Clinical Trials BC
British Columbia Academic Health Science Network

CLINICAL TRIALS BC (CTBC)

ADVISORY COUNCIL MEETING MINUTES

Tuesday, November 26, 2019
2:00 to 5:00 pm

Attendees:	Rob McMaster, Chair Cindy Trytten Robert Olsen Tania Bubela Soren Gantt Scott Garrison	Melanie Reid Steven Reynolds Wendy Hurlburt Kendall Ho Stephania Manusha
Ex-Officio:	Alison Orth	Terri Fleming Jean Smart
Regrets:	Margaret Macdonald Gavin Stuart Geoff Payne Stirling Bryan	
Recording Secretary:	Sarah Hanif	
Guest:	Korin Yunker Marc Saunders Olga Arsovska	

1. Call to order/Roll Call

1.1 The Chair welcomed all members to the meeting of the Clinical Trials BC Advisory Council (AC) and thanked everyone who joined in person and by Zoom.

2. Approval of agenda

2.1 The agenda was approved as presented.

3. Review and approval of previous minutes

3.1 July 30, 2019 minutes were approved and motioned by Tania Bubela

3.2 A. Orth proposed that minutes be posted on the CTBC website to meet with Terms of Reference guidelines to make them publicly available.

Council agreed going forward, minutes will be posted on the CTBC website on the 'CTBC Advisory Council' page as soon as feasible (ideally within two weeks). Agreement and approval of the minutes will be communicated via email.

4. Member Changes / Introductions

4.1 Catalina Lopez-Correa, Chief Scientific Officer from Genome, BC has moved back to Columbia to be COO of a biotech company called Ruta N Medeelin.

4.2 Wendy Hurlburt, President and CEO of LifeSciences BC has joined the Advisory Council as a new member.

Action: Aim to identify a new member to the AC from Indigenous Health/First Nations. Alison will meet with Harmony Johnson in January 2020 to explore this further. Chair would like to have a new member on-board by the next meeting in February 2020.

5. Review and Approval of Terms of Reference

5.1 Attachment: ToR dated 11 November 2019
5.2 Motion to approve Terms of Reference.

Proposed Additions

1. The Chair may continue to hold a meeting without quorum; however, quorum will be required to ratify any business. Online or electronic votes will be acceptable.
2. Travel expenses will be reimbursed by Clinical Trials BC when Advisory Council members are requested to attend in person meetings.

Additions 1 and 2 were acceptable to the council.

A question was raised as to whether the AC will have access to the policies that are referenced in item three in the TOR?

A. Orth advised AHSN is working on a Confidentiality Agreement for the organization. The privacy policy and COI policies are still under development. When these are available, they will be shared with the AC.

This topic will be tabled for the next meeting in February. ToR not approved at this time.

6. Clinical Trials BC – Updates and Action

6.1 Attachments:

- *CTBC Operations Report to AC Nov 18, 2019*
- *CTBC Newsletter Oct 29, 2019*

6.2 **Operations/Stakeholder Relations**

A. Orth presented a summary report of CTBC activities over the past few months and a brief verbal update.

Question around the new job board. A. Orth confirmed that only jobs related specifically to clinical trials or clinical research are eligible. It was explained that the new job board has replaced the Clinical Research Professionals of BC's job board, as they could no longer support it.

W. Hurlburt mentioned LSBC will be having an event on January 18th where institutions can come together and profile what a career looks like in their particular sector, with the option to recruit if they have opening positions at that time. As well as this, there will be advertisement of potential funding programs. CTBC will be hosting a booth at the event, as will CHEOS. If the event is of value, LSBC would consider hosting similar events in other regions such as Vancouver Island, Northern and the Interior.

A. Orth advised that there has been a lot of work through ACRP and their Workforce Innovation Committee, which CTBC is a member of, around promoting awareness of clinical research as a profession. CTBC is exploring offering more education sessions and A. Orth will be giving a talk in December at BC Children's Hospital around continuing education and certification.

A Orth mentioned cases of undergraduate students reaching out with queries about how they could get access to a clinical research site as they are interested in clinical trials and advised they don't really know where to start.

Action: W. Hurlburt to send group more details about the event, and it would be great if the group could promote it.

Action: T. Bubela will put W. Hurlburt in touch with co-op coordinators/Health Canada who can assist with the event.

C. Trytten mentioned that as we move into the realm of quality and regulatory compliance, it will be even more challenging to find experienced or qualified personnel with expertise in those areas to support institutions and sites with clinical trial activity.

6.3 **Regulatory/Quality Update**

J. Smart discussed the following:

- *Refer to the CTBC newsletter Oct 29th for more details*

- ICH (International Council on Harmonization) meeting held in Singapore – November 2019
- Quality risk management will be updated which is a big focus area due to it being a required component under good clinical practices.
- Pediatric extrapolation – progress has been made on the E11A draft Technical document. Thanks to Soren Gantt and BCCHRI for their input and the Pediatric Standing committee at ICH.
- BC Level – There has been a lot of inspection activity with a focus on qualified investigator-initiated studies. A lot of CTBC's Reg and Quality Officer's time has been spent helping sites prepare for this.

J. Smart can provide a full report upon request

- Quality
    - Still conducting a large number of Quality Management System training and program development throughout the province.
    - Most recently with Interior Health who are moving into the implementation stage, Island Health, Children's & Women's, UBC centres.
    - Main challenges have been around resources, continuity of resources and compliancy.

- CTBC Conference 2020 (June 17th and 18th)

    Day 1 (17th) – speakers

    - Keynote speaker will be Allan Hacksaw from UK College of London, Professor of Epidemiology and Medical Statistics.
    - Innovative Designs to Accommodate New Therapies
    - Diverse Populations
    - Regulatory Modernization - New Approaches
    - Leadership
    - Reception

    Day 2 (18th) – breakout sessions

    - Table Topics Forum – Advisory Council
    - Research Team Development Forum – meeting December
    - Pragmatic Trials Forum
    - New Investigator Training

    Action: Guidance requested from council members for 'Innovative Designs to Accommodate New Therapies' and 'Table Topics for the Advisory Council'

- If council members are not speaking, they will be asked to moderate or introduce somebody

Thursday 18th – plan for council members to have a breakfast meeting to review old business items and then go into table topics.

7. Clinical Trial Management System (CTMS)

7.1 Provincial Initiative – Overview & Discussion – Presented by Guest Korin Yunker

Korin Yunker is the Provincial Project Manager (based in Kelowna) for the CTMS Initiative that we are supporting across the province currently. She was seconded to BC AHSN within the CTBC operating unit in September 2018 from BC Cancer, PHSA.

It was explained that the CTMS will be very beneficial for auditing purposes and compliancy due to the ease of tracking and managing clinical trials within the system.

There was discussion around quantification of support that may be required for individual groups to adapt the system to an individual trial and how much training will be needed on an ongoing basis, as well as the costs involved in these processes.

7.1.1 Attachment: Slide Presentation

8. Communication of Clinical Trial Results Provincial Working Group

8.1 A. Orth explained that during analysis of the Clinical Trial Participation Survey conducted by BCCRIN/CTBC, it was found that a large number of participants fail to receive results of the study or hear of any findings. CTBC formed a provincial working group to tackle this issue.

8.2 Attachments:

- List of Working Group Members
- Best Practice Document for feedback from the AC

8.3 Two members of the working group were invited to inform the AC of work to date and ask for feedback from the council. M. Saunders and O. Arsovska presented on the Best Practice Document and draft KT plan.

Action: AC feedback on Best Practice document and planned KT activities requested to be sent to A. Orth prior to Feb 15th.

9. BC Showcase / Asset Map

Tabled to next meeting due to time constraints

10. Priority Setting Discussion

Reference: BC AHSN Strategic Plan https://bcahsn.ca/wp-content/uploads/2019/09/Looking-Forward.pdf

Attachment: Priority Setting Discussion Document

Chair facilitated a discussion around current CTBC strategic priorities and the new BC AHSN strategic plan with a focus on identifying areas for future attention and to inform the table topics at the upcoming conference in June.

Discussion around understanding how competitive BC is both nationally and internationally in Clinical Trials. What are the barriers to attracting more trials and building capacity?

It was mentioned that it would be an interesting topic to understand how other jurisdictions around the world track trial metrics.

Action: Alison to circulate *The Canadian Advantage, a Business Case by the Clinical Trial Canadian Coordinating Centre*. This document explains the benefits of conducting a clinical trial in Canada.

It was discussed that another interesting topic to add would be around 'data' – access to data and moving data in a global clinical trial. It is a challenge within BC due to data restrictions.

There was a request to advocate to increase access for clinical trials outside of the Lower Mainland and move towards being more of a population-based generalizable clinical trial setting.

It was mentioned that it would be good idea to have a representative from Innovative Medicines on the Council or in some way accessible by way of a working group or subcommittee. Action: For future discussion.

A point was raised about the amount of paperwork that is involved for people who sign up for clinical trials. It was advised that it would be a good idea to centralize the patient or volunteer's information so that they don't have to input all of their information each time they sign up for a trial.

A suggestion was made for people within administration to have a research background like a PhD whose role is to look at initiatives that people are intending to roll out and conduct them in a way that allows the data to be used in support of regulatory or policy decision making (e.g. research grade data collection and reporting).

It was agreed to add a new table topic – Health Authorities and Ministry Support for Integrating Clinical Research with healthcare.

There was discussion around how should Clinical Trials BC access researchers who are interested in the industry and develop their skills.

Potential table topics for conference:

- Quality of devices
- Quality of data from the devices
- Software as a device
- How do you expediate research knowledge getting into the system?

11. Meeting Adjourned at 4:55 pm

Upcoming meeting dates: February 18th, 2020 TBD, June 18, 2020 (Vancouver)