

ADVISORY COUNCIL MEETING MINUTES

Tuesday, October 26th, 2021

2.00pm-4:30pm

Attendees:	Gavin Stuart, Chair Tania Bubela Wendy Hurlburt Stephania Manusha Melanie Reid	Rob McMaster, Past Chair Lisa Elser Kate Keetch Srinivas Murthy
Ex-Officio:	Alison Orth Danielle Lavallee	Jean Smart Terri Fleming
Regrets:	Kendall Ho, Harvey Howse, Rob Olson	
Recording Secretary:	Rhonda Tolley	
Guests:	Stirling Bryan and Bev Holmes	
Unit Staff:	Stef Cheah Aisling Quigley Marc Saunders	Nhan Do Rishi Sahni Robyn Tkatch

1. Call to order / Welcome

- 1.1 The Chair welcomed all members to the meeting of the Clinical Trials BC Advisory Council (AC) as well as Bev Holmes and Stirling Bryan. He advised the meeting attendees that the meeting would be recorded for minute taking purposes and that the recording would be deleted after the minutes are transcribed.
- 1.2 The chair offered territorial acknowledgement.

2. Approval of Agenda / Additions

- 2.1 The chair asked for additions to the agenda and, as there were none, the agenda was approved as presented.
- 2.2 A roundtable of introductions was held.

3. Welcome of New Council Members

- 3.1 The chair welcomed the new Council Members:
 Kate Keetch, Director, Department of Evaluation and Research Services, Fraser Health
 Lisa Elser, Patient and Public Representative
 The chair noted that Alison will be connecting with each current Council member over the next month. He also stated that he and Alison are actively speaking with potential new members and Council members should feel free to reach out to him or Alison at any time.
- 3.2 The chair acknowledged the contributions of Council members whose appointment terms have ended: Cindy Trytten, Scott Garrison, Margaret McDonald and Anne Babineau.

4. Michael Smith Health Research BC update



4.1 Stirling thanked the Council for the opportunity for him and Bev to provide an update on the new organization, Michael Smith Health Research BC. The consolidation agreement of the single health research organization was signed off as of October 1st. He informed the Council that Bev is the CEO and that he has taken on the role of Chief Scientific Officer. He assured members that the operating units, CTBC, REBC and the SU will be maintained and are integral to the new organization. He also let Council members know that advisory councils for all Units will be continued.

Bev also thanked the Council for time on the agenda and provided a quick overview of the purpose of consolidation to strengthen BC's health research system. She spoke to the transition Board of Directors, the diverse skills and experience and that the members do not speak on behalf of their organizations, regions, or stakeholder groups. Bev also informed the Council of the funding request that has been submitted to government. Congratulations from Council members were conveyed.

Bev and Stirling exited the meeting at 2:30 pm.

5. CTMS Program update

5.1 Marc provided a PowerPoint presentation that included an update on the program, usage metrics and user feedback. He informed the Council that a security specialist has been contracted to perform annual reviews of the system and server security. The chair asked for comments or questions from council members. A good discussion on the current focus of increasing uptake and sustainability was held. It was suggested that a mandatory approach to CTMS at the health authority level would be supported. The effect of COVID-19 and Cerner on the implementation of CTMS was discussed and it was the general feeling that although the timing is impactful, the systems are felt to be different. Marc was advised to reach out to the membership for assistance. The chair thanked Marc for his thorough update.

6. Health Canada Regulatory Modernization

6.1 Alison provided an update on the Health Canada consultation on the modernization of regulations. She informed the Council that Clinical Trials BC contributed a formal response paper (circulated with meeting package) focused on sections related to modelling, regulatory processes, harmonization, and alignment with an international policy on the conduct of clinical trials. CTBC also called for mandating public reporting of clinical trial results, including reporting to the clinical trial participants. Jean, Danielle, and Crystal were thanked for their input to the help formulate the response letter. As a follow up, it was suggested that the link of the summary of Health Canada's modernization of their clinical trial regulations as well as our Clinical Trials BC response to the recent open public consultation be circulated. A summary of the consultation feedback provided to Health Canada by diverse stakeholders. Tania reported that SFU is also going to respond to Health Canada's consultation and that their submission is currently circulating within their network. Their response covered some of the same areas and is synergistic. They too noted the lack of definitional transparency and clarity of decisions as well as data challenges.

7. Immediate Impact of recent approval of ICH E8 – R1

7.1 Jean spoke to the approval of the ICH E8RI, the impact it will have and the response by CTBC. The changes include an educational update, patient participation requirements, and implementation of quality. CTBC's readiness and response includes bulletin and newsletter information articles. She reported that the special education series targets on new topics of quality



and patient engagement, patient engagement in clinical trials community of practice, quality leadership training course and quality management system program. Jean invited Council members to the November 3 lunch hour talk synopsis. The chair thanked Jean for her update.

8. Clinical Trials BC Service Awards 2021/22

8.1 Jean talked to the 2021/22 upcoming Clinical Trials BC Leadership and Service Awards as well as the nominations and review process. The call for nominations will be sent out in the next few weeks with a closing date of January 16, 2022. Jean is looking for volunteers for the review process in the form of two reviewers and two seconders for the Nominations and Selection Committee taking place February/March 2022. The commitment would include review meetings scheduled for March 3 and 10 for approximately 2.5 hours. The awards presentation is to take place on May 20, 2022 – International Clinical Trials Day. If interested in volunteering for this, please contact Jean directly.

9. REACH BC Marketing and Evaluation Plans

9.1 Stef and Aisling reviewed the goals of REACH BC and provided a PowerPoint presentation that included a marketing strategy to promote awareness of the platform and to drive traffic to the website. The importance of outcomes and evaluation as a measure of success was emphasized and the evaluation timeline was reviewed. A good discussion was held and feedback from Council was sought on the communications and marketing strategy. Specifically, the Council was asked if they had any other ideas for measuring impact and any other key metrics, they would be interested in. Recommendations that came forward included the start of an education roll out plan, the placement of posters at practitioner offices, as well as pharmacies and to talk to nurse practitioners. The chair thanked Stef and Aisling for their comprehensive presentation.

10. Biostatisticians for CTs – building capacity in BC

10.1 Gavin brought forward for discussion the issue of the need more for biostatisticians in BC for clinical trials. He noted the shortfall in our landscape, the role to growing capacity, to make linkages, and the need for consolidated services to be built into grant application. It was suggested that we take stock of what we have but that there are other pieces missing including monitors, submissions, and regulatory specialists. It was proposed that the SPOR SU methodology group provide an update and/or asset map development. Wendy advised the Council members that LSBC is working on a labor market survey for the province and that she would include Alison going forward. Discussion centered around the potential to look at skills needed in the future and any gaps that would need to be filled. Wendy added that broad governance oversight over the project and inclusion of post-secondary institutions is intended. Expanding training for graduate students and traditional degrees was also brought forward. The Sitel Group, statistician was mentioned for consulting services. The chair suggested that this be kept as a future agenda item.

11. 3CTN Conference – themes

11.1 Gavin talked of the key themes and take-aways of the 3CTN conference he recently attended virtually. He noted that CTBC is already looking at how to enable decentralized and remote trials/hybrid trials but wondered what else we should be thinking about with regards to conduct of clinical trials and patient engagement. He advised the Council that the Canadian remote access framework for Clinical Trials (CRAFT) initiative from 3CTN helps to enable clinical trials participants for patients who live far from the healthcare site where the trial is primarily offered and that with the development and implementation of CRAFT, the Network aims to provide equitable access to clinical trials for all Canadians, regardless of their location. The chair also brought forward questions



such as cross pollinating enough within BC, how do we learn lessons from others, and do we need to be more inclusive in gaining information? Alison spoke to the original vision of CCTCC but that its funding was part of CIHR SPOR. She noted that the CCTCC model version 9 is being re-established. The chair suggested that this be kept as a regular agenda item.

12. New Business

12.1 For the next meeting agenda:

- E8- study design – role of clinical trials.
- patient engagement and rural and remote participation
- Council members were asked to send along other agenda items for the next meeting to Alison or Gavin.

Adjournment

The meeting was adjourned at 4:31pm PST.

2022 meeting schedule:

Tuesdays from 2:00-4:30 pm on:

February 22, 2022

June 21, 2022

October 25, 2022

