

CCTCC Executive Committee – Meeting Minutes
Thursday, December 8, 2016 10:30 am – 12:00 pm EST
Toll Free: 1 (877) 394-5901 | Participant PIN Code: 3950626#

Executive Committee	Dr. Duncan Stewart (Chair) Dr. Jane Aubin Dr. Shurjeel Choudhri Dr. Lawrence Korngut
Support Staff	Ms. Claire Samuelson Ms. Nancy Mason MacLellan Dr. Chander Sehgal Dr. Tina Saryeddine
Guests	Ms. Connie Côté
Staff	Ms. Elena Aminkova Ms. Kathryn Nijssen (Secretariat)

1. Welcome and approval of agenda and minutes from November 2016 meetings.

- 1.1 A correction to the meeting minutes from November 16, 2016 was requested. Under Section 5 – CCTCC Status Updates – Funding: Dr. Stewart and Ms. Samuelson indicated that their understanding was that HealthCareCAN would renew funding at a similar level for 2017. The amount has not yet been specified.

2. Action Items:

- 2.1 FDA Form 1572: The drafting of the letter is taking longer than anticipated. IMC hopes to have it circulated for internal review before the end of the year. The issue being encountered is one of alignment among the members. An update will be provided in the New Year.
- 2.2 TransCelerate: A meeting is being scheduled in early next year.
- 2.3 CCTCC Projects:
- mCTA: The slides and reviewed documents will be going to the core WG shortly for their feedback
 - REB Final Recommendations (FRs): This item is on the agenda for discussion. Peter Monette will be joining the meeting at 11:10 am to provide an update from Health Canada’s perspective on the FRs. With regards to FRs V & VI, Dr. Aubin has followed up with the appropriate individuals. For FR V, Susan Zimmerman indicated that their opinion was that there is no need for a study. The topic has been looked into extensively and is well understood. The provinces have already done considerable work to harmonize the REB review process. There are also agreements in place, often online. While there are some IT issues to be worked out, the recommendation would be to continue promoting the work that is being done and additional collaboration where possible. For FR VI, there is currently a network of people working on cross institution projects focused on the study of real and perceived barriers. The work is just getting underway, and it is therefore recommended that the CCTCC continue to follow its development but in terms of the official response merely acknowledge what is

being done. Dr. Aubin will look up and provide the information regarding the group that is doing the work.

- 2.4 CCTCC Renewal Activities: This is an agenda item that will be discussed late in the meeting.
- News Release: The Support Staff met on December 7 and provided feedback regarding the structure and content of the Press release. The executive suggested that the press release should not focus on the funding amount or that is currently only for a year. Rather, it should highlight what has been done using quotes from key stakeholders. The funding should be referenced simply by saying something to the effect of: CCTCC funding has been renewed and the organization is continuing to work to enhance the Clinical Trial Landscape in Canada. The CCTCC is looking forward to involving stakeholders in strategic discussions in the coming year. Ms. Aminkova will re-draft the press release based on feedback received and will circulate the new version for review by the executive.
- 2.5 The Terms of Reference for CCTCC Presidents' Committee will be available early next year.
- 2.6 Re-purposing of CCTAM Communications WG: This is an agenda item and will be discussed later in the meeting.

3. Financial Update:

The financial statement from October 2016 is available. There are still some expenses from November to be recorded and the statement will be available when that is complete.

4. HCCC Update:

The HCCC Governing Council met on November 24, 2016 and on reviewing the information provided, motioned to continue hosting the CCTCC. Ms. Côté has spoken with the Canadian Cancer Society who have agreed to continue offering office space. A contract to extend the lease are currently being negotiated. More information regarding other matters related to HCCC will be provided during discussion of those action items.

5. CCTCC Status Update

5.1 Operational Items:

- CCTCC Executive Committee Chair as of Jan, 2017: The Chair of the Executive committee changes over in January. Dr. Aubin is next in the rotation and has accepted the appointment.
- CCTCC Advisory Group for 2017: No meetings of the Advisory group have been scheduled for 2017 to date. Dr. Korngut informed the executive that he would be stepping down as the Chair of the Advisory Group but would remain involved with the committee and the activities of the CCTCC.
- CCTCC Executive Committee Meetings for 2017: Meetings for 2017 will be booked shortly.
- CCTCC Administrative and Project Assistant position: This position is currently filled through a staffing agency. Ms. Aminkova proposed with the extended CCTCC mandate to hire directly through the organization instead. The cost will not increase. Ms. Côté and Ms. Aminkova have discussed this plan and agree that it is feasible through a fixed term contract and will work on the details. The Executive Committee approved moving forward with the plan. Ms. Nijssen will begin her contract with the CCTCC on January 9, 2017.
- Christmas Closure: Ms. Aminkova will be leaving for Bulgaria on December 14, 2016 but will be connected via e-mail and skype. Ms. Nijssen will be in the office until December 23, 2016, returning on January 9, 2017.

- Opportunity to organize a CT panel: The CCTCC was recently approached by the Conference Board of Canada about organizing a CT panel at the upcoming Healthy Canada Conference 2017. The theme for this year's conference is access to affordable medicines. As a session sponsor, a cost of \$7500, CCTCC would receive 2 full conference registrations, exhibit space and the ability to organize a concurrent session. Organizing a session includes picking the topic and selecting the panelists. This could line up with the discussion of organizing a high impact event similar to the one at Bio 2016. The Advisory Group agreed that this could be a good opportunity to showcase what the CCTCC does and there does not appear to be any potential downsides, if the budget permits. Ms. Aminkova has reviewed the budget and assured the executive that it can be accommodated. In addition, selecting the topic ensures that it aligns with the CCTCC objectives. Final decision is to be made after a very careful budgetary review.

5.2 **CCTCC Projects:**

- mCTA: As discussed in action items, the mCTA is moving forward and the latest version along with a report will shortly be sent to the core WG for feedback and then for stakeholder distribution.
- REB Final Recommendations: Health Canada (HC) worked with 4 directors – 2 in Clinical Trial Review, in Drugs and Biologics, 1 in Regulatory Affairs and 1 in Strategic Policy to develop their feedback. These individuals have a very good understanding of what needs to be done in terms of research ethics boards and were very supportive from the beginning. HC had two goals going into the process; the first to gain an understanding of what was happening in the Canadian REB area and second, to look at how regulations affect REBs. HC is now looking at working towards making the information from REBs more publicly available and promoting best practices for REBs through regulatory changes or through targeted guidelines and directives. These objectives are addressed in the REB WG's FRs. There was a deviation in the FRs from the Senate Report due to the development of provincial harmonization efforts. That investment means that a national system will not be feasible at this time. Next steps, for HC, can be to support of FRs II & III. HC already collects information on the REB but are looking at improving the form and make it publicly available. Looking to gain information on the number and diversity of REB that are functioning in the country. FR III is about acknowledging the standards that currently exist rather than creating a single standard. FR VII is the final one which HC is focusing on. It simply states that this is merely the start of the conversation and nothing has been completely resolved. There needs to be a mechanism to resolve these issues going forward and to develop communication among the provincial systems, to move toward a mutual acceptance of REB reviews amongst the provinces. This is the ultimate goal and can only be achieved through collaboration with CCTCC and other stakeholders.
- The CCTCC is proposing repurposing the CCTAM Communications WG to create a CCTCC Communications WG. The CCTAM no longer has the need for a dedicated communications group but the CCTCC does. This was discussed at the previous Executive Committee meeting and a list of the prior members was requested. Communication specialists from the funding organizations will be added. Andrew McColgan, who was on the previous committee, from CIHR is available to join the committee and Kathryn Shaver has been nominated from IMC. It was also recommended that ISED, GAC and the Provincial Organizations be contacted regarding nominating members. Katie Porter from Hamilton Health Services was also put forward and will be contacted.

- The Provincial Clinical Trial Organizations meeting took place on November 21, 2016. There were some representatives missing - from ON and QC. The meetings went well and positive feedback was received from the participants. It was perhaps the best meeting of this series so far.

5.3 **Request for a Letter of Support (LOS) by CTO in application for a CIHR grant:**

- CTO has approached the CCTCC requesting a LOS in their application for a CIHR SPOR Grant which they will be using to study patient/public engagement in clinical trial design. By providing the LOS, CCTCC would be agreeing to help distribute both the survey and the results. The grant application is due on December 11 and they have therefore requested a response by the end of the day on December 9.
- The Executive Committee was generally supportive of the application. However, in order to maintain transparency and because it is a CIHR matching grant it was noted that it is important to emphasize it is CCTCC as an entity offering the support. Although there are no funds being requested, it is important to ensure that the LOS is not being counted as matching support towards the grant. Ms. Aminkova will verify this before completing the letter. Due to a conflict of interest, because of her position within the CIHR, Dr. Aubin, recused herself from the final decision regarding the LOS. The remaining members of the Executive Committee will submit their response via e-mail by the end of the day on Friday, provided that CCTCC's in-kind contribution is not counted as matching funds towards the grant.

5.4 **CCTCC extension:**

- Plan of projects and activities: The list of operational priorities for 2017 has been reviewed and revamped where required based on current available resources. The major focus is the continuation of projects that have already been started. The one project that has not yet started is the collection of sustainable CT metrics which is anticipated to start in early 2017. This project is key because it provides the CCTCC with a method of demonstrating the impact of its work and a gauge of Canada's CT performance. The Provincial Clinical Trials Organizations' meetings are expected to continue as they are important for the development of collaboration amongst key stakeholders in the provinces.
- Draft Budget: The draft budget has been provided. The major difference between this draft and previous versions is the moving of the salary for the admin resource from contracted support to salaries and benefits as discussed previously.

5.5 **CCTCC renewal activities:**

- Plans for renewal activities, including the renewal survey and mini-summit, are currently being discussed worked on with the Support Staff.

6. **In Camera Session:**

The in-camera session took place following the meeting.

Action items - CCTCC October Executive Committee Meeting

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#	Details	Responsible	Status/Deadline
1.	FDA form 1572 - draft a letter that provides guidance to Canadian companies of what can be done if asked to sign the FDA Form 1572	IMC MAT	Anticipated in early 2017
2.	TransCelerate – book a meeting between TransCelerate’s management team and the CCTCC’s Exec. Cmt.	Exec. Cmt.	In Progress
3.	<p><u>CCTCC projects:</u></p> <p>mCTA:</p> <ul style="list-style-type: none"> Updated report re the mCTA survey consultations and open houses with pharmaceutical companies mCTA engagement from big sites (i.e. UHN) <p>REB Final Recommendations (FRs):</p> <ul style="list-style-type: none"> Share widely the FRs and SHRER report Public response to FRs Update sections on FRs V & VI based on information provided by Dr. Aubin Send Updates to Peter Monette Identification of group working on FRs VI Approval of updated REB FRs CCTCC Response 	<p>CCTCC</p> <p>CCTCC & Dr. Stewart</p> <p>CCTCC CCTCC and HC</p> <p>CCTCC</p> <p>CCTCC Dr. Aubin Exec. Comm. via e-mail</p>	<p>Due mid-November, 2016</p> <p>In progress</p> <p>In Progress</p> <p>Exec Cmt call package for Dec 8, 2016</p>
4.	<p><u>CCTCC Renewal Activities:</u></p> <ul style="list-style-type: none"> Names of hospitals, VPRs for the mini-summit/survey Accomplishments report with budget and communication strategy Draft the Renewal Survey with feedback from the support staff Draft budget (to be also distributed to the President’s committee) 	<p>HealthCareCAN</p> <p>CCTCC/Support Staff</p> <p>CCTCC/Support Staff</p> <p>Ms. Aminkova</p>	<p>Exec Cmt call Package for Dec 8, 2016</p> <p>In Progress</p> <p>In Progress</p>

#	Details	Responsible	Status/Deadline
	<ul style="list-style-type: none"> Update News Release based on feedback provided by Support Staff and Executive Committee and send for further feedback Provide Feedback on updated draft News Release Send message to Advisory Committee regarding funding renewal 	<p>Ms. Aminkova</p> <p>Exec. Comm. & Support Staff</p> <p>Ms. Aminkova</p>	
5.	Draft Terms of Reference (TOR) for CCTCC Presidents' Cmt – to be sent to the Executive for feedback/review	Ms. Aminkova	In Progress – Anticipate in January 2017
6.	Repurpose CCTAM's Comm WG into CCTCC Comms WG with representation from each funding organizations' communication specialist <ul style="list-style-type: none"> Additional Recommended Representatives: <ul style="list-style-type: none"> Katie Porter, HHS ISED Foreign Affairs Provincial Organizations CQDM (after January) 	CCTCC – to follow up with individuals and organizations recommended by Exec.	
7.	CTO Request for Letter of Support <ul style="list-style-type: none"> Ensure that CTO is not counting LOS as in kind contribution towards matching grant If there is no conflict, complete and Send letter of support 	Ms. Aminkova	By December 9, 2016
8.	CCTCC Operational Priorities for 2017 <ul style="list-style-type: none"> Recreate Operational Priorities document as a table, including additional information regarding what key stakeholders could be involved with/take the lead on different projects. 	CCTCC	Before strategic discussion to take place in January
9.	Book Executive Meetings for 2017 <ul style="list-style-type: none"> First meeting mid-January 	CCTCC to coordinate	
10.	Send Christmas and Vacation details to executive Committee	Ms. Aminkova	By December 14, 2016
11.	Healthy Canada Conference 2017 <ul style="list-style-type: none"> Contact Conference Organizers to indicate the CCTCC is interested in Sponsoring and hosting a concurrent session. 	CCTCC	