

## CLINICAL TRIALS BC (CTBC)

### ADVISORY COUNCIL MEETING MINUTES

Tuesday, February 18, 2020

2:00 to 5:00 pm

<b>Attendees:</b>	Rob McMaster, Chair Cindy Trytten Robert Olson Tania Bubela Scott Garrison	Melanie Reid Wendy Hurlburt Kendall Ho Stephania Manusha Gavin Stuart
<b>Ex-Officio:</b>	Alison Orth Stirling Bryan	Terri Fleming Jean Smart
<b>Regrets:</b>	Margaret Macdonald Geoff Payne Soren Gantt	
<b>Recording Secretary:</b>	Sarah Hanif	
<b>Guest:</b>	Anne Babineau, Innovative Medicines Canada Stef Cheah, REACH BC Platform, VCHRI	

#### 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 / Additions

- 2.1 The agenda was approved as presented.
- 2.2 November 26, 2019 minutes were approved prior to the meeting by all members and have been published on the CTBC website.

#### 3. Member Changes

Steven Reynolds has resigned to focus on other commitments, and his position will be filled in due course.

**Action: AC members** to bring forward any names to fill this position as an Active Clinical Trialist.



### **3.1 Welcoming our New President for AHSN**

Stirling Bryan has moved into a new role at AHSN as President, previously serving as Scientific Director for the BC Support Unit.

Stirling gave a big thanks to Tom Noseworthy, past-President for AHSN and advised it is an honor to take on this new position.

It was advised that AHSN is in a strong position with currently three operating units: BC Support Unit, Clinical Trials BC and Research Ethics BC. There are no immediate intentions to make any substantial changes to the units in the near future, update on the focus areas for AHSN.

A big focus currently is learning health systems which is a frame for the strategic plan for AHSN developed last year. Building a bridge as an effective link between the health system and academic world is an area where AHSN want to build their strengths. AHSN are supporting two networks: Emergency Medicine Network and the Rural and Remote Network; both of these organizations can assist with AHSN building on these strengths.

It was asked whether there could be additional funding from AHSN for networks due to the organizational partnership with Michael Smith Foundation. It was confirmed that this could potentially be the case for clinical and academic networks.

AHSN is recruiting for a Scientific Director Assistant. Once the position is filled, the new member will attend CTBC AC meetings in that ex-officio role currently filled by Stirling.

## **4. Terms of Reference – old business**

### **Confidentiality, privacy and COI policies**

The council advised the Unit Director that they wish for the ToR to have AC specific language around these pieces and to not wait for an organization wide policy that may not be applicable or specific enough.

Action: A. Orth to raise with AHSN executive and board. Language to be developed and approved by June 2020.



## 5. Clinical Trials BC – Updates and Action

### 5.1 Operations/Stakeholder Relations

Current activities are focused heavily on the upcoming CTBC conference in June.

CTMS program is moving along and there is current engagement with consultants around change management where gaps have been identified. An in-person Working Group meeting is being held next week with members across the province. There will be some changes around the program to ensure that there are appropriate and efficient resources.

CTBC renewed their members as an ACRP Partner in Workforce Advancement. Partners in Workforce Advancement is a multi-stakeholder collaborative initiative to grow the clinical research workforce and to set and support standards for workforce competence.

<https://acrpnnet.org/acrp-partners-in-workforce-advancement/>

Job board has been going well and there was a lot of interest at the recent Career Connect day hosted by LSBC in January.

Clinical Trials Ontario (CTO) are holding their provincial conference in March. They have a new program focusing on Participant Experience which has also been a focus for CTBC to develop tools and best practices. More presentations will be coming in due course about the work CTBC has been doing.

The CTBC provincial working group has finalized their Best Practice Recommendations for Communicating Study Results to Participants. The Best Practices document will be published and presented nationally in April at the Canadian Association of Research Ethics Board Administrator's Conference and at the CTBC conference in June in partnership with a patient partner WG member. We will want to consider what the next areas are to address and improve the participant experience.

CTMS - There are conversations around long-term funding for the system. BC Cancer are self-supporting the CTMS through industry trial revenue. However, some sites don't have the number of industry trials they need to cover the fixed costs to support the platform.

The timeline for go-live date at authorities will be better known after the implementation and deployment plan is discussed at the Working Group meeting next week. The current anticipated date for one site in the province is going live is July.

It was decided that the CTMS project should be discussed at every AC meeting to track progress and assess metrics for BC on a routine basis. Alison Orth advised that the CTMS program has an advisory committee in place.

New members are encouraged to view Korin Yunker's presentation on the CTMS project and the Zoom video recording from the last AC meeting in November if they want to learn more. The vision is to have a single CTMS system for the province.



## 5.2 LSBC Career Connect Day

*Please see Wendy Hurlburt's presentation – Career Connect Day*

Notes from presentation:

- LSBC would like to conduct the event again next year as it was a very good outcome and exceeded expectations.
- There was a photographer on site to take photos for attendees' LinkedIn accounts.
- There was an untapped need to figure out how to have science students learn about life sciences business world.
- In addition to the job fair, there was support for under-grads regarding future opportunities and funding, as well as general advice.
- CTBC were connecting students with funding programs through BioTalent Canada and many students came to the CTBC table to enquire about job opportunities.
- Exhibitors enjoyed connecting with each other so in the future it could be considered to hold an exhibitor session.
- LSBC are considering hosting an event on the Island.
- CTBC are intending to be a conduit between the students and the clinical trial organizations to assist with the recruitment and networking process.

## 5.3 Regulatory / Quality

- The current focus is around device regulations and the modernization of clinical trials
- Medical device regulations are changing rapidly internationally. The EU has announced they are not extending the implementation period for their new regulatory changes and the new regulations will be effective in May. Canada is now conducting stakeholder meetings to review their medical device regulations.
- The ICH Clinical Trial Renovation Package is in progress. This is a feature of the upcoming Clinical Trial BC Conference 'The Modernization of Clinical Trials'. The Conference keynote and featured speakers are addressing the renovation and modernization of clinical trials from the international, national and local level perspectives.
  - E6 R2 Good Clinical Practice is now effective and implemented in most countries. It was approved in November 2016 and came into effect in Canada in May 2017 with full implementation in April 2019.
  - E9R1 'Statistical Principles for Clinical Trials' was approved in November and is now for implementation
  - E8 'General Considerations for CTs' is scheduled for final approval and implementation at the end of May 2020. This is the document that covers methodology, critical to quality factors, innovative and adaptive trial types and broader design options (Canada is a lead on this initiative).
  - E6 R3 Good Clinical Practice is now in progress with the ICH (Canada is a lead on this initiative). This version will focus on new trial types and variable data sources including RWCT and pragmatic trials.
- Jean will be running Regulatory Update sessions. AC members will be invited to attend (in-person or join in via webinar)



## 6. Conference Update

### 6.1 CTBC has a new conference event manager: Venue West.

Venue: Vancouver Convention Centre West, 3<sup>rd</sup> floor, on June 17<sup>th</sup> and 18<sup>th</sup>.

Day 1:

- Day 1 divided into 3 sections:
  - Innovative trials (Rob as moderator)
  - Diverse Populations (Gavin as moderator)
  - Leadership and Regulation (Cindy as moderator) – 2 speakers from Health Canada and Alan Hacksaw coming from UK.

Day 2

- 4 concurrent forums:
  - Investigator Training
  - Advanced Research Team Development
  - Pragmatic Trials
  - Clinical Trials BC Advisory Council – 3 or 4 table topics (breakfast meeting)

### **Table Topics**

Advice is needed from AC members on what topics should be prioritized for the conference and which topics can be reviewed later in the year. Below are the topics under consideration:

Collaborative Research

Industry Sponsored Clinical Trials

Clinical Research Capacity Building

Participant Experience

Health Authorities and Ministry Support for Integrating Clinical Research with Health Canada

Business Development

**Action: AC members** to review table topics document and provide feedback.



## 7. REACH BC

### 7.1 Provincial Initiative – Overview & Discussion – Presented by Stef Cheah

*Please see Stef's presentation – REACH BC*

Notes from presentation:

- Stef thanked AC members for their support. Members can contact her with any questions.
- Security threat risk assessment (STRA) was conducted and is being reviewed by IMITS. It will also be circulated for review by provincial HIPSOC members. The Privacy Impact Assessment has been completed and is pending approval of the STRA.
- Ethics – there has been engagement with REBC around ethics and throughout the development there were Research Ethics members on the working group. Ethics boards will be consulted to inform of the launch.
- Webinar was conducted for Research Ethics professionals.
- Cindy Trytten asked where there would be the ability to select REACH as a method of recruitment in ethics applications?
  - Terri Fleming confirmed that this change has been put into the queue.
- Scott Garrison asked about the extent of social media outreach for the platform and explained the results of a recent social media campaign which resulted in more people signing up for a trial.
  - Stef confirmed that there is an intention to run some Facebook Ads.
- Kendall Ho asked if volunteers and researchers using the platform can share information if they have a bad experience.
  - Stef confirmed that volunteers can contact the REACH BC office about experiences, but a researcher would not be able to share details about volunteers with other sites.
- Jean Smart asked if there is a statement on the website to warn people that they cannot be enrolled in more than one trial at a time.
  - Stef advised not currently, but this can be added to the website.
- Geoff Payne raised the concern of people in rural areas and trials not available to them. Do they need to come for their follow-ups in an urban setting? This can lead to people feeling that they don't have access.
  - Stef confirmed volunteers can choose what regions they are willing to travel to.



## 8. Innovative Medicines Canada (IMC)

### 8.1 Overview and discussion

*Please see Anne Babineau's presentation – Innovative Medicines Canada*

Notes from presentation:

- Cindy Trytten expressed concern about the potential impact of the potential for retaliatory response from industry regarding clinical trial withdrawal from Canada as a result of the government's efforts to control rising pharmaceutical prices.
- How does IMC work with the federal government around escalating pharmaceutical prices – what discussions and compromise happen there as it's a big challenge to the Canadian Health System?
  - IMC agrees that there needs to be a mechanism to address pricing and have been working with the federal and provincial governments to find a balance to create sustainability as well as predictability.
  - The pan Canadian Pharmaceutical Alliance for the past 6-7 years has brought provincial, territorial and federal governments together to leverage their collective buying power to jointly negotiate drug prices with manufacturers.
- IMC has a [sponsorship program](#) that is aligned with the strategic pillars of the organization. Funds are allocated to organizations across the life sciences ecosystem.
- Alison Orth asked whether there will be new data around the economic development for Canada and BC.
  - Anne advised there is a process underway to understand the data by province with an approximate timeline of 6 months.
  - Wendy confirmed LSBC are gathering data including all stakeholders from BC to get a better understanding on the economic contribution within the province. In addition to this, they are working on an asset map but it can be a challenge to get certain data due to confidentiality.
- **Action: Alison** to send 2014 BCCRIN Economic Analysis Report to Anne and AC members.
- Each country has their own regulations on drug pricing and the value of medicines to citizens. New regulations in Canada could mean being one of the most stringent on a global scale.

## 9. BC Showcase / Asset Map

Tabled to next meeting due to time constraints

## 10. Meeting Adjourned at 5:10pm

**Upcoming meeting dates: June 17 and 18, 2020 (CTBC Conference)**

October 2020, February 2021, June 2021