCC's mission is to improve the Canadian clinical trial landscape by promoting operational efficiencies and advocating for the streamlining of clinical trial processes for industry and clinical researchers. The organization was originally conceived only to fully operationalize the nine recommendations emanating from the 2012 action plan that arose from the National Clinical Trials Summit in 2011. However, the extensive stakeholder consultation conducted in 2017, as well as an awareness of the current environment, have reinforced the continuing need for a pan-Canadian organization such as the CCTCC so that the work to enhance Canada's clinical trial landscape can extend beyond CCTCC's original mandate.

The nine recommendations contained in the Clinical Trials Summit action plan were aimed at overcoming the multiple barriers that had been impeding clinical trials, such as burdensome operational and administrative processes, rising costs, low patient enrollment rates, and the need for review and approval across multiple research ethics boards (REBs), to name a few. Since its inception, the CCTCC has served a three-year mandate to strengthen the Canadian clinical trials environment by promoting Canada as a leading destination for clinical trials globally and through initiatives aimed at introducing operational efficiencies. The accomplishments and progress on the recommendations are highlighted on the CCTCC website and in *The CCTCC 2014–2017 Report to Stakeholders*.

In April 2017, the CCTCC embarked on a two-phase strategic consultation with clinical research stakeholders across Canada. To provide context for the consultation, an environmental scan was conducted that assessed the value of current initiatives and identified trends, threats, and opportunities to inform the strategic planning process. The first phase of the consultation was an online survey, which had two separate purposes. The first was to assess the past performance of the CCTCC and to draw inspiration from past successes and accomplishments. The second was to identify key issues, trends, and opportunities that could help establish a direction for future planning needs. Over 82 percent of the survey respondents agreed that a pan-Canadian organization is needed to meet new challenges and facilitate existing efforts to improve the Canadian clinical trial landscape. The second phase of the strategic consultation consisted of two one-day workshops convened in June and September 2017. The purpose of these workshops was to identify the future objectives for a pan-Canadian clinical trials organization.

The need for a pan-Canadian clinical trials organization has clearly been identified through the strategic planning process, as have some of the key areas on which such an organization should focus. The workshop that was held in September provided the opportunity to focus in greater detail on strategic objectives within five key result areas that a pan-Canadian organization should fulfill, both to respond to the needs of the current clinical trial landscape and to the evolution of clinical trials in Canada over the last five years.

These key result areas and identified strategic objectives were felt by the workshop participants to be important for advancing Canada's competitiveness in attracting clinical trials. It was also felt that achieving these objectives would best be facilitated at a pan-Canadian level. The key result areas identified are:

1. Marketing and promotion of Canada's clinical trial brand
2. Maintain an informing, influencing, and advocating role with regulators, funders, and governments
3. Facilitate the collection and sharing of national data
4. Operational efficiencies
5. Patient engagement in the clinical trial process

It is important to note that work in some of these areas is already being done by existing organizations and groups. In creating a new iteration of a pan-Canadian clinical trials organization, the partners are not seeking to duplicate work that is already being done but, rather, to coordinate and facilitate these efforts at a pan-Canadian level. The future iteration of the CCTCC will focus on ensuring the work that is already being done is recognized and that it is coordinated across provinces and organizations. To ensure that Canada remains relevant on the global clinical trials stage, another important focus of the organization will be to promote initiatives that make Canada a desirable destination for clinical trials. The key result areas discussed at the strategic workshops and the strategic objectives they highlighted will provide a framework to ensure the organization is able to respond to the current needs of the clinical trials field in Canada while allowing it to be innovative and to seek opportunities to be proactive.

Having gathered the perspectives, input, and suggestions on the next chapter or iteration of CCTCC from stakeholders through various consultative methods, the next step will be to consider establishing a new entity that has greater participation from a broad stakeholder group and a new governance structure. The goal of this document is to highlight the feedback received and present a framework for developing a new pan-Canadian organization focused on coordinating efforts in the clinical trial field in Canada to ensure our country's continued relevance on the global stage.

Background

The Need

Canada's participation and leadership in clinical trials has led to many medical discoveries and innovations, attracted world-leading clinicians and researchers, benefited patients and families, and resulted in important benefits for the economy. To ensure that this path toward future success remains uncompromised, certain challenges and operational barriers must be addressed to secure the future human, social, and financial benefits that clinical trials have provided to Canada thus far.

The current trends in Canadian clinical trials show a clear decrease in the number of clinical trials, clinical trial sites, and clinical investigators, and an increase in the impact of issues related to the cost, quality, and time required to conduct clinical trials. Other countries facing the same issues are using the full force of their unique populations, environments, and competitive advantages to enhance their ability to attract global clinical trials. Although their strategies may vary, there is collaboration across geographic regions to maximize the harmonization of processes and the populations available for recruitment into trials. In Canada, nearly every province has invested in strategies for strengthening clinical trials, yet many of these initiatives are not fully coordinated across the country. Establishing and implementing a plan that can harness these efforts, build on the various strengths, and successfully address issues related to cost, quality, and speed, will help secure and expand Canada's position as a leading environment for clinical research.

Context

On September 15, 2011, Canada's Research-Based Pharmaceutical Companies (Rx&D),[1] the Association of Canadian Academic Healthcare Organizations (ACAHO),[2] and the Canadian Institutes of Health Research (CIHR), co-sponsored a day-long, in-person conversation to develop a multi-sector action plan to improve the capacity for attracting clinical trials to Canada. Approximately 130 individuals from government, industry, academic healthcare organizations, universities, and other related organizations attended the event. A full copy of the proceedings can be found on the CCTCC website.

Capturing the important discussions that took place at the 2011 Clinical Trial Summit resulted in a series of recommendations that were circulated for feedback from stakeholders. The final recommendations were released six months after the event. In that time, the steering committee used interpretative license to shape the recommendations into a strategic action plan specific enough to provoke immediate activity toward the overall directions to be pursued. The action plan was intended as a road map to help all stakeholders determine how they might contribute to re-establishing Canada's leadership in clinical trial competitiveness and to address issues related to cost, quality, speed, and relationships as they pertain to clinical trials in Canada. The action plan contained nine recommendations. The first recommendation was to establish a national headquarters to oversee and enable the implementation of the remaining action plan recommendations. In 2014, the CCTCC was established in response to this recommendation.

Accomplishments to Date

Since its inception, the CCTCC has served a three-year mandate to strengthen the Canadian clinical trials environment by promoting Canada as a leading destination for clinical trials globally and by developing initiatives aimed at introducing operational efficiencies. These initiatives derived from the recommendations of the 2012 action plan to attract clinical trials to Canada, and from the more recent needs of the Canadian clinical trials environment. The accomplishments and progress on these recommendations are highlighted on the CCTCC website.

Recommendation	Progress on the Initiatives Set Out to Achieve the Recommendations
1. Establish a national headquarters and resources for implementation and coordination	**The Canadian Clinical Trial Coordinating Centre was established in 2014 to implement the Clinical Trial Summit action plan.** **Advisory Group:** The CCTCC Advisory Group was created to provide direction and input on projects and initiatives. The group is composed of experts in the clinical trial field from across Canada who offer timely advice and support in a fast-changing field.
2. Measure, monitor, manage, and market clinical trial performance improvements	**Clinical Trials Metrics Collection:** This initial set of metrics was collected through IMS Brogan in 2015 and helped inform the development of an investment case (see recommendation 9). A working group has been established to collect a more detailed set of metrics, including operational metrics. This initiative will provide a "pulse check" of Canada's clinical trials performance.
3. Integrate health system and research infrastructure	**Provincial Collaborations:** In November 2015, the CCTCC facilitated the first joint meeting of provincial clinical trials organizations to discuss trends and opportunities within the Canadian clinical trial field. Since then, three additional meetings have been hosted to foster collaboration and project engagement, identify emerging issues and challenges in the clinical trials field, and prevent duplication of efforts.

[1] Now known as Innovative Medicines Canada.
[2] Now known as HealthCare*CAN*.

Recommendation	Progress on the Initiatives Set Out to Achieve the Recommendations
4. Improve efficiencies of ethics review and advance strategic issues (like accreditation)	**Research Ethics Boards Report:** In August 2016, the CCTCC REB Accreditation Working Group released its final recommendation aimed at ensuring Canada's REB competitiveness globally based on the Canadian experience of REB centralization and harmonization. The CCTCC collaborated with Health Canada to release a joint response to the final recommendations in January 2017, outlining next steps for the two organizations. The key final recommendation involves establishing a national strategic leadership forum to champion, shape, and direct the development of research ethics on a pan-Canadian level.
5. Develop a "database of registries" and consider a national patient recruitment strategy	**British Columbia Clinical Research Infrastructure Network Pan-Canadian Survey on Clinical Trial Participation:** This pan-Canadian expansion of the BC Clinical Research Participation Survey was the first survey in Canada that asked patients about their experiences with clinical trials and what motivated their decision to join or not join a trial. This survey is an opportunity to gather insight and information from patients who have agreed to join a trial and those who have declined. In addition to sharing the survey with their stakeholders, the CCTCC provided financial support to translate the survey into French for use across Canada. **Patient Registries to Assist with Recruitment:** The CCTCC's Patient Registries Project is a complement to the Canadian Clinical Trials Asset Map (CCTAM). Criteria were developed for identifying active patient registries able to assist in recruitment efforts for clinical trials. Descriptions and contact information for active patient registries are actively being sought and entered into the CCTAM.
6. Adopt common standard operating procedures, training, and certification	The CCTCC has not initiated any projects to adopt common standard operating procedures and training, as this objective is already being capably addressed by the Network of Networks (N2).
7. Improve and use the common clinical trials contract	**The Model Clinical Trial Agreement:** This is a Canada-wide initiative to standardize clinical trial agreements by providing a standard contract template. The CCTCC partnered with the Common Language Evaluation and Reconciliation (CLEAR) initiative, a project supported by TransCelerate Pharma Inc. that developed language for the five most contentious clauses in contracts.
8. Optimize intellectual property protection policy and SR&ED[3] tax credits	This objective was beyond the scope of the CCTCC; however, the CCTCC has taken every opportunity to advise its stakeholders about the availability of both federal and provincial tax credits.
9. Signalling our interest globally: Open a concierge (storefront) service for investors	**The Canadian Clinical Trials Asset Map:** The CCTAM is a unique, robust, and searchable Web-based database designed to communicate Canada's clinical research strengths to all stakeholders, including clinical trial sponsors. The purpose of the CCTAM is to: showcase Canadian clinical trial assets, better enable sponsors of clinical trials to identify clinical research sites and investigators, and position Canada as an attractive destination for the conduct of clinical trials in the global marketplace. **An Investment Case Entitled "Clinical Trials: The Canadian Advantage":** This investment case is an in-depth, concise narrative that communicates Canada's clinical trial strengths. Canada's advantages as a clinical trial destination in terms of speed, quality, and incentives, as well as its unique characteristics, such as an ethnically varied population with access to universal healthcare, are showcased. The investment case is already being used by many key

[3] Scientific Research and Experimental Development Program.

Recommendation	Progress on the Initiatives Set Out to Achieve the Recommendations
	stakeholders: pharmaceutical companies, provincial governments, Canada's trade commissioners, and federal government agencies such as Global Affairs Canada and Innovation, Science, and Economic Development Canada. **Raising Canada's Profile Internationally:** Over the past four years, CCTCC staff as well as members of working groups and the executive committee have presented at numerous national and international conferences to promote Canada as a destination for clinical trials. These efforts include webinars, conference calls, small-group and conference presentations, panels, and booths, such as the following: 2016: • Canada Talks Pharma (presentation and booth) • BIO International Convention (panel—see details below) • International Congress on Personalized Health Care (booth) • 16th Clinical Trials in Canada Summit (presentations) • Innovative Medicines Canada (IMC) stakeholder conference (booth) 2017: • Pharmaceutical Marketing Club of Quebec (presentation) • Pharmed Canada 2017 meeting (presentation and panel) • Society of Clinical Research Associates (SOCRA) Conference: Conducting Clinical Trials in Canada (presentation) • DIA 2017 (conference presentation and panel chair) • iPolitics Live: Cutting-Edge Care – Growing Clinical Trials in Canada (panellist) • Outsourcing in Clinical Trials Canada 2017 (Panel) • Research on the Rock, Canadian Association of Research Administrators (CARA) and Canadian Association of Research Ethics Boards (CAREB) Atlantic Conference (presentation) **Clinical Trials Panel at BIO 2016:** The CCTCC organized a clinical trials panel at the BIO International Convention in 2016. Senior leaders from industry, government, and healthcare organizations gathered to discuss the strengths of the clinical trials environment and some recently introduced operational efficiencies. The audience, which consisted of representatives from pharmaceutical companies, biotechnology firms, government agencies, and Canada's trade commissions, provided feedback on how Canada can further improve its competitiveness as a destination for clinical trials. **Featured Articles:** Several articles have been written about CCTCC initiatives. These include: • "National asset map for clinical trials launched" by Shannon Lough, *Canadian Medical Association Journal* (June 2015) • Open column by Senator Kelvin Ogilvie, *Hill Times* (June 2015) • "More clinical trials are good for Canada" by Russell Williams (Rx&D), *Huffington Post* (July 2015) • "Canada's leadership in clinical trials: An edge worth protecting" by Belinda Vandersluis (CCTCC), *Policy* (September/October 2015) • "Let's make Canada a go-to destination for clinical trials" by Dr. Chander Sehgal (IMC), *Huffington Post* (December 2016) • "The CCTCC: A unique partnership for promoting Canada as a destination for clinical trials," a two-part article by Dr. Shurjeel Choudhri (Bayer Inc.) and Elena Aminkova (CCTCC), ClinicalTrialsArena.com (May 2017)

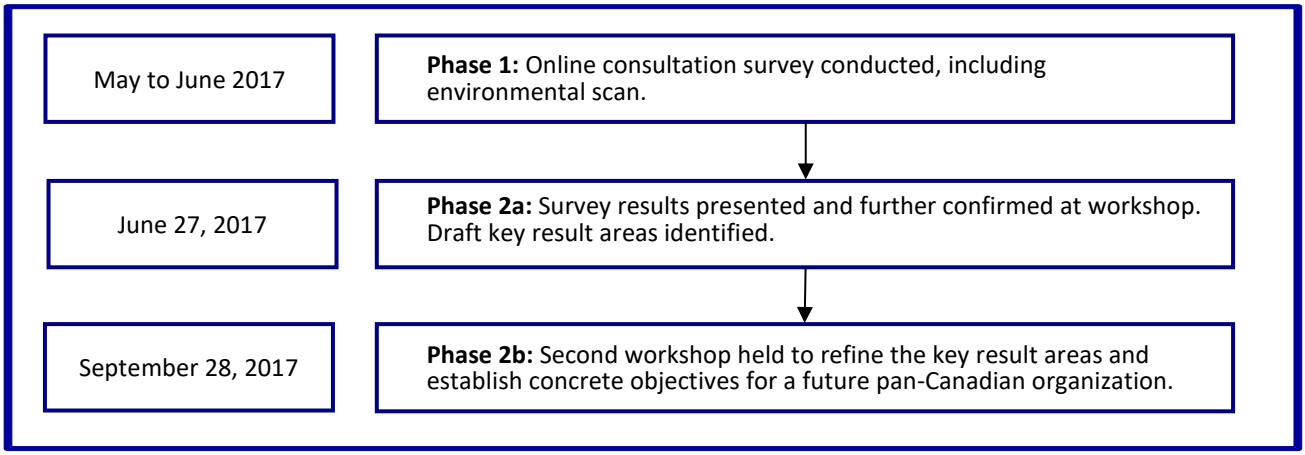
Recommendation	Progress on the Initiatives Set Out to Achieve the Recommendations
10. **New!** Relevant emerging requirements	**The Fair Market Value Project:** To help accelerate clinical trial start-up times, CCTCC launched the Fair Market Value project, which is aimed at addressing issues in the budget negotiation process. This initiative is not directed at controlling cost but at providing tools and resources for a more streamlined and efficient process for finalizing clinical trial budgets, especially taking into account provincial and institutional differences.

As the Canadian clinical trial landscape continues to evolve, the CCTCC is utilizing its funding extension to look boldly into the future. CCTCC's current funding partners (IMC, CIHR, and HealthCare*CAN*) have embarked on a strategic consultation process to determine the role a pan-Canadian clinical trial coordinating organization could play in response to existing environmental conditions. New perspectives, input, and suggestions on the next chapter or iteration of CCTCC have been gathered from stakeholders through various consultative methods; the next steps include considering the establishment of a completely new entity with new governance and funding structures, and with greater participation from a broader stakeholder group.

Methodology

In April 2017, the CCTCC hired the Intersol Group to conduct a two-phase strategic consultation with stakeholders across Canada. Phase one of the consultations was an online survey. The survey was designed to assess the past performance of the CCTCC and perform an environmental scan to identify key issues, trends, and opportunities that could help establish a future direction. Phase two of the strategic consultation included two day-long workshops held in June and September 2017. The purpose of the June workshop was to identify if there was a need for a pan-Canadian clinical trials organization. Based on the positive response from participants, a second workshop was convened in September to focus on the key result areas that would be undertaken by such an organization.

Figure 1: Strategic Planning Timeline



Environmental Scan

The CCTCC strategic planning approach included an environmental scan and two full-day strategic planning workshops. The environmental scan was conducted to assess the value of current CCTCC projects and to identify trends, threats, and opportunities that would inform the strategic planning process.

The Intersol Group used a structured online survey to perform the environmental scan. Every effort was made to reach the key stakeholders who are invested in Canadian clinical trials. This included directly emailing the survey link along with the background information and context in both English and French to over 375 stakeholders across 19 different affiliations and disseminating the survey link to stakeholders within the CCTCC member organizations (IMC, CIHR, and HealthCare*CAN*)

The objectives of the survey were to:

1. Gather stakeholder views on any future role(s) a pan-Canadian clinical trial organization could or should play in promoting Canada as a globally competitive destination for clinical research investment
2. Gather stakeholder views on what pan-Canadian activities would support the shared goals between the current mandate of the CCTCC and other provincial and pan-Canadian organizations involved in clinical trials
3. Identify areas of need that are not currently being addressed.

A total of 165 respondents participated in the survey. The key trends and observations that emerged from the survey were presented to stakeholders and helped accelerate the discussion at the June strategic planning meeting. A full report of the results from the environmental scan is available separately.

Strategic Challenges and Opportunities

Data from the environmental scan identified the following key challenges and opportunities. These elements were taken into consideration when identifying the critical priority areas for the pan-Canadian strategy over the next three to five years.

Challenges

Communications

- Insufficient communication of current clinical trial initiatives and CCTCC's achievements was identified as an important shortcoming. Major impacts included working in silos, duplicating efforts, and lack of awareness.
- Lower patient engagement due to low access and low awareness of ongoing trials.

Efficiencies (harmonization, standardization, policies)

- Inconsistencies and lack of standardization associated with REBs and the research approval process, causing major delays.

- Concern that REB reviewers are not always experts or adequately qualified to review the study protocol.
- Differing privacy regulations between provinces.
- The need for greater harmonization of regulations across provinces.

Recognition and competitiveness of Canada in the international clinical trial landscape

- Increasing fragmentation of the Canadian clinical trials field.
- Risk of losing competitiveness due to initiatives by other countries to attract international clinical trials.

Rising costs

- The rising cost to undertake clinical trials in Canada, coupled with fewer funding opportunities.
- Less attractive incentives and high costs for quality researchers to bring their clinical trials to Canada.

Opportunities

- Leverage existing Canadian strengths to promote and market Canada as an ideal country in which to conduct clinical trials.
- Use existing data to develop materials (e.g., build examples, business cases, anecdotal experiences) that will help promote Canada.
- Promote operational efficiency efforts via centralized REB reviews and streamlined processes (start-up, approval, harmonization of clinical trial agreements).
- Use/engage Canadian and international organizations to facilitate the promotion of clinical trials in Canada.
- Utilize various existing strengths such as capacity, long-term tracking, and quality of researchers.

In summary, the clinical trials landscape in Canada is complex and consists of a diverse set of stakeholders. There is global competition for clinical trials and Canada stands to lose clinical trial investment unless it can effectively leverage its strengths and address areas where it is losing competitiveness. Over 82 percent of the survey respondents agreed that a pan-Canadian organization is needed to meet these challenges and to facilitate existing efforts to improve the Canadian clinical trial landscape.

Proposed Vision

Canada is seen both nationally and internationally as the ideal country in which to do clinical trials, thereby bringing clinical trial investment to Canada, contributing to high-paying STEM (science, technology, engineering, mathematics) jobs, enhancing research innovation, and enhancing patient access to novel treatments.

Key Result Areas and Strategic Objectives

The strategic workshop participants identified the following key result areas and strategic objectives as ones that would be best achieved or facilitated by a pan-Canadian organization.

Key Result Area 1: Marketing and Promotion of Canada's Clinical Trial Brand

Strategic Objectives

1.1 Establish a concierge service to help proponents navigate the Canadian clinical trial landscape and to identify the required systems resources.

1.2 Promote Canada as a preferred and competitive destination for clinical trials.

1.3 Communication and engagement

- 1.3.1 Internally build awareness of ongoing initiatives, capabilities, roles, etc. and build a value chain of services to facilitate collaboration and to limit duplication.
- 1.3.2 Externally communicate the value proposition for clinical research in Canada to bring more trials to Canada.

Key Result Area 2: Maintain an Informing, Influencing, and Advocating Role with Regulators, Funders, and Governments

Strategic Objectives

2.1 Identify opportunities to enhance Canadian federal and provincial clinical trials policies and practices.

- 2.1.1 Align the review processes and times for medical devices and natural health products with those for medicines.

Key Result Area 3: Facilitate the Collection and Sharing of National Data

Strategic Objective

3.1 Identify and leverage data sources to establish a sustainable process for collecting clinical trial metrics in Canada. These should include the most meaningful metrics to highlight Canada's clinical trial performance, to measure and improve operational efficiencies, and to make decisions that guide policy development.

Key Result Area 4: Operational Efficiencies

Strategic Objectives

4.1 Develop a clear understanding of all steps in the clinical research approval process in order to identify inefficiencies and bottlenecks.

4.2 Promote adoption of operational efficiency tools, such as the model clinical trial agreement.

4.3 Continue to identify new operational efficiencies through the sharing of best practices across the different national and provincial research organizations and institutions.

4.4 Develop and implement a single REB review process for Canadian multi-centre trials by implementing the working group report recommendations and by leveraging existing initiatives to streamline and harmonize the REB process.

4.5 Develop a tool to enable efficient, consistent budget negotiations that demonstrate transparent values and processes.

Key Result Area 5: Patient Engagement in the Clinical Trial Process

Strategic Objective

5.1 Facilitate enhancement of patient involvement in clinical trials.

Conclusion

Although Canada remains an important global player in clinical research, its ability to remain competitive is becoming increasingly compromised as other countries continue to implement measures to attract clinical trials. The clinical trials landscape in Canada remains complex and consists of a diverse set of stakeholders. This, combined with increasing global competition for clinical trials, means that Canada stands to lose clinical trial investment unless it can effectively leverage its strengths and address areas where it is losing competitiveness. Canada must begin to take proactive action to secure a strong future for clinical trial investment. Clinical trials currently bring an abundance of financial, social, and human benefits to Canada and threats to these benefits could be devastating.

The economic benefit of clinical trials comes from the successful funding of contracts that stimulate research organizations to grow and develop, creating new employment opportunities. Clinical trials also supply a wealth of research data that offers evidence-based guidance, informed decision-making, effective medical guidelines, and better health outcomes. Well beyond the corporate and social gains, clinical trials are especially important for patients. Trials can offer life-altering treatments, improve quality of life and even extend life. Testing drugs safely is a primary concern and a vital step in preparing for the inevitable healthcare strain that comes with an aging baby-boomer population. A key component of clinical trials is successful patient enrollment. More effective communication strategies are needed to help bridge the awareness gap associated with the low enrollment rate for clinical trials. Apart from communication barriers, addressing the other key result areas identified in the strategic planning sessions, such as lack of inter-provincial harmonization, inadequate REB review processes, and operational inefficiencies, will ensure that medical innovation continues to advance and that patients continue to receive optimal care.

Through the strategic planning process that the CCTCC has undertaken over the last 10 months, there is an evident need for a pan-Canadian organization. Over 82 percent of the survey respondents agreed that a pan-Canadian organization is needed to meet these challenges and to facilitate existing efforts to improve the Canadian clinical trial landscape. This message was echoed in the strategic workshops in June and September.

The CCTCC's achievements over the past four years include advancing the implementation of the Model Clinical Trial Agreement, looking at the REB landscape in Canada, and increasing awareness of initiatives that are being done at a local, provincial, and national level, to name a few. These achievements emphasize the importance of having a pan-Canadian coordination centre. In addition, the changing landscape and opportunities in the clinical trials field are such that if this initiative is not undertaken now, it is likely that Canada will lose further ground.

Academia, government, provincial research organizations, research networks, and industry will remain integral parts of the future of clinical trials. Redefining the future role of the CCTCC will result in a pan-Canadian organization that will help make Canada a successful destination for clinical trial investment.

Appendix A: Proposed Operational Plan

Key Result Area	Strategic Objectives	Initiatives	Expected Results and Deliverables	Responsible Lead and Partners
1. **Marketing and promotion of Canada's clinical trial brand**	1.1 To establish a neutral, centralized concierge process (human and online) to connect potential customers and research sponsors (e.g., pharmaceutical, biotechnology, and medical technology companies; researchers; and foreign and domestic contract research organizations [CROs]) with the right person in other relevant resource organizations to help identify resources and navigate systems.	**Canada Clinical Trials** Establish an office and website to serve as the central source of information about how to do clinical trial research in Canada and that contains resources, knowledge, and guidance to facilitate, expedite, and promote the placement of clinical trials in Canada.	**Expected results:** Increased placement of clinical trials in Canadian centres. Growth in new sponsors and CROs initiating work in Canada for the first time. Growth in revenues as determined by research and development tax credits (as the bellwether). Growth in applications for other site-level data as may be available (per patient budget, target number of subjects). Analytics demonstrating month-over-month increase in website traffic. **Benefits:** Employment growth, tax revenue growth. **Deliverables**: Bringing trials to Canada that would not have otherwise come. Increase in allocation of research sites as a percentage of total sites to Canada.	**Lead:** Newly established concierge who is an employee of Canada Clinical Trials. **Partners:** All stakeholders; Innovation, Science, and Economic Development Canada; Global Affairs Canada; Clinical Trials Ontario investigators; Canadian sponsors; CROs; etc.
	1.2 To promote Canada as a preferred and competitive destination for clinical trials.			
	1.3 Communication and engagement 1.31 **Internally** build awareness of ongoing initiatives, capabilities, roles, etc. and build a value chain of services to facilitate collaboration and to limit duplication. 1.3.2 **Externally** communicate the value proposition for clinical research in Canada to bring more trials to Canada.			

Key Result Area	Strategic Objectives	Initiatives	Expected Results and Deliverables	Responsible Lead and Partners
2. **Maintain an informing, influencing, and advocating role with regulators, funders, and governments**	2.1 To identify opportunities to enhance clinical trials policies and practices. 2.1.1 Align the review processes and times for medical devices and natural health products with those for medicines.	Expedite the approval process for medical devices and natural health products. Identify, characterize, and report on friction areas in a clinical trials approval process for medical devices and natural health products.	**Expected result:** Health Canada would establish a target review timeline for medical devices and natural health products that would be equivalent to that for clinical trials using drugs. In cases where risk is low, the review timelines would be even shorter. High-level outcome would be an increase in business and increased satisfaction with private industry, and an increase in clinical trial activities. **Deliverable:** Expedited review of medical devices and natural health products.	**Leads:** Pan-Canadian organization that has an association with medical device manufacturers and producers of natural health products. **Partners:** Would include industry representatives, patient groups, and also practitioners and groups of practitioners who would prescribe these products.
3. **Facilitate the collection and sharing of national data**	3.1 To identify and leverage sustainable data sources to identify and standardize the most meaningful metrics to measure and improve operational efficiencies, and to use standardized data to make decisions that guide policy development.			
4. **Operational efficiencies**	4.1 To develop an understanding of all steps in the research approval process to identify inefficiencies.	**Site Approval Process** Map out the site approval process and find bottlenecks.	**Expected result:** Understanding of the pieces of the approval process and faster approval time.	**Lead:** TBD. **Partners:** TBD.
	4.2 To promote adoption of the model clinical trial agreement by incorporating broad stakeholder input and sharing best practices.	**Adoption of the Model Clinical Trial Agreement** • Continue the work being done on the Model Clinical Trial Agreement initiative facilitating the feedback to ensure the document is updated/maintained. • Undertake measures to create greater awareness of the document, assessing metrics to determine if it is improving speed (metrics are complicated, as budget impacts speed). Identify groups most likely to benefit and adopt and engage further. Implement a streamlined feedback process that is not labour-intensive.	**Expected result:** Improvement in efficiency and turnaround times. **Deliverable:** Certain percentage of adopters and improvement in timelines.	**Lead:** Pan-Canadian organization. **Partners:** Provinces, institutions, IMC, physicians.
	4.3 Continue to identify new operational efficiencies through the sharing of best practices across the			

Key Result Area	Strategic Objectives	Initiatives	Expected Results and Deliverables	Responsible Lead and Partners
	different national and provincial research organizations and institutions.			
	4.4 To develop and implement a single REB review process for Canadian multi-centre trials.	Continue the work begun on the single REB review process focusing on the recommendations of the working group.		
	4.5 To enable efficient budget negotiations that demonstrate transparent values and processes.			
5. Patient engagement in the clinical trial process	5.1 To facilitate enhancement of patient involvement in clinical trials.	5.1.1 Undertake an environmental scan • Target international initiatives (UK, US, Europe, etc.) with similar culture: What are the impacts from these initiatives on participation rates in clinical trials? • Gather the results of different surveys about patient participation in clinical research (from different organizations, associations, etc.): What are the concerns and positive aspects identified by these surveys? • Gather metrics about the participation of patients in clinical trials in different provinces: Do some provinces perform better than others? 5.1.2 Conduct a survey about participation in clinical trials from the patient's perspective (from British Columbia). 5.1.3 Undertake an awareness campaign or awareness day. 5.1.4 Host a workshop • For discussion: Host a workshop: patient engagement in protocol design for clinical trial (patient's perspective)	**Expected results**: A clear understanding of best practices and who is doing what, which can help in planning activities at the national, provincial, and institutional level.	