

ADVISORY COUNCIL MEETING MINUTES

Tuesday, March 2nd, 2021

2.00pm-4:30pm

Attendees:	Gavin Stuart, Chair Rob McMaster, Past Chair Melanie Reid Cindy Trytten Margaret MacDonald Tania Bubela	Stephania Manusha Wendy Hurlburt Scott Garrison Srinivas Murthy Kendall Ho
Ex-Officio:	Alison Orth Danielle Lavallee	Jean Smart Terri Fleming
Regrets:	Rob Olson	
Recording Secretary:	Brianna Stowell	
Guests:	Stirling Bryan- President, BC AHSN	

1. Call to order / Roll Call / New Members

- 1.1 The Chair welcomed all members to the meeting of the Clinical Trials BC Advisory Council (AC).
- 1.2 The Chair welcomed the new Recording Secretary to the Council, Brianna Stowell.

2. Approval of Agenda / Additions

- 2.1 The agenda was approved as presented.

3. BC AHSN / MSFHR Consolidation Update

Stirling Bryan updated the Council on the BC AHSN/MSFHR Consolidation.

- The Memorandum of Understanding has been signed by both Boards to explore the possibility of consolidation.
- At the point in the process where we feel we can make a public statement of our intent to consolidate.
- This decision has not been confirmed but is on the right path for finalization.

4. Conference Feedback Roundtable

Top takeaways from the CTBC Conference (**See also Appendix A**)

- Positive feedback from all council members
- Everyone enjoyed the virtual platform and the content of the presentations.
- Council members are aware that there is still a lot of work and conversations needed to continue to make changes and streamline processes within BC for supporting the conduct of Clinical Trials.

5. Strategic Priority Discussions

See Appendix A

6. Quality Management System Program

Jean Smart provided a detailed description of two featured Quality Programs offered by CTBC:

- Audit and Inspection Preparation Program (AIPP)
- CTBC Quality Management Program

Feedback from the Council:

Cindy: Noted that she believes that it is critically important that the Quality Management work that has been done be maintained as a focus. “The work done is very important and much appreciated.”

Stephania: Agreed with Cindy, mentioning that often Quality Measures are put in as a reaction to a finding vs as a preventative measure.

Srinivas: Suggested the need to clarify the messaging as to the need for this type of process. To help Clinicians understand this is an important part of doing research.

7. CTMS Update – Briefing Note for information only

Alison Orth provided the Council with an update on the CTMS Program.

- 33 Users between Fraser Health, Island Health & Interior Health.
- Northern Health still to enter into a participation agreement.
- Vancouver Coastal Health are working on VCHRI resourcing to support their system and sites.

8. Business from the floor

N/A

9. Adjournment

The meeting was adjourned at 4:31pm PST.

Upcoming meeting dates: June 22nd, 2021 & Oct 26th, 2021

APPENDIX A

Highlights from the Clinical Trials BC Advisory Council Meeting

Meeting date: March 2nd 2021

Conference Feedback Roundtable

Advisory Council members shared feedback about the “*The Modernization of Clinical Trials Conference*”, held on January 26-28, 2021.

The conference was an overwhelming success with 670 registrants and over 200 attendees at each session.

- The virtual format increased engagement and inclusion, ensuring that all who wanted to attend could do so.
- The program, content and format were outstanding. Pre-recorded presentations followed by robust expert discussions were a refreshing change from long zoom presentations.
- Audience engagement was high. Audience members used the discussion questions and the chat function to engage with the panelists and with each other.
- The conference created unexpected connections between different stakeholders who came together under a broad reaching common objective. Clinicians learned about the clinical trials issues and opportunities from other disciplines. The program encouraged interactions between the speakers and created some interesting linkages between ideas.
- CTBC received very positive feedback on patient engagement, however some very different perspectives on patient involvement were represented.

Opportunities for Clinical Trials BC highlighted by the conference.

- *Increase diversity*, not only within clinical trial populations, but also within the clinical trial teams and investigators.
- *Leverage technology to streamline clinical trials*. Decentralized/virtual clinical trials reduce costs and participant burdens and increase the capacity to engage rural and remote populations. Evidence shows that the use of technology to consent patients improves the comprehension and the quality of the consent process.
- *Clinical trials are part of, and not separate from health care*. Integrate clinical trials more deeply by exploring different opportunities to collaborate and partner with the health system. An example would be to partner with the biobanking infrastructure.
- *Pragmatic clinical trial implementation in health care is an opportunity*. The challenge will be in operationalizing and demonstrating beneficial outcomes for patients and the health system.
- *BC is an ideal environment for demonstrating the value of clinical trial innovations*. BC has diverse populations in terms of ethnicity, gender and age. There are existing relationships and collaborations between people who set policy, people who implement policy, and people who do the research around it.

- *People outside of our immediate sector are now paying attention.* Even those who are outside of the clinical trial space increasingly recognise that the clinical trials sector has a great deal of value to both the BC economy and the life sciences sector.

Challenges for Clinical Trials BC highlighted by the conference.

- *We need to communicate the value of clinical trials.* We need strong arguments to demonstrate the long-term value of clinical trials and their products beyond short-term economic horizons. One way is to emphasize the value of clinical trials as an investment to improve quality of life, improve the care environment and to create jobs.
- *We need to reflect on what we can do that is reasonable and impactful with the resources we have.* The conference provided inspiration and momentum; however, we can't afford to do everything we want and so need to be deliberate about selecting our priorities.
- *A bigger question is whether to use our health system as a driver for economic development ("the best"), or to deliver improved health care for the majority.* The way that this conflict is addressed has major implications for how patient partners view Clinical Trials BC's commitment to patient involvement.
- *Address the relative lack of bio statistical and methodological support.* We really need to aggregate and support this area better in BC.
- *Promote much stronger and meaningful patient participation in clinical trials as a partner rather than a participant.* This could be an area of collaboration with the BC SUPPORT Unit.

Potential future conference themes.

- Diversity, including some unexplored areas such as specialized populations.
- Economics and the long-term benefits of clinical trials.
- A report back on change and progress from this conference to the next. This could capture some of the key ideas from the concluding session and measure how the suggested changes were implemented.

The Advisory Council commended Jean Smart and Alison Orth for their hard work. Alison thanked all Council members who supported the conference and served as speakers or moderators.

Strategy Priorities Discussion

Clinical Trials BC is critically evaluating their two-year work plan, which ran from mid- 2018 to 2020. The conference provided a timely opportunity to examine and refresh the work streams. This is not a reinvention of the strategic priorities. Key points discussed by the Advisory Council are summarized under three key headings.

1. Clinical Trials BC has an important and timely opportunity to embody the learning health research system.

- The learning health research system concept currently exists in the academic spheres but doesn't exist in the healthcare system or operational spheres.

- The dynamic of a learning “research” system might be highlighted as an organizational value or as an area in which we choose to measure progress by identifying what we want to do and measure ways to prove that we are doing it.
- The consolidation and alignment with the Michael Smith Foundation and the Ministry of Health provide a timely opportunity to build core expertise and to inform both policy and research.
- A learning research system (beyond health) may facilitate greater involvement with the Indigenous communities and in developing the relationships that are vital moving forward.
- BC AHSN already focuses on the learning health system; the 2019 AHSN Strategic Plan entitled “*Looking Forward*” has strategy about continuous learning and adjusting our activities around it.

2. Prioritizing equity, diversity and inclusion (EDI) is a measure of excellence.

Clinical Trials BC needs to prioritize “*Improve Participant Experience*”.

- This goal is important enough to become part of the mission of Clinical Trials BC.
- Patient Engagement needs to be a key component in the workplan.
- This needs to be expressed as a commitment to involving patients in clinical trials, in the goals of clinical trials and the connections between clinical trials and public health. This commitment might be a separate bullet.
- Communications and public awareness efforts should be strengthened.

Indigenous populations need to be considered.

- The issues of equity, diversity, inclusion and Indigeneity are topical with respect to our relationships with Indigenous communities as well as our relationship with other racialized communities.
- We need to specifically address cultural safety with trauma-informed approaches to engage Indigenous peoples. A key to success will be to regain and maintain trust with Indigenous peoples, which will require addressing some of their negative historic experiences with research. Part of building trust is ensuring that patient needs, and interests are met.

Indigenous-led research represents a paradigm shift.

- This approach is reflected in the latest CIHR strategy document which refers to research *by* partners and community rather than research *on* or *with*. Research institutes and post-secondary institutions are now taking a secondary role in support of research that is led by Indigenous communities. Industry needs to be on this journey as well.
- For Indigenous communities, the issue is sovereignty over data, biomaterials and research results.
- British Columbia is well positioned for Indigenous-led research, because of the structure of our health system including the tripartite agreement with the First Nations health authority and the Nations that are taking on active research agendas.

- BC AHSN will be engaging with an EDI consultant or a group to help develop priorities with an EDI perspective.

Increase clinical trial diversity.

- A clear patient engagement framework is necessary as are outreach activities to target specific populations; patient partners have a role in these outreach activities.
- We need to be much clearer when communicating the benefits-risks of clinical trials to patients. Evidentiary standards change in a post-market surveillance or pragmatic clinical trial environment, and many agents are experimental and have conditional market authorization only.
- Diversity from a clinical trial team perspective is discussed below.

3. Increase BC's Clinical trial capacity and sustainability.

Find new ways to increase the capacity, sustainability and infrastructure to conduct clinical trials in BC, especially as we are aiming for Provincial excellence.

- The pandemic has created new ways of working together we need to fully explore. This includes the shift towards EDI and expanding the regional scope of trials; there is a segment of the population, largely Indigenous/rural/remote, not getting access to any clinical trials.
- Decentralized/remote/virtual clinical trials have the ability to support efforts in this area but require infrastructure and policy to support them.

Address the dire need to develop Provincial clinical trial infrastructure: investigators, coordinators, regulatory affairs professionals.

- Clinical trial investigators and staff are needed in industry, academia and government, yet few students seem interested in these career options. The industry is dependent on people coming out of university with an awareness that clinical trials are a viable career path, as either a direct career path, or something that can be integrated into the role of a specialist or physician.
- Reaching out to students. It is our responsibility to show learners and trainees the academic perspective, the industry perspective and regulatory affairs opportunities that exist in clinical trials. Early students are resistant to regulatory affairs or regulation; there is an opportunity to capture their attention when they have had a bit more experience within the system.
 - CTBC did a presentation on careers in clinical trials to the Faculty of Health sciences students 101 in Northern Health that was well received.
 - CTBC is partnering with an Association of Clinical Research Professionals (ACRP) Task Force on workplace innovation, and have access to resources to help with this.

Build research into job descriptions of staff who are providing direct care to patients, and provide clinical trial training at all levels.

- Implementing Covid-19 clinical trials in the ICU highlighted some challenges. Although staff who were providing direct patient care had the skills and knowledge to conduct the trials, they lacked the time to be certified for trials, and research was not built into their job descriptions. This is a health system challenge and not unique to Indigenous and Northern/Rural Populations.
- This must be addressed on a provincial level and not just limited to the large urban area around Vancouver.

Increase BC's capacity for pragmatic/adaptive trial design and computing.

- BC already has the skill set required for pragmatic/adaptive trials; some of the leading world experts on adaptive trials framework live and work for Vancouver-based companies but primarily contract outside of British Columbia.
- We need to connect with these experts to have the capacity and experience necessary, especially in the areas of trial design and background computational analysis. This is something that needs to be available and on demand, not something that we are offering as a service.
- We may have an opportunity to contribute to the ICH E20 for Adaptive Clinical Trials. Although creating a guideline almost goes against what an adaptive trial is, the adaptive Covid-19 trials have changed the landscape.

Address Clinical Trials BC's human resource capacity challenges.

Staffing shortages are limiting Clinical Trials BC's capacity.

- VCHRI has tried to get a position classified to support the implementation of the CTMS at VCH for the last six months. Staff support is needed. Researchers are already engaged and implementing this technology will help to streamline processes.
- The pandemic has highlighted CTBC's role in facilitating connections, with one third of Alison and Jean's time spent on linking and navigating people and organizations to BC pathways, infrastructure and supports. In June 2018, Clinical Trials BC and Life Sciences BC, created an allocation for a shared business development role; it may be time to revisit this position which would benefit both organizations.
- Staff support is also needed to conduct a wider consultation to identify BC's competitive advantages for clinical trials. This would include a summary of expertise by region, identify the core competency gaps on a provincial level, and would highlight the ACRP training to address the gaps.
- Increased communications and Public Education and Awareness around clinical trials is needed.