ACCOMPLISHMENTS REPORT
OF THE CANADIAN CLINICAL TRIALS COORDINATING CENTRE
DRAFT, FEB. 17, 2016

When reviewing, please keep in mind the following:

- Review for content. Once the content is finalized, there will be graphic design solution developed for the report.
- The intention of the report is not to provide comprehensive information about each project but to provide overall introduction and to refer to the website for more information. Therefore, this is not a briefing- style report but a communication and marketing-oriented material.

The primary mode of distribution will be electronic due to printing cost vs. usability considerations.

Title: About the CCTCC

Established in 2014, the Canadian Clinical Trials Coordinating Centre (CCTCC) is a unique collaboration between government - Canadian Institutes of Health Research (CIHR), industry - Innovative Medicines Canada, and healthcare institutions - HealthCareCAN.

In the past three years, the CCTCC has worked on initiatives stemming from an Action Plan aimed at strengthening and improving the clinical trials environment in Canada and some more recent needs of Canadian clinical trials' field.

Title 1 of 5: Catalyzing and facilitating pan-Canadian collaborations for clinical trials

Subtitle 1.1: Provincial collaborations

✓ *Recommendation #1 of the Action Plan - Establish implementation and coordination headquarters and resources:*

CCTCC facilitated the first joint meeting of provincial clinical trial organizations in 2015 to discuss trends and opportunities within the Canadian Clinical Trials environment. . Participants included Clinical Trials Ontario, Montreal InVivo, BCCRIN, Clinical Trails New Brunswick, Nova Scotia Health Authority, Alberta Innovates Health Solutions and other provincial and national bodies. The three to date meetings organized by the CCTCC, aimed to foster collaboration, engagement for projects, help identify emerging issues and challenges in the Canadian clinical Trails field, and to prevent duplication of effort in Canada.

Link for more info

Subtitle 1.2: Advisory group

- ✓ *Consistent with Recommendation #1 of the Action Plan - Establish implementation and coordination headquarters and resources:*

The CCTCC Advisory Group provides our Executive Committee with input about action plans and recommendations. The group is composed of about a dozen experts from across Canada who offer timely advice and support in our fast-changing field. [Add hyperlink: http://www.cctcc.ca/index.cfm/about/national-advisory-group/]

Link for more info

Subtitle 1.3: The first pan-Canadian survey about clinical trial participation

- ✓ *Consistent with Recommendation #5 of the Action Plan - Develop a 'database of registries' & consider a national patient recruitment strategy*

The pan-Canadian expansion of the British Columbia Clinical Infrastructure Network (BCCRIN)'s BC Clinical Trials Participation Survey has been one of the key collaboration accomplishments of the CCTCC. This is the first survey of this nature in Canada. Until recently, there's been little effort to learn from patients about their experiences with clinical trials and what motivates their decision to join a trial or decline it. This patient participation survey is a unique opportunity to gather invaluable insight and information from both patients who agreed to join a trial and those who declined. Funding from the CCTCC and outreach efforts by provincial clinical trial organizations and N2 has catalyzed the survey's reach. [Link: http://www.cctcc.ca/index.cfm/news/the-canadian-clinical-research-participation-survey-and-survey-distribution/] The results will inform Canadian clinical trial practices about patient communication, engagement, outreach and study protocol design [www.bccrin.ca/survey]

Title 2 of 5: Helping speed up clinical trials start-up times

Subtitle 2.1: A world-class database – the CCTAM

- ✓ *Recommendation #9 of the Action Plan - Signaling our interest globally - open a concierge (storefront) service for investors*

In June 2015, the CCTCC launched the Canadian Clinical Trials Asset Map (www.cctam.ca), the first, searchable database in Canada that showcases our country's clinical trials capabilities. This bilingual, free database communicates Canada's clinical-

research strengths to industries, governments, academics, investigators and clinical-research sites around the world. Benefits include:

- marketing opportunities for clinical-research organizations and investigators;
- showcasing talent and expertise among Canadian research institutions who conduct cutting-edge clinical trials;
- efficient placement of clinical trial and reduced clinical trial start-up times; and
- the facilitation of investigator initiated research

Since June 2015, the site has seen a 50 per cent increase in assets (to over 1100 entries). Our tracking of usage indicates that the search function is the most popular part of the site, with an average of 50 per cent return visitors. Main users of the site include the pharmaceutical industry and federal government agencies, including Canada's trade commissioners in Europe and the U.S., Global Affairs Canada and Innovation Science Economic Development Canada.

CCTAM's success has been enhanced by a number of partnerships with organization across the country.

The new functionality of the database will continue to be motivated by feedback provided by the users of the CCTAM - sponsors, sites and investigators alike. The CCTCC is committed to maintaining, growing and developing the CCTAM, so it continues to meet the ever evolving needs of the Clinical Trial community.
Contact us to access or to be added to the CCTAM.
Link for more info
Link to contact us

Subtitle 2.2: A patient registry to assist with recruitment

- ✓ *Recommendation #5 of the Action Plan - Develop a 'database of registries' & consider a national patient recruitment strategy*

The CCTCC's Patient Registries Project is complimentary to the CCTAM. A criteria for identifying active patient registries able to assist in clinical trial recruitment efforts was developed. Descriptions and contact information for the patient registries being actively sought and imputed into the CCTAM.

Link for more info
Link to contact us

Subtitle 2.3: The ultimate model

- ✓ Recommendation #7 of the Action Plan - Improve and use the common clinical trials contract:

Aimed for a launch in 2017, the model Clinical Trial Agreement (mCTA) is a Canada-wide initiative to standardize clinical trial agreements by providing a standard contract

template. The CCTCC have partnered with the CLEAR Initiative, a Transcelerate supported project, which is developing language for the 5 most contentious clauses in contracts[1].. The goals are of the CTA project are reduce contract negotiation times, accelerate clinical trial initiation times and reduce study start-up costs. The overarching motivation is to increase Canada's global competitiveness in attracting clinical trials.

Subtitle 2.4: The value in the Fair Market Value project

- New priority

Following its mandate to help speed-up clinical trials start-up times, CCTCC has a launched the FMV initiative, aimed at addressing another critical bottleneck in the initiation of clinical trials in Canada - the budget negotiation process. Representatives from both the sponsors and sites have come together to develop more effective and efficient budget negotiation processes.

Link for more info

Title 3 of 5: Promoting Canada as the destination for clinical trials

Subtitle 3.1: Advantages and advances

- *New priority,* also consistent with *Recommendation #9 of the Action Plan - Signaling our interest globally - open a concierge (storefront) service for investors*

What do you get when you combine speed, quality and incentives? An investment case titled "Clinical Trials: The Canadian Advantage," 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 ethnically varied population with access to universal health care, are showcased. The case is already being used by many key stakeholders – pharmaceutical companies, provincial governments, Canada's trade commissioners and federal government agencies, such as Global Affairs Canada and Innovation Science Economic Development Canada. To access, please visit: [link to: www.cctcc.ca/index.cfm/our-initiatives/investment-case-canada-the-clinical-trials-advantage/]

Subtitle 3.2: Raising Canada's profile

- *New priority,* also consistent with *Recommendation #9 of the Action Plan - Signaling our interest globally - open a concierge (storefront) service for investors*

[1] Transcelerate is a non-profit organization made up of representatives from the global offices of pharmaceutical companies

The CCTCC organized a clinical trials panel at the BIO International Convention in 2016. Senior leaders from industry, government, and health care organizations gathered to discuss the strengths of the clinical trials environment and 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. Link for more info

Title 4 of 5: Checking our pulse rate

Subtitle 4.1: How's Canada performing?

- ✓ *Recommendation #2 of the Action Plan - Measure, monitor, manage and market CT performance improvements*

Due later in 2017, the CCTCC has started gathering clinical trials metrics ; an initiative that will provide a pulse check of Canada's clinical trials performance. Metrics that could be vital for the future of clinical trials in Canada include:
quantitative metrics provinding a reference for the numbers of new trials, newly opened sites and patient recruitement
operational metrics such as timelines for contract and budgets negotiations, research ethics boards),
qualitative metrics attesting to the high quality of clincial trial data in Canada, and investment metrics - especially total investment in clinical trials in Canada thus, providing a snapshot of how Canada compares to its global competitors.
[Link to website)

Subtitle 4.2: Research Ethics Boards Report

- ✓ *Recommendation #4 of the Action Plan - Improve efficiencies of ethics reviews & advance strategic issues (like accreditation)*

The CCTCC Research Ethics Board (REB) Accreditation Working Group released its final recommendations based on the Canadian experience of REB centralization and harmonization (link to the website)
The CCTCC collaborated with Health Canada to issue a joint response to the final recommendations, outlining further steps that the two organizations can take. 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 basis. This recommendation underpins all other recommendations, which include developing a registry of REBs that review clinical trials and pursuing regulatory options for standards equivalency of REBs.

In 2017, CCTCC and Health Canada will work on approaches to establishing the national leadership forum.

Title 5 of 5: The future of the CCTCC

The CCTC is utilizing its funding extension for 2017 to look boldly into the future. A strategic consultation and related activities are being planned to determine the role that CCTCC will play in Canada.