Determining Canada's needs for a pan-Canadian Clinical Trials Organization

FINAL REPORT

STRATEGIC PLANNING WORKSHOP

JUNE 28, 2017 TORONTO, ON.

PREPARED BY:

Intersol

Purpose of this Document

The Canadian Clinical Trials Coordinating Centre (CCTCC) organized a one-day strategic planning workshop on June 28, 2017 in Toronto.

The objective of the workshop was to identify Canada's needs for a pan-Canadian Clinical Trials Organization.

What follows here is a written report that includes some background information, the strategic planning approach that was used and the results of the 1-day workshop such as identified key result areas and strategic objectives. The strategic objectives are to be used to define the next iteration of the Canadian Clinical Trials Coordinating Centre.

Table of Contents

Background and Context

Past to Present

In 2011, a Clinical Trials Summit was held to improve the clinical trial (CT) landscape in an attempt to counter the decline in CT investment that Canada was experiencing. The results and feedback from the Summit produced a 2012 Action Plan containing three goals and nine recommendations. The very first recommendation of the Action Plan was to establish headquarters and resources dedicated to inter-provincial clinical trial improvement activities. In response, the Canadian Clinical Trial Coordinating Centre (CCTCC) was established in 2014 to promote Canada as a desired destination for CT investment. The CCTCC has since served a three-year mandate that aimed to strengthen clinical trials environment for Canadians and carry out several initiatives contributing to the evolution of clinical trials in Canada. Funding for the CCTCC has reached its final year and the time has come to re-evaluate the future role of the organization to determine the next steps. The current funding partners of CCTCC (IMC, CIHR and HealthCare*CAN*) are open to perspectives and advice of stakeholders regarding what the next chapter or iteration of CCTCC should be – this openness includes the willingness to consider establishment of a new entity with a new governance and funding structure with greater participation of key stakeholders.

Bringing Government, Industry and Health Care Institutions Together

The CCTCC is the first of its kind to effectively bring together government, industry and health care institutions. It represents a unique collaboration between three funding organizations:

- Canadian Institutes of Health Research (CIHR) - ***Government***
- Innovative Medicines Canada (IMC, formerly known as Rx&D) - ***Industry***
- HealthCare*CAN* –***Health Care Institutions***

One of CCTCC's important committees is its Executive Committee*, made up of senior representatives from each of the funding partner organizations.

Name	Role	Funding Organization
Michelle Peel	Acting Director General, Science, Knowledge Translation & Ethics	CIHR Representative
Shurjeel Choudhri	Senior Vice President & Head, Medical and Scientific Affairs	IMC Representative/Executive Committee Chair
Duncan Stewart	Executive Vice-President, Research	HealthCare*CAN* Representative
Currently Vacant	-	Chair of the Advisory Committee

**Executive Committee as of June 28, 2017*

The Executive Committee of the CCTCC is responsible for overseeing all steps of the strategic planning process.

Overview

In April 2017, the CCTCC embarked on a two-phase strategic consultation with stakeholders across Canada. The first phase of the consultation was an online survey. The survey had two separate purposes, the first was to assess the past performance of the CCTCC and to draw inspiration from past successes and accomplishments and the second was to identify key issues, trends and opportunities that could help establish a direction for future planning needs. The second phase of the strategic consultation was a one-day meeting held in June 2017. The purpose of the workshop was to identify Canada's needs for a pan-Canadian Clinical Trials Organization, though it was clarified that if the need for a pan Canadian organization was identified, it was not presumed that the CCTCC would fill this role. The workshop agenda can be found in Appendix A.

Participants

Approximately 30 key stakeholders and delegates were invited to attend the workshop. Stakeholders were strategically selected in order to bring a diverse array of opinions and knowledge to maximize strategic input. A list of workshop attendees can be found in Appendix B.

Facilitation Team

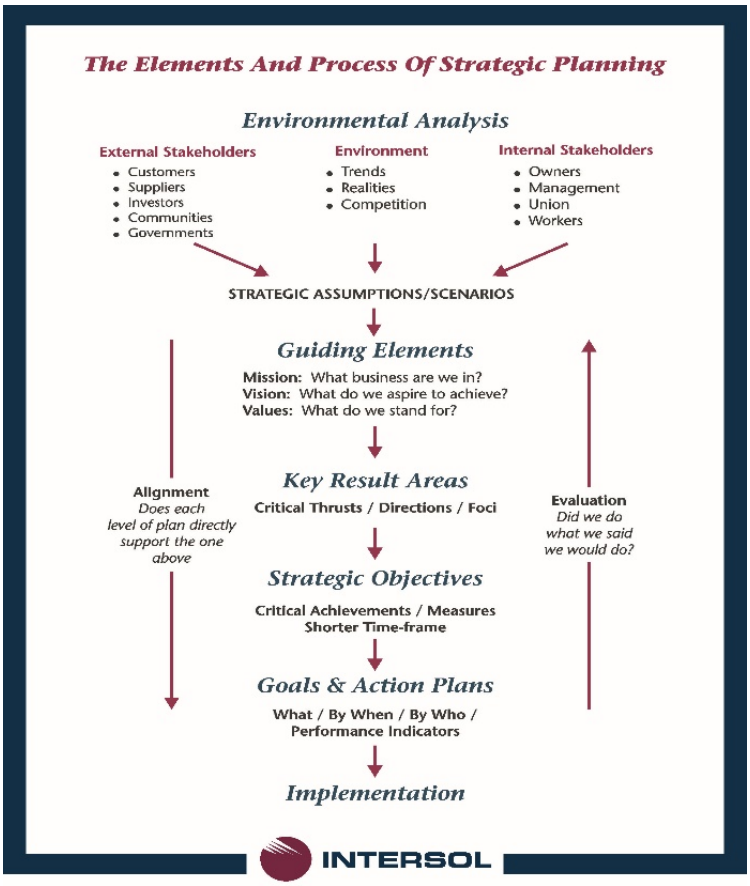
Marc Valois and Sue Perron of the Intersol Group assisted the CCTCC by providing services to develop and conduct and analyze the online pre-engagement survey as well as to design and facilitate the strategic consultation meeting.

Strategic Planning Approach

At its core, strategic planning is about choices – choices that orient an organization's decisions, actions and resources toward achieving a vision of success that is shared by all. There are numerous, sometimes conflicting definitions of strategic planning, the steps that should be followed, and the time horizon to consider.

Intersol's Strategic Planning Process

The approach used for the development of the strategic planning workshop is based on a five-phase process that was adjusted to the unique circumstances of the broad and diverse range of stakeholders invited. The strategy creation and development process is fundamentally a strategic thinking process where each phase raises questions for which executives and stakeholders engage in a dialogue formulating broad direction at each step of the way.



Environmental Scan

Developing a strategic plan requires a look into an organization's environment in order to extract trends, realities and challenges. A valid environmental scan provides insight into the threats and opportunities that need to be considered in contrast with strengths and weaknesses. Data from the environmental scan was collected using an online survey tool called "Survey Monkey" to efficiently enable meaningful participation across multiple networks, in a short amount of time.

During the planning phase, the Intersol team met with the executive team and the staff of the CCTCC to collect additional and relevant information for the development of the survey. Intersol then worked with the CCTCC to select the participants and design invitations with appropriate background information packages.

The objectives of the survey were to:

1. Gather stakeholder views on any future role(s) a pan-Canadian Clinical Trial (CT) 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; and
3. Identify areas of need that are not currently being addressed.

The survey was launched on May 19th, 2017 and closed June 9th, 2017 which gave participants three weeks to respond. Key trends and observations that emerged from survey results were used to assist and accelerate the discussion at the strategic planning meeting. The survey was circulated to over 375 representatives spanning across 19 different affiliations and resulted in 165 responses. Relevant trends were assembled and presented to stakeholders at the strategic planning meeting. A full report of the results from the environmental scan is provided separately. (An organizational representation of survey respondents can be found in Appendix D).

Strategic Opportunities and Challenges

The analysis of survey results revealed that there is not enough communication of current clinical trial initiatives and respondents fear this could result in duplicated efforts. Survey respondents identified several other key challenges related to the clinical trials environment in Canada including the following key messages:

- Approval timelines are too long for contracts and REB approvals, causing delays.
- Clinical trials in Canada are not well recognized.
- There is a lack of harmonization of regulations across provinces.
- There is no standardized process for REB reviews.
- There is a rising cost to running clinical trials in Canada in addition to less funding opportunities.
- Canada has an increasing competitive disadvantage with respect to other emerging markets, competition between provinces and less attractive incentives for quality researchers.
- There are ethics complexities and inefficiencies such as the need for multiple approvals for the same trial at various sites.
- Privacy regulations may differ between provinces.
- There is lower patient engagement due to low access and low awareness of ongoing trials.

A full report of the survey results is provided separately.

Looking to the Future

A Strategic Planning Workshop was held on June 28th, 2017 in Toronto to identify Canada's needs for a pan-Canadian Clinical Trials Organization. The workshop began with a summary of the survey results which highlighted trends and focus areas. Following a discussion of the survey results, participants were invited to engage in an exercise to envision a preferred future for the clinical trials environment in Canada. In this light, focusing on the key challenges and opportunities identified in the previous discussion, participants were asked to identify important outcomes to be achieved by June 28th, 2020 and beyond.

A total of 48 responses were recorded, each representing an outcome (provided in Appendix E) that participants deemed critical to improving the clinical trials environment in Canada

Based on feedback and direction from participants at the workshop, each outcome was sorted into one of the following four categories:

Category #1: Can best be done at a pan-Canadian level

Category #2: Would benefit from pan-Canadian facilitation

Category #3: Falls within the provincial domain

Category #4: Is already managed elsewhere

Once categorization was complete, it was noted that Category #2 was significantly larger than the other three categories, suggesting that a **pan-Canadian facilitation approach** (in contrast to the current coordination approach) was the most promising direction.

Key Result Areas

From the identified outcomes, the following Key Result Areas (KRAs) were identified (listed here in no particular order).

KEY RESULT AREA 1: CONCIERGE

Objectives:

- Communication and engagement (internal and external)
- Promotion
- System efficiencies

KEY RESULT AREA 2: SINGLE UNIFIED VOICE WITH REGULATORS AND GOVERNMENTS

Objectives:

- Cooperatively advocate for shorter review times and increased government investments in Clinical Research

KEY RESULT AREA 3: NATIONAL DATA

Objectives:

- Metrics/benchmarking
- Inputs and outputs

KEY RESULT AREA 4: OPERATION EFFICIENCIES

Objectives:

- Contracts and budgets
- Research Ethics Board (REB) harmonization
- Sharing best practices

Desired Objectives

The following information presents the KRAs, along with statements of desired objectives relative to each KRA. These objectives define the desired end state the strategy proposes to achieve for each KRA. In addition to the objectives, a series of initial steps have been listed to help begin the process.

KEY RESULT AREA 1: MARKETING AND PROMOTION OF CANADA'S CLINICAL TRIALS BRAND

Objective: Concierge

Establish a concierge to help proponents navigate the Canadian clinical trials systems resources.

Ideas to achieve the objective

- Establish a network and platform to identify a key point of contact
- Educate concierges to act as experts to guide foreign and domestic interest

Objective: Promote

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

Strategic Initiatives

- Engage marketing experts

Objective: Communication and Engagement

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

Ideas to achieve the objective

- Send a newsletter of major outcomes
- Hold regular board meetings that provide an opportunity for knowledge exchange
- Develop an innovative communication strategy

KEY RESULT AREA 2: SINGLE UNIFIED VOICE WITH REGULATORS AND GOVERNMENTS

Objective

Cooperatively advocate for shorter review times for medicines, medical devices, natural health products in clinical trials and increased government investments in clinical research and clinical trial infrastructure. Increase patient access to novel medical devices, drugs and cellular therapies that challenge the current system while maintaining data protection and intellectual property protection.

Ideas to achieve the objective

Put in place a government "navigator" to assist and guide through the Canadian processes, pathways for getting clinical trials authorized and getting drugs approved.

KEY RESULT AREA 3: NATIONAL DATA

Objective

Identify and leverage sustainable data sources to identify and standardize the most meaningful metrics to measure and improve operational efficiencies.

Ideas to achieve the objective

- Communicate a data-driven value proposition to promote Canada as a preferred destination for clinical research

KEY RESULT AREA 4: OPERATIONAL EFFICIENCIES

Objective: Model Clinical Trial Agreement

Improve operational efficiencies by establishing a clinical trial agreement model that is universally used by stakeholders across Canada.

Ideas to achieve the objective

- Work with IMC to support sponsor adoption (including advocating with global)
- Work with HealthCareCAN, provincial CT organizations, provincial medical associations (to reach community based physicians)
- Develop metric framework, collect metrics and demonstrate time lines for studies where model CTA is used
- Identify and communicate to stakeholders who accept the mCTA

Objective: Research and Ethics Board Harmonization

Develop a single REB review process for Canadian multi-centre trials.

Ideas to achieve the objective

- Gather provincial organizations that are currently in the process of supporting single REB review within the province
- Identify barriers to harmonization

Objective: Sharing of Best Practices

Enhance recruitment efficiencies by assessing current recruitment activity and identifying best practices and gaps that could be addressed at a national level.

Ideas to achieve the objective

- Environmental scan of current activity in recruitment

Objective: **Contracts and Budgets**

Enable efficient budget negotiations that demonstrate transparent values and processes**.**

Ideas to achieve the objective

- Support the Fair Market Value working group

Next Steps

Some critical next steps were identified at the end of the meeting. These are listed in the table below.

Action Item	Lead	Timeline
Prepare the draft report of the workshop	Intersol Group Ltd	July 4-14th
Review and revise the report and apply feedback	Executive Committee and CCTCC	July 14- 31st
Circulate to key stakeholders for review and input of the key result areas	Executive Committee and CCTCC	August 2017
Compile feedback, apply changes and communicate at Fall workshop	TBD	September 2017

Appendix A – Meeting Agenda

AGENDA

Strategic Planning Workshop

Organized by the Canadian Clinical Trials Coordinating Centre

June 28, 2017
Toronto Marriott Bloor Yorkville Hotel, 90 Bloor St E, Toronto
9:00 – 16:00

Purpose: To identify Canada's needs for a pan-Canadian Clinical Trials Organization

8:30 **Continental Breakfast/Coffee**

9:00 **Start-Up**

Opening Comments ***(Executive Committee)***

a. Welcome
b. Why we're here
c. What we hope to accomplish

Review of Agenda and Approach *Marc Valois, Intersol*

Participant Introductions

9:30 **Environmental Scan**

a. Presentation of results of survey *Sue Perron, Intersol*
b. Discussion to complete the scan
c. Identification of strategic assumptions and implications for pan-Canadian CT organization

10:30 **"E-mail" Break**

15 minutes

10:45 **Preferred Future:**

List of short statements that describe what we have accomplished that will enable us to celebrate success.

12:00 **Working Lunch**
Categorization of statements

13:00 **Identification of Key Result Areas (KRA)**
The goals that are specific to the pan-Canadian organization

a. For each KRA, identification of the outcomes to be achieved by the end of the planning period.

14:30 **"E-mail" Break**
15-minute break

14:45 **Debrief and Finalization of Discussion**

15:30 **Summary of Next Steps**

16:00 **Wrap-Up**
Closing Remarks

Appendix B – Participant's List

A glossary of terms for all listed acronyms follows this table.

	Participant Name	Participant Title	Organization Name	Email
CONFIRMED				
1	Susan Marlin	President & CEO	CTO	Susan.Marlin@ctontario.ca
2	Frank Naus	Vice President, Research	Hamilton Health Sciences Corporation	naus@hhsc.ca
3	Carole Legare	Director, Office of Clinical Trials	Health Canada	carole.legare@hc-sc.gc.ca
4	Agnes Klein	Director, Centre for the Evaluation of Radiopharmaceuticals and Bio-therapeutic Products in the Biologics and Genetic Therapies Directorate	Health Canada	Agnes.V.Klein@hc-sc.gc.ca
5	Heather Harris	Director	Can-SOLVE CKD Network	hharris@cansolveckd.ca
6	Patty Moore	VP Operations, Allphase Clinical Research Inc.	CRO (Delegate for Jeff Smith)	pmoore@allphaseclinical.com
7	John Akitt	President	Trial Management Group Inc. (Delegate for Jack Corman)	john@tmginvestigators.com
8	Karri Venn	President	Research LMC	karri.venn@LMC.ca
9	Karen Arts	President, Executive Director	N2, 3CTN	Karen.Arts@oicr.on.ca
10	Jacquelyn Legere	Regulatory Compliance Manager Research Services	New Brunswick Health Research Foundation (Delegate for Dr. Bruno Battistini)	Jacquelyn.Legere@HorizonNB.ca
11	Fran Paradiso-Hardy	Senior Direct, Medical Affairs	Astellas	Fran.Paradiso-Hardy@astellas.com
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15	Benoit Leduc	Senior Economist, Emerging Technologies	ISED	Benoit.leduc@canada.ca

16	Diane De Melo	Senior Policy Advisor	Ministry of Economic Development and Growth/Ministry of Research,Innovation and Science,ON (Delegate for Dr. Reza Moridi)	dianedemelo@ontario.ca
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19	Ms. Laura Accettola	Global Study Management	Roche	laura.accettola@roche.com
20	Barbara Nicholls	Director, Clinical Development - Respiratory, ID, CVMet	GSK (Delegate for Dr. Amyn Sayani)	Barbara.R.Nicholls@gsk.com
21	Tammy Mah-Fraser	Director, Platform Operations, SPOR and Provincial Platforms	Alberta Innovates – Health Solutions	tammy.mah-fraser@albertainnovates.ca
22	Rob McMaster	Vice-President Research, VCH and Executive Director, VCHRI	VCHRI	robert.mcmaster@vch.ca
23	Cheryl Litchfield	Manager, Grants and Contracts	Lawson Health Research Institute	Cheryl.Litchfield@LawsonResearch.com
24	Shannon Rugalski	Director of Programs	Research Manitoba (Delegate for Ms. Christina Weiss)	shannon.rogalski@researchmb.ca
25	Salah Mahmoud	Director Clinical Trials platform	Manitoba SPOR Unit	Salah.Mahmud@umanitoba.ca
26	Pamela Degendorfer	Program Director, Cancer Clinical Research Unit	UHN Princess Margaret (Delegate for Dr. Bradley Wouters)	Pamela.degendorfer@uhn.ca
27	Amit Oza	Chief, Division of Medical Oncology and Hematology	UHN Princess Margaret (Delegate for Dr. Bradley Wouters)	Amit.oza@uhn.ca
CCTCC Funders & Staff				
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3	Shurjeel Choudhri	Senior Vice President & Head, Medical and Scientific Affairs	IMC Representative	shurjeel.choudhri@bayer.com
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5	Declan Hamill	Vice President, Legal, Regulatory and Policy	IMC Representative	dhamill@imc-mc.ca

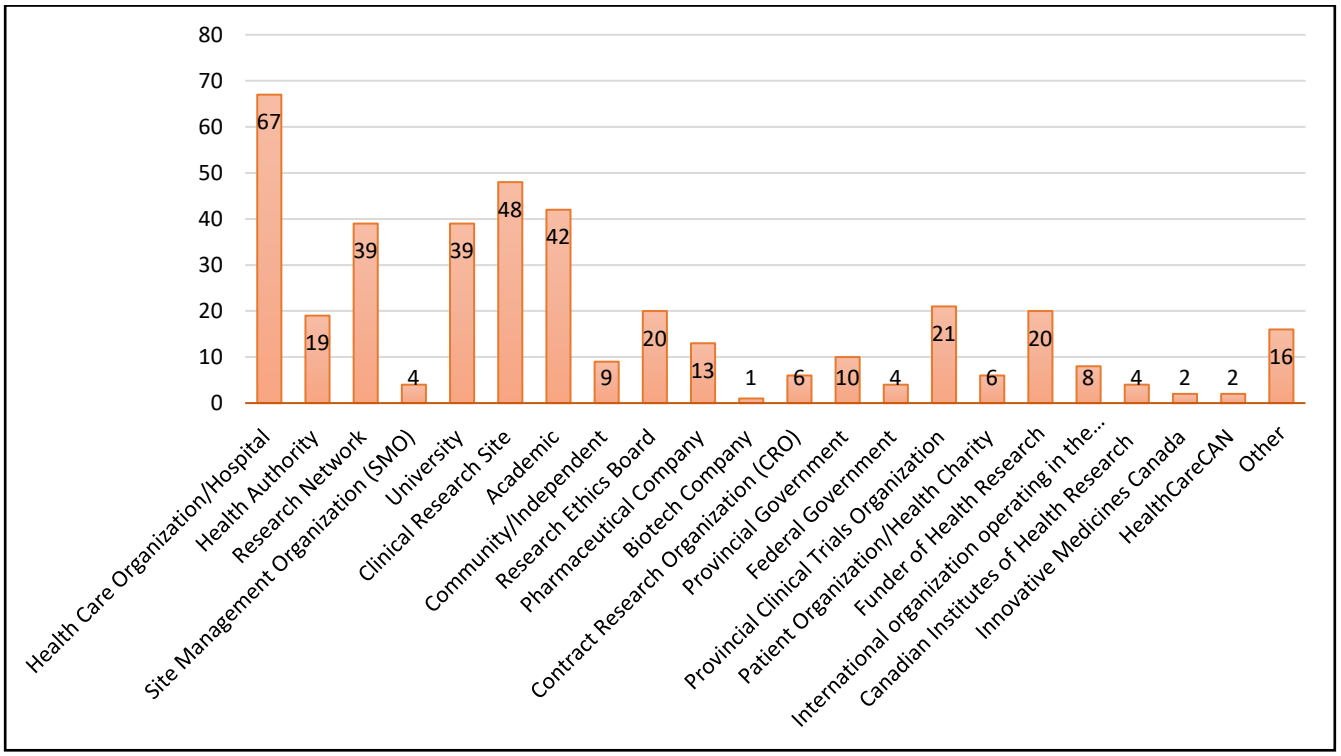
6	Duncan Stewart	Executive Vice-President, Research	HealthCare*CAN* Representative	djstewart@ohri.ca
7	Colleen Galasso	Policy Analyst, Research and Innovation	HealthCare*CAN* Representative	cgalasso@healthcarecan.ca
8	Elena Aminkova	Interim Director of Project Facilitation	CCTCC Staff	eaminkova@cctcc.ca
9	Kathryn Nijssen	Initiatives Manager	CCTCC Staff	knijssen@cctcc.ca
Declined				
1	Bruno Battistini (Identified delegate)	President & Chief Executive Officer and Scientific Director	New Brunswick Health Research Foundation	bruno.battistini@nbhrf.com
2	Dan Chiche (Will send delegate)	Vice-President, Clinical Development and Medical Affairs	NEOMED Institute/CQDM	dchiceh@kompasmedical.com dchiche@neomed.ca
3	Bruce Mazer (No delegate)	Interim Executive Director & Chief Scientific Officer	MUHC	bruce.mazer@mcgill.ca
4	Lawrence Korngut (Out of the country)	Assistant Professor of Neurology, Neuromuscular Clinic	University of Calgary	Lawrence.Korngut@albertahealthservices.ca korngut@gmail.com
5	Michael Salter (Identified delegate)	Chief of Research, Research Institute	SickKids	Michael.salter@sickkids.ca
6	Reza Moridi (Will likely send PA)	Minister of Research, Innovation and Science	Ontario Government	reza.moridi@ontario.ca
7	Amyn Sayani (Identified delegate)	Interim Director, Health Economics and Outcomes Research & Specialty Pharmaceuticals	GSK/ IMC Medical Advisory	Amyn.P.Sayani@gsk.com
8	Kim Ryel (Identified delegate)	Deputy Director, Life Sciences	Global Affairs Canada	Kim.Ryel@international.gc.ca
9	Jeff Smith (Identified delegate)	President	Allphase Clinical Research Inc.	jsmith@allphaseclinical.com
Did not attend/Not available at the last minute				
1	Corrine Guenette	Director, Life Science Industries Directorate	Innovation, Science and Economic Development Canada	corinne.guenette@canada.ca
2	Allan Edwards	Embed Officer of GAC in Medec	Global Affairs Canada (Delegate for Mr. Kim Ryel)	Allan.Edwards@international.gc.ca

3	Thérèse Gagnon-Kugler (Sent delegate)	CEO	Q-CROC QC	tgagnon-kugler@qroc.ca
4	Bradley Wouters (Sent delegates)	Executive Vice-President, Science & Research	UHN	bwouters@uhnresearch.ca
5	Jack Corman (Sent delegate)	President	CAICRC	jhcorman@icloud.com
6	Louise Binder	Chair	Canadian Treatment Action Council	louise.binder@rogers.com

Appendix C – Glossary of Terms

3CTN – Canadian Cancer Clinical Trials Network
AIHS – Alberta Innovates – Health Solutions
BD – Business Development
CAICR - Canadian Association of Independent Clinical Research
CCTCC – Canadian Clinical Trials Coordinating Centre
CIHR – Canadian Institutes of Health Research
CQDM – Consortium Québécois sur la Découverte du Médicament (Quebec Consortium for Drug Discovery)
CRA – Clinical Research Associate
CRO – Contract Research Organization
CT – Clinical Trial
EU – European Union
GAC – Global Affairs Canada
GSK – GlaxoSmithKline
HCCC – Health Charities Coalition of Canada
HCPs – Health Care Practitioners
HHSC – Hamilton Health Sciences Corporation
IMC – Innovative Medicines Canada
IRB – Institution Review Board
ISED – Innovation, Science, and Economic Development Canada
KRAs – Key Result Areas
mCTA – model Clinical Trial Agreement
MUHC – McGill University Health Centre
N2 – Network of Networks
NBHRF – New Brunswick Health Research Foundation
Q-CROC - Quebec - Clinical Research Organization in Cancer
REB – Research Ethics Boards
R&D – Research & Development
SOP – Standard Operating Practice
SR&ED - Scientific Research and Experimental Development
UHN – University Health Network
US – United States
VCHRI – Vancouver Coastal Health Research Institute

Appendix D – Organizational Representation



Details are provided under a separate cover.

Appendix E – Outcomes

Imagine - It is now June 28th, 2020 and we have returned to this place to celebrate what we've achieved since our meeting in June 2017. Write short statements that describe what we have accomplished that will enable us to celebrate success.

Data from Facilitate Pro platform

- Single IRB is very important
- People working in clinical research are aware of all the various stakeholders involved in clinical trials and their various initiatives.
- Meaningful metrics have been identified and tracked
- Broadly used and accepted PanCanadian mCTA
- Inventory of Missions/Objectives from the various organizations - understand who does what to limit duplication and to join forces to support common goal
- Harmonization of efforts with regards to REB
- Establishment of fair market value from the perspective of multiple stakeholders
- - Having digital infrastructure (powerful software) that automatically updates a national patient registry (which exists in the US).
- Where are the funding opportunities - internal & external to Canada? Create inventory.
- Recruitment support - centralizing recruitment to support areas that are key to Canadian success? Who are the key patient advocacy groups we could pair up with to build out these opportunities?
- Establishment of Transparency when it comes to costs for clinical trials
- adoption of the model clinical trial agreement by all stakeholders
- Coordinated Federal and Provincial support for doing clinical trials
- Bring the outside perspective for stakeholders
- Tracking timing of ethics approval, contract negotiation, areas of delay
- Look at data which give accurate metrics of where we've been and where we are going
- - Coordinate the various provincial initiatives that impact CT, and inform provinces of other initiatives regarding model contracts/review process and standards.
- Ensuring provincial engagement and sharing of best practices - facilitating communication across the country
- Match the speed, quality and efficiency of other jurisdictions, particularly the US and EU (with supporting indicators/metrics)
- facilitation and communication among the key stakeholders - create understanding of what is happening in the clinical trial landscape
- Regular PanCanadian summits to bring the stakeholders together.
- Engage internationally on best practices in clinical research and bring them back to Canada

- Clear articulation of the roles and responsibilities of the different stakeholders and educating each other on our strengths, opportunities, capabilities and values.
- Faster Health Canada approvals for clinical trials involving devices.
- Improved patient awareness of the value of clinical trials
- Address the language barriers and cultural differences to ensure that ethnic communities are actively participating in clinical trials
- BD - more therapeutic focused conferences vs. general conferences to build awareness of centers of excellence
- what resources exist to share?
- By 2030, will have good measure of the cost of doing R&D in Canada compared to other jurisdictions, and why other SR&ED models are more supportive of doing CTs.
- Develop guidelines for organizations to have common points of reference for SOP, budgets etc.
- Establish reliable metrics regarding how Canada is competing on the international stage and with regards to speed and harmonization
- By 2020 we will have a cross-provincial board so the provinces can make decisions on how to implement common standards, and share best practices (e.g. the master CTA cannot be used in all provinces due to legal differences). Provincial board would need authority to advise provincial health authority on what aspects need to be mandatory or voluntary.
- Facilitation role:
- policy development, liaison with regulators (federal, ?provincial)
    - same language on high level policy issues as much as possible
- bringing the provincial groups together - share best practices
    - build on existing connections and networks
    - what can we leverage
    - avoid duplication
    - work with the existing groups
    - opportunity to grow the sector
- information from international perspective
- The development of one REB for Canada
- Incentivize research by involving current and next generations of researchers to become involved in CT, at national level. Gaining funding support to achieve this goal.
- Recognition by the Federal and Provincial Ministries of Health that clinical trials are part of the healthcare continuum
- Hospitals/academic institutions - dedicated support staff to support/streamline studies i.e. pharmacy/MRI technicians. How could hospitals support community efforts in drawing more attention to access to studies in Canada. i.e. community site access to hospital services
- CRA training support - to improve more qualified/eligible candidates to better support CRO's. Lack of workforce is complaint to better support Canadian trials.
- Support clear / updated Health Canada inspection guidelines - coming soon! Will support more transparent and clear inspections.

- Improving skill set/workforce - jobs of the future - what will it look like? What are the hot trends/areas that Canada can compete
- Business Development Plan - support of marketing/communications
- Continued face to face collaboration between Industry, Academia and CIHR
- Effective communication to and engagement of all Canadian stakeholders
- Health Canada - consider ensuring device/natural health products follow same 30-day timelines for study approvals.
- An organization that can serve as a concierge for international parties/organizations who want to do clinical research in Canada. This organization will also promote Canada as an ideal place to do clinical trials
- Connect CTs across Canada (with the proper digital infrastructure) so that all patient populations can be involved in national (provide opportunity for patients in all provinces to join CTs)
- Aligning Health Canada with the innovation cycles for drugs and medical devices.
- why Canada - create resource that clearly explains Health Canada submission process i.e. how does it compare to IND/ITA
- Improve awareness of HCPs and especially general practitioners of the clinical trial opportunities and the outcomes from clinical trials

first, we need to take a step back and determine if there is a need or not for a pan-Canadian organization

- not clear if we have a consensus or not on the need
- it would be good to hear from different stakeholders about different initiatives happening across the country
- facilitation role rather than coordination
- Health Canada - regulation - one source of communication and contact
- One website as a point source for information including outputs from clinical trials - could be posted on Health Canada website
- regulators see benefits in dealing with one agency instead of multiple agencies on high level policy issues
- What is the future - what is possible - avoid a big laundry list - don't get into the weeds
- Challenge for CCTCC in implementing programs
- provincial units, provincial SPORs, implementation considerations are local but policy considerations could be developed through a pan \Canadian organization
- Facilitation role:
- policy development, liaison with regulators (federal, ?provincial)
- same language on high level policy issues as much as possible
- bringing the provincial groups together - share best practices
- build on existing connections and networks
- what can we leverage
- avoid duplication
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