

**CCTCC Executive Committee and Health Canada Meeting
Re CCTCC REB Accreditation Working Group's (WG) Final Recommendations (FRs)**

Action Items

Sept 16th, 2016 – 12:30 pm to 1:00 pm EST
Toll Free: 1-866-866-2244 | Participant PIN Code: 1684740

For CCTCC	<p>Dr. Shurjeel Choudhri, Senior Vice President & Head, Medical and Scientific Affairs, Bayer Inc., Executive Committee member for Innovative Medicines Canada</p> <p>Dr. Duncan Stewart, Executive Vice-President, Research, OHRI, Executive Committee member for HealthCareCAN</p> <p>Dr. Danika Goosney, Director General of the Science Strategies and Initiatives Branch, CIHR</p> <p>Ms. Elena Aminkova, Interim Director of Project Facilitation, CCTCC</p>
For Health Canada	<p>Dr. Carole Legard, Director of the Office of Clinical Trials</p> <p>Dr. Agnes Klein, Director of the Centre for the Evaluation of Radiopharmaceuticals and Biotherapeutics</p> <p>Mr. Laird Roe, Executive Director of the Science Policy Directorate, and</p> <p>Dr. Peter Monette, Manager, Bioethics and Science Advice, Science Policy Directorate</p>
Secretariat	Ms. Marianna Medvid , CCTCC
Regrets	Dr. Jane Aubin , Chief Scientific Officer, Vice-President, Research, Knowledge Translation and Ethics Portfolio, CIHR, Executive Committee member for CIHR

Action Item	Responsible
1. Feedback about FRs at the Executive and Advisory meetings	CCTCC
2. Public response regarding after receiving feedback from CCTCC's Executive and Advisory meetings	CCTCC & Health Canada
3. Disband the WG once public response is provided	CCTCC & Health Canada
4. Provide an update to the REB WG about the outcomes of this meeting.	CCTCC

Recommendation 2 – Establish a registry of REBs that review and approve clinical trials that could ultimately be expanded to encompass all REBs in Canada

Recommendation 3– Actively pursue regulatory options for standards equivalency for REBs that review regulated clinical trials

Recommendation 7 – Establish a national strategic leadership forum

Overview of the WG was provided. Did consultations on challenges and opportunities. There are many initiatives provincially that provided room for a national coordination approach. WG went to conferences for feedback after consultations. Recommendations identify the challenges and opportunities.

HC recommendations on #2 may be interesting to pursue and 7. Rec. 7 discussion on REB challenges and way to move forward.

Agnes – recommendations directed to regulated CTs. Recommendations overlap in policy development. Not sure how much authority regulator has within the Food and Drugs Act to deal with REB regulations of . 2 ways: regulate as such and regulate as standards. Regulation by standard is easier. Regulation by reference, other than direct regulation. Conduct a policy analysis that will look at all recommendations. Something would be very useful when inspectors go, having registry and knowing they are following standards would place in good GCP arena. At bare minimum recommendation 2 would be useful. Look and see what is the desire and ability and priorities are. Good strong rationally. Policy analyst to come up with a way of doing it.

Carole- from regulatory standpoint, look at authorities and how can this be regulated. Regulating industry and making requirements to use accredited REBS. From her perspective look at this issue and see how can contribute. Premature to have anything more concrete

Laird – 2 and 3, 7 would allow to get to some other recommendations as well.

Duncan – looking forward to discuss ourselves and at the advisory to get idea how useful recommendations could be.

Shurjeel – other countries are moving ahead with REB streamlining. We have done some work in establishing REB registries, working with Provinces to see if , metrics and benchmarks.

Peter- Accreditations in terms of future of CCTCC. Acknowledge the work of the WG. Strong interest to continue with the discussions and see what we can do together. We have to continue working together. CCTCC valuable place to continue working together.

Next steps: When make a decision of CCTCC moving forward. CCTCC will continue until mid of next year. Pull together a strategic document and strategic priorities. Work of REB should be part of the strategic discussion. National Strategic Forum – National organization (CCTCC) work with representatives from Provinces and target issues. Need to make regulatory changes provincially. CCTCC well positioned to do this kind of work.

Next steps – public response on the recommendations. Public response is a possibility. Work on this internally. Go potentially – go to HPFP take route up and communicate at higher level. SPB –Adm to Adm. Peter and Elena can work on it together after the Executive and Advisory Call. Elena update the WG.