# Clinical Trials BC Advisory Council
## Meeting Agenda

**Date** | **Time** | **Location**  
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Tuesday, July 30, 2019 | 2:00 – 4:00 pm

### Link to WebEx
- **Join the meeting**  
- Meeting No.: 999 421 526  
- Call-in: 1-844-445-4475  
- Access Code: 999 421 526

### Attendees
- Tania Bubela  
- Rob Olsen  
- Scott Garrison  
- Geoff Payne  
- Kendall Ho  
- Melanie Reid  
- Catalina Lopez-Correa  
- Steven Reynolds  
- Margaret MacDonald  
- Gavin Stuart  
- Stephania Manusha  
- Cindy Trytten  
- Robert McMaster (Chair)

### Ex-Officio
- Alison Orth, Unit Director, Clinical Trials BC  
- Jean Smart, Regulatory Affairs and Quality Officer, Clinical Trials BC  
- Terri Fleming, Unit Director, Research Ethics BC  
- Stirling Bryan, Scientific Director, BC SUPPORT Unit

### Guest
- Tom Noseworthy, CEO, BC Academic Health Science Network

### Regrets
- Soren Gantt

### Minutes
- Rosamma Varghese, Administrative Assistant, BC AHSN

### Agenda Item

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<th>No.</th>
<th>Description</th>
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<tr>
<td>1</td>
<td>Call to order / Roll Call</td>
<td>R. McMaster</td>
<td>2:00</td>
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<tr>
<td>2</td>
<td>Approval of Agenda</td>
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<td>3</td>
<td>Welcome and History of Clinical Trials BC</td>
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<td>4</td>
<td>Review and Discussion of Terms of Reference</td>
<td>R. McMaster</td>
<td>2:15</td>
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<td>• to be approved at next meeting</td>
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<tr>
<td>5</td>
<td>Roundtable Introductions</td>
<td>All</td>
<td>2:20</td>
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<tr>
<td>6</td>
<td>BC AHSN Strategic Plan</td>
<td>T. Noseworthy</td>
<td>2:40</td>
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<tr>
<td>7</td>
<td>Clinical Trials BC Overview and Current Initiatives</td>
<td>A. Orth &amp; J. Smart</td>
<td>3:00</td>
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<td>8</td>
<td>Clinical Trials Provincial Conference June 2020</td>
<td>J. Smart</td>
<td>3:30</td>
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<td>• topic and speaker suggestions</td>
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<td>9</td>
<td>Suggestions for Council Membership</td>
<td>R. McMaster</td>
<td>3:40</td>
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<tr>
<td>10</td>
<td>Business from the floor</td>
<td>R. McMaster</td>
<td>3:50</td>
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<td>11</td>
<td>Adjournment</td>
<td>R. McMaster</td>
<td>4:00</td>
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**Next Meeting:** October TBD, February TBD, June 17, 2020 (Vancouver)
1. Call to order/Roll Call

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

2. Approval of agenda

2.1 The agenda was approved as presented.

3. Welcome and History of Clinical Trials BC

3.1 The Chair provided the history of how Clinical Trials BC was built upon and expanded the functions of the former BC Clinical Research Infrastructure Network (BCCRIN). He noted that in February 2016 BCCRIN was renamed, reorganized and evolved into the BC Academic Health Science Network with a new expanded mandate. In June 2017, it was announced that BCCRIN’s functions would be transitioned into the BC Academic Health Science Network organization under the new name of Clinical Trials BC and as of October 2018 a team, including a Unit Director, Regulatory Affairs and Quality Officer and Project Manager was in place.

4. Review and Discussion of Terms of Reference

4.1 The draft Terms of Reference was circulated for review prior to the meeting and it was noted that these will be finalized and approved at the next meeting. It was clarified that the Council is
to report through the BC AHSN CEO (via the Operating Unit Lead) to the BC AHSN BoD. R. McMaster stated the Council now has a three-year budget through AHSN, which is a sign of strong support. The Chair affirmed the Council will meet three times per year and that he will remain as Chair for one year at which time the Advisory Council will nominate a Chair and Vice Chair for a two-year term. The Council discussed the idea of staggered appointments and extended term lengths for continuity. Suggestions for quorum included one half of active members and, to pass a vote, quorum plus one. It was added that the options to vote online or electronically were acceptable.

5. Roundtable introductions

5.1 The Chair initiated a roundtable Introduction of all Council members, ex-officio and guest.

6. BC AHSN Strategic Plan

6.1 Tom Noseworthy offered an overview of the newly developed BC AHSN Strategic Plan. A paper copy was distributed at the meeting and he informed the AC the Plan is embargoed and not for circulation at this time.

He highlighted the placemats on pages 11 and 12 where the mission is supported through a series of goals, strategies, and measures to achieve the vision. He noted the AHSN requires the help of Advisory Councils to achieve the vision and suggested that Advisory Councils look at the strategies to develop a business plan to line up the Strategic Plan to the resources and build it into their budget that will automatically be included within the AHSN budget.

Stirling Bryan added that the frame of the Strategic Plan is learning health systems. Patient engagement, ethics, research, health research, and clinical trials are being thought of in the context of learning health systems. The BC AHSN wants to ensure the evidence is supported and generated and the data is actionable to bring improvement to the healthcare system.

A full discussion was held on the AC priorities and what is feasible. It was noted that the AC will help identify what is needed to support clinical trials and what it will look like. Further discussion is to be brought forward at the next meeting along with the possibility of a CT asset map and access to clinical trials. The Chair summarized that to map activities to goals is achievable and that time at the next meeting should be spent to map activities to networks and that some of the activities can be used to emphasize research to practice, to capture more data and educational capacity with emphasis on training programs.

7. Clinical Trials BC Overview and Current Initiatives

7.1 Alison Orth and Jean Smart provided a PPT presentation highlighting their activities of the last eleven months that includes clinical research navigation, professional development and training, regulations and quality assurance, improving the participant experience (access and duration) and program development and support. A. Orth noted that it is anticipated that the mission and
vision will evolve in the next year to reflect the role of CTBC. The slide deck is attached to these minutes for convenience.

The Chair informed the Council members that the SUPPORT Unit has a patient participation matching program (REACH) that also involves the investigator who can register their interest as well. It was suggested that the REACH group and the Emergency Medicine Network be invited to a future meeting to demonstrate their programs. Council members were recommended to visit the Mayo website for their patient participation program and as well, Ontario also has a program on their site that all provinces can use.

Suggestions were raised around possible areas to explore: the science of clinical trials, global trends, things to introduce, Interdisciplinarity research, genetics, engineering – evolve – different kinds of trials.

8. Clinical Trials Provincial Conference June 2020

8.1 Jean Smart (Conference Chair) informed members that CTBC will be holding their first provincial Clinical Trials Conference on June 17 and 18, 2020 in Vancouver at the Convention Centre West. The overarching theme is Renovation and Modernization of Clinical Trials. The first day will include an all-day investigator training session, leadership meetings, coordinator tools for investigators and pragmatic trials and real-world clinical trials. Jean Smart thanked Gavin Stuart for organizing full CME credits and international GPC certification. A clinical trials application workshop will be held in the afternoon.

Day Two includes a keynote speaker - Allan Hackshaw (CT UK) has been confirmed. A planning committee has been struck with a conference coordinator and communications lead. Help with topic and speaker suggestions are welcome as well as to populate sub committees. Fundraising is being looked at, but it was suggested that careful consideration be given to funding sources. An eCOP has been set up to get people involved and a save the date has been distributed. With regards to accessibility for those not in Vancouver, components of the conference will be broadcast.

9. Suggestions for Council membership

9.1 The Chair brought forward the matter of council membership noting that one more member is needed. After much discussion it was determined that three potential members should be considered. FNHA (coordinate with other Units), Mitch Moneo (Pharm/Ministry/Policy), and LSBC Wendy Hurlburt. General consensus was that the Chair and CTBC Director should move forward with an invitation to W. Hurlburt before the next meeting. Adding additional members beyond 15 would require revision to the Terms of Reference but the council agreed they are open to this possibility.

10. Business from the floor

Topic Ideas for future meetings:
• Update on asset map
• Ethics harmonization for multi-site CTs, REBC
• Biobanks, Peter Watson
• Corinne Hohl, adverse drug reactions for prescribed drugs
• Indigenous health
• REACH
• CTMS update
• Fee for service pragmatic trials
• Patients as partners in clinical trials

11. Adjournment

11.1 With there being no further business, the meeting was adjourned at 3:58 pm.

Upcoming meeting dates: October 2019 TBD, February 2020 TBD, June 17, 2020 (Vancouver)

Advisory Council members will be polled for their availability.
We’re a unit of the BC Academic Health Science Network:

Clinical Trials BC
British Columbia Academic Health Science Network

BC AHSN
British Columbia Academic Health Science Network

More information at clinicaltrialsbc.ca
Clinical Trials BC

Vision:
Establish and promote British Columbia as a world-class destination for Clinical Trials

Mission:
To maximize the health, educational, and economic benefits of clinical trials to the citizens of British Columbia
What We Do

We contribute to national and international clinical research communities, and connect with governing bodies and forums.

- **Clinical Research Navigation** – Business development opportunities; global marketing of BC’s clinical trials excellence; facilitating connections and partnerships

- **Professional Development and Training** – Provincial access to online clinical research tools, resources and e-learning programs; professional certification support and guidance; site education and training

- **Regulation and Quality Assurance** – Regulatory compliance and quality consulting; Quality Management System (QMS) framework, implementation and support; audit and inspection preparation; program implementation

- **Improve Participant Experience** – Generating data/knowledge on patient/participant experience; engaging with partners to advocate clinical trials practice improvements clinical trials by helping to remove barriers and enhance the participant experience.

- **Program Development and Support** – Workforce innovation and mentoring; program development planning; strategic planning and infrastructure activities
Certified Research Professionals Support

- Invest in people through facilitating certification
- SoCRA or ACRP Clinical Research Professional certification program
- 71 Clinical Research Professionals certified to date
- 17 in 2018 and 8 in 2019
- Support of certification fees $350 CDN
- Exam preparation sessions
- Recognition
Network of Networks (N2)

• With funding support from the BC SUPPORT Unit, we provide province-wide access to best-in-class tools and resources from the Network of Networks.

• N2 is focused on enhancing clinical research capability and capacity.

• N2 benefits are available for clinical researchers working in health authorities and academic organizations in BC, as well as for some independent investigators.

• Tools and resources that are available through N2 membership include Educational courses (available via CITI-Canada), Standard Operating Procedures, Quality Tools, Tools to Engage Participants and more.

n2canada.ca
Learning Management System (LMS)

- Access to ACRP e-learning library of 30 educational courses.
- Essential part of achieving the highest level of patient safety, data quality and regulatory compliance
- Up to 100 researchers/research staff in BC
- Over 300 users to date
- Hosted by VCHRI and Clinical Trials BC

New User?
- Email: education.award@vch.ca
Enabling Quality

- Framework
- Infrastructure
- Ongoing Support & Training
- Talent Development
- Resource Building
- Regulatory and Quality Consults
Our Regulatory Programs for BC

- Audit and Inspection Preparedness Program (AIPP)
- Compliance Education
- Investigators Only Training
- Regulatory Guidance and Consultation
- Quality Management Systems (QMS) – includes Risk Management
- Inter-Provincial Regulatory Review
- Resource Bank
QMS / Risk Management Update

- Training Program in QMS (for all institutions and programs) - book
- QMS and subsystems (lunch and learn series/workshops for sites)
- QMS Manual and SOPs (full set) forms and templates
- Institutional/Health Authority/Program Assessments and Development Planning (Ongoing)

Clinical Trials BC
Updated and New Resources 2019-20

General Regulatory Consulting Service
- Study set up, study issues assistance, regulatory resource, document reviews

Province-wide Access to N2 Resources
- Free for university, health authority and community research teams
  - Clinical Trial Education and Awareness toolkit
  - SOPs
  - CITI Training Courses e.g. GCP, HC Div 5 Regs, Privacy, Ethics, TDG/IATA

Workshop/Lecture Series Spring Summer 2019

Audit and Inspection Preparation Program V4
2019 Clinical Trials BC Syllabus
Spring and Summer Lecture and Workshop Series

2019 Feature Lectures
1. Risk Management
2. HC Guidance 0100
3. Learning from the Canadian Clinical Research Participant Experience
4. Presentation: Canadian Regulatory Environment: Influences, Changes and Trends
5. 2019 ICH E6 (R2) GCP Impact and Resources

ASQ US Series
The ASQ TOPIC series was popular under the former BCRIIN dating back to 2011. The Sessions are designed to fit into a short time session. Bring your lunch! These are short mini presentations on hot topics combined with equal time to ask questions. The ‘just ASQ Us’ FORUM Dates and ASQ HOT TOPICS will be announced in our newsletter.

Investigators Only Series (IOS)
(Module 3-7 available Fall Winter Syllabus of 2019/2020)

Clinical Trials BC Audit & Inspection Preparedness Program (AIPP) 2019 Version
Workshop #1 – Advance Preparation: Be Prepared: From Notice to Knock
Workshop #2 – Interview Techniques: inspection interview Responses
Workshop #3 – Hosting Skills and Audit Conduct: The Do’s and Don’ts
Workshop #4 – Document Handling: Control of Documents During an Inspection
Workshop #5 – Exit Meeting
Workshop #6 – Follow-Up Activities: The Post Audit 5 C’s: Common Findings, Classifications, Clarifications, Corrections & CAPA

The Program comes with access to an audit kit, tools and access to the Clinical Trials BC AIPP Manual V3 and workshop handouts at sessions. Training Certificates are issued at the end of the series.

Clinical Trials BC Quality Management System Training Program
This Training Program was established with BCRIIN in 2012. It has been modified and is now in version 4. A full compliment QMS with nine systems is available for programs, centres and institutions within British Columbia.

CORE Workshops
1. Good Documentation Practices (GDP) Records
2. Privacy and Security in Clinical Research
3. Introduction to ICH Guidance Documents - The Basics for Clinical Trials
4. Quality and the Calibration & Maintenance of Equipment in Clinical Trials

Clinical Trials BC Workshop and Lectures Bank
Clinical Trials BC maintains an archive of lectures. Staff are available to speak on topics of interest or provide an update on any previous topic that has been presented that relates to Clinical Trials. We are also happy to take suggestions for new topics.
Enhancing Clinical Research Participation

**Objectives**
Engage with the research community, industry and the public around results of our survey with research participants/decliners

- identify key areas for improvement, barriers to bust
- make recommendations for action
- Provincial Working group established in Feb 2019 to tackle first key finding
  
  *Lack of Communication of Results to participants*

**Recent Activities**

2019
- June – Pediatric results presented at BCCHRI
- April – national N2 webinar – recording available

2018
- March - workshop with researchers at Island Health
- May - Dialogue with CT participants and the public at Island Health
- Nov – workshop with research teams and CT nurses at Interior Health

May 7th – Co-hosted with Island Health Research
NOTABLE, NEW, STAY TUNED...

- Resource Bank 2011 – 2019
- Advanced Training Courses 2019
- Advisory Council July 2019
- Clinical Trial Management System (CTMS)
- ACRP Workforce Innovation Steering Committee (WISC)
- Communities of Practice (eCOPs)
  - Results WG
  - Quality Forum
  - Directors Forum – coming soon
- Provincial Clinical Research Job Board
- Provincial Clinical Trials Conference 2020
- CTBC Updated Workplan 2020
Thank You and Questions

Twitter: @clintrialsBC
Web: clinicaltrialsbc.ca
Email: info@clinicaltrialsbc.ca