ADDENDUM

Towards Health & Prosperity…An Update on an *Action Plan to Help Attract More Clinical Trials to Canada*

As was noted on pages 12-13 of *"Towards Health and Prosperity – An Update on an Action Plan to Help Attract More Clinical Trials to Canada"*, provincial efforts on issues related to the action plan's recommendations provide a significant opportunity to catapult future progress. As such, in this Addendum[1] our colleagues in the provinces have helped us to elaborate briefly on the bullets presented in the Communiqué. The same table presented in the Communiqué is below. After the table, you will find brief paragraphs. Please note that these descriptions are not intended to be exhaustive or used for business analysis or inventory purposes. They are examples only. Our thanks to all who contributed.

Summary of Initiatives (as shown on pages 12-13 of Communiqué)

Provincial Body	**Examples of activity areas relevant to *To Your Health & Prosperity Action Plan* Recommendations (potential leverage points for future)**
British Columbia and BC Clinical Research Infrastructure Network and BC Ethics Harmonization Initiative	✓ Undertaking a patient recruitment survey to determine why patients in BC (n=1000) partake or refuse to partake in CTs. ✓ Advancing common training & professional development. ✓ Completing an economic impact assessment for clinical trials ✓ Advanced mCTA in BC ✓ Implementing an electronic version of BCCRIN's asset map. ✓ Entering into collaborative ethics review agreements between the major Health Authorities and the four largest Universities ✓ Developing a collaborative review model for streamlining initial review and post-approval activities
Alberta (Alberta Innovates & partners)	✓ Developed a provincial roadmap for researchers from study start-up to closure, and provincial tools and templates to assist them ✓ Development of a provincial Confidentiality Disclosure Agreement resource template and promotion of mCTA ✓ Established legal reciprocity across Alberta's six REBs designated under the Health Information Act of Alberta ✓ Established reciprocal ethics review for multi-centre protocols ✓ Transitioning all health REBs to common electronic platforms. ✓ Development of automated tools for informed consent as well as common electronic application and other forms

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	✓ Advancing common training standards & professional development for clinical researchers
Saskatchewan and Centre for Patient Oriented Research	✓ Harmonization of provincial ethics review boards in progress. ✓ Efforts made to achieve harmonization with BC & Alberta. ✓ Established and maintained some of North America's oldest patient registry databases.
Manitoba	✓ Health Sciences Centre and St. Boniface do a large number of clinical trials in Manitoba ✓ Ethics reviews go through the University of Manitoba ✓ Health Sciences Centre has a business office that assists in the start up of both industry led and academically led trials ✓ An area of particular interest is the creation of infrastructure to assist smaller hospitals and sites partake in clinical research.
Ontario & Clinical Trials Ontario	✓ Launched Clinical Trials Ontario to help provide a single point of entry for clinical trials and promote reformed CT infrastructure through performance metrics to global decision makers. ✓ Three strategic pillars include improving speed and costs of clinical trials; enhancing patient recruitment through public awareness and education; and leveraging strategic partnerships. ✓ Current focus is on information technology platforms; streamlining ethics reviews; and on legal and liability issues across institutions.
Quebec & FQRS	✓ FQRS has five clinical trial related working groups under Quebec's Innovation Strategy and a government, academic, healthcare, and industry standing committee. ✓ The areas of focus are ethics reviews, common contracts, metrics, training, and streamlining administration issues ✓ A preliminary report was provided to MDEIE with recommendations on common contracts, metrics, training, and streamlining administration issues
Nova Scotia (Dalhousie, Capital Health, IWK)	✓ Implementing a region wide REB for multicentre trials ✓ Increasing inter-institutional collaboration for contracts ✓ Engaging with New Brunswick and Prince Edward Island to build critical mass and maximize streamlining
New Brunswick (multiple partners)	✓ Established a province-wide strategy for advancement of competitive research landscape. ✓ Harmonized contract review & pricing across the province. ✓ Developed a series of networks and research offices.
Newfoundland & Labrador	✓ Established a Centre for Clinical Research that brings the majority of clinical research physically together which

Provincial Body	Examples of activity areas relevant to *To Your Health & Prosperity Action Plan* Recommendations (potential leverage points for future)
	improves oversight and coordination of clinical trial activity. ✓ A single Health Region Ethics Authority has been established which provides oversight and review of all health research in Newfoundland and Labrador.

British Columbia: The British Columbia Clinical Research Infrastructure Network highlights a number of important initiatives for advancing excellence in clinical research for British Columbia. It has completed a business plan; identified six key priorities including recruitment and awareness, streamlining and standardization of processes, and professional development for members of our clinical research teams, to highlight a few. It has participated actively in the clinical trials contract template agreement and has continued to work across sites and with insurers to identify opportunities for consistency across sites. It has launched a Clinical Trial Participation Survey, designed to capture a 1000-person sample on why people take part in clinical trials, and why they do not. It has undertaken an economic impact assessment of the clinical research sector in BC which will allow it to benchmark where we are today and make projections for the future of the clinical research enterprise in BC. It is also converting its Clinical Trials and Preclinical Research Asset Map into an online, searchable database. In the areas of ethics reviews, the BC Ethics Harmonization initiative is entering into collaborative ethics review agreements between the major Health Authorities and the four largest Universities. They are also developing a collaborative review model for streamlining initial review and post-approval activities.[2]

Alberta: The Alberta Clinical Research Consortium (ACRC) and the Health Research Ethics Harmonization (HREH) are moving Alberta forward and in turn strengthening Canada's competitive advantage in retaining and attracting clinical research investment. These initiatives involve both academic and community-based researchers and representatives from the health care systems collaborating together to streamline processes from study start up to closure. The partnering organizations include Alberta Health Services, College of Physicians & Surgeons, Covenant Health, Universities of Alberta, Calgary and Lethbridge, and Alberta Innovates Health Solutions (AIHS). Over the past year, the province has agreed upon a roadmap to guide clinical researchers through the administration process. It is working on efficiencies in legal reviews both through participation in the mCTA pilot and through the development of a province wide CDA, which will streamline and reduce the legal review process. Extensive work is being done to improve training and reduce administrative burdens. The latter includes the development of provincial reference documents to assist with budget templates, feasibility assessments, archiving and other areas. In the area of ethics harmonization, Alberta's six Health Information Act (HIA) designated REBs have established legal reciprocity and agreed on common review and approval processes, including a process for reciprocal review of multi-site studies. The REBs

are migrating to common electronic platforms that will align processes, standardize workflow and enable capture of provincial level information for health research ethics. This information will inform ongoing learning and improvements of the harmonized system. In parallel implementation are a common application form and a common reporting form. Common informed consent form templates for clinical trials and health research have been developed and are currently being automated as electronic tools to support development of protocol specific consent forms.[3]

Saskatchewan: The Saskatoon Centre for Patient Oriented Research (SCPOR) is a new facilitative collaboration of the Saskatoon Regional Health Authority, the Saskatchewan Cancer Agency, and the University of Saskatchewan. SCPOR provides support for both investigator-initiated and externally sponsored research trials. Significant headway has been completed in harmonizing provincial Research Ethics Boards. Networking in clinical research is well underway in the three most western provinces including harmonization and adoption of common standard operating procedures for conduct of ethical research in human experimentation. This will provide a population base in excess of 10 million and provide a fertile ground for the conduct of clinical research. Saskatchewan holds some of the longest standing patient databases in North America, furthering the capacity for preclinical and translational work. Intervac and VIDO are actively engaged in vaccine development while the efforts at building a world class facility for imaging using the combined efforts of the Canadian Light Source, Synchrotron and the recently announced Canadian Centre for Nuclear Innovation (CCNI-$30M) funded research cyclotron and PET-CT.[4]

Manitoba: Manitoba has a rich tradition of clinical trials and clinical research. Manitoba is composed of several regional health authorities, however the Health Sciences Centre and St. Boniface Health Centre, do many clinical trials. It is estimated that the Health Sciences Centre, does about 200 clinical trials a year, both industry funding and investigator led. At the Health Sciences Centre, there is a Health Trials program that assists in the startup of clinical trials. All research ethics reviews go through the University of Manitoba. One of the key considerations in Manitoba is how to engage the smaller hospitals that have interest in clinical trials, but who need to build infrastructure capacity. This presents an interesting opportunity for coordination and collaboration, associated with this are the challenges of developing mutually acceptable reciprocal ethics review processes.[5]

Ontario: In response to declining clinical trial activity in Ontario, the Ministry of Economic Development and Innovation (MEDI) sponsored the inception of a new not-for-profit entity called Clinical Trials Ontario (CTO). CTO was officially launched at the 2012 BIO International Convention. Clinical Trials Ontario vision is to help make Ontario a preferred location for global clinical trials activity while maintaining the highest ethical standards and serve as a single point of entry for industry to Ontario. Its vision rests on the three pillars of its Strategic Plan (available: www.ctontario.ca): (1) Improve speed and reduce the cost of multi centre clinical trials by streamlining the research ethics approval process

to a single review in Ontario and harmonizing other administrative platforms; (2) Leverage strategic partnerships with investigators, industry, and government to gain access to global decision makers for clinical trials and attract clinical trial investment to Ontario based on CTO success; (3) Engage patients and the public to recognize the benefits of clinical trials for their own health and that of their families and society and to improve patient recruitment and retention through education. Since its inaugural meeting in July, CTO has established 3 Working Groups on (a) Research Ethics Board Review Streamlining; (b) Information Technology Harmonization; and (c) Institutional Legal Agreements and Liability Issues. These Working Groups begin their work in September 2012 with completion of recommendations by early 2013.[6]

Quebec: In 2009, Quebec's Minister of Economic Development, Innovation and Exports (MDEIE) released a Biopharmaceutical Strategy for the Province of Quebec. This strategy is designed to be complimentary to Quebec's Research and Innovation Strategy and Quebec' Drug policy. As part of this strategy, one of the objectives is to promote Quebec's image as international pharmaceutical hub and to create a very attractive environment for clinical research. To this end, a "Permanent Forum for Information Exchange" (Forum permanent d'echanges) was established that includes representation from the MDEIE, Ministry of Health (MSSS), Rx&D, Fonds de recherche du Québec- Santé (FRQS), Genome Quebec, and Biotech Quebec. FRQS, which represents Quebec's 19 research centers and which has provided funding to the research centers to Improve partnership strategies with industry and enable the resolution of various operational issues related to clinical trials, has created a "Provincial Coordination Committee" (comité de pilotage) which will implement five working groups focusing on resolving the most common cross cutting areas involved in clinical trials in partnership with Industry. These are: (1) streamlining and improving multicenter ethics review; (2) harmonization of contracts and contract negotiations; (3) training in ethics for clinical trialists and staff; (4) streamlining and harmonizing administrative processes in research centers and setting up a mentoring environment (5) defining Provincial Clinical Research Performance metrics. To date a preliminary report was provided to MDEIE with recommendations on common contracts, metrics, training, and streamlining administration issues; a proposal for ethics review harmonization has been developed.[7]

New Brunswick: Clinical research in New Brunswick is supported through a variety of partnerships with key stakeholders, including the New Brunswick Health Research Foundation, specialized research centres like the Atlantic Cancer Research Institute, the medical programs at Dalhousie Medicine New Brunswick in Saint John and Sherbrooke's Centre de Formation Médicale NB, and the two regional health authorities, Vitalité and Horizon Health Networks. Recognizing the importance of creating a favorable research environment, an ambitious strategy to attract and foster research investment, including clinical trial activities, has been undertaken. We have developed units dedicated to clinical trial support, research methodology, and the administration of clinical research agreements. To facilitate the review of ethics submission, regional ethics committees have

been established within each health authority and significant progress in developing inter-institutional reciprocity agreements for ethics review has been made. As we continue to expand our research infrastructure, we will be working with our stakeholders in identifying knowledge clusters within the province, allowing us to leverage expertise and develop new partnership models for advancing research activity.[8]

Nova Scotia: Dalhousie University, Capital District Health Authority and the IWK Health Centre have provided leadership in streamlining procedures for conducting clinical trials in Nova Scotia. A region wide REB and improved collaboration around contracts is being implemented. A larger initiative to bring collaboration across the three Maritime Provinces and increased expertise to all Maritime Provinces is underway in conjunction with the Canadian Institutes of Health Research Strategy on Patient Oriented Research. Internationally, we are striving to position the Maritimes as an added value venue, where sophisticated trials using resources such as our 10 bed inpatient Challenge Unit and sophisticated imaging capabilities including research dedicated MRI and MEG can be an advantage.[9]

Newfoundland and Labrador: Two new initiatives are in place that will streamline and facilitate clinical research trials in Newfoundland and Labrador. In December 2010, construction was completed on the Newfoundland and Labrador Clinical Research Centre. The Centre is a joint initiative of Eastern Health and the Faculty of Medicine at Memorial University, with infrastructure support coming from the Provincial Government and other funding foundations. This Centre for Clinical Research brings the majority of clinical research physically together which improves oversight and coordination of clinical trial activity. Many clinical trials across the clinical spectrum will be coordinated through this Centre. A single Health Region Ethics Authority has also been established which provides oversight and review of all health research in Newfoundland and Labrador. On 1 July 2011, new legislation was proclaimed creating the Health Research Ethics Authority (HREA). Under this Authority, all Clinical Trials research in the Province must be approved by a newly created Health Research Ethics Board. The new central review process for clinical trials is anticipated to simplify, coordinate and expedite clinical trial ethical review in the Province of Newfoundland and Labrador.[10]

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[1] This Addendum was assembled by ACAHO through the contributions of many individuals in different parts of the country. In some cases, submissions used in 2011 for the Summit Background paper were re-used as the basis of these updated paragraphs.

[2] More information on BC's initiatives is available through British Columbia's Clinical Research Infrastructure Network (BCCRIN) and the BC Ethics Harmonization Initiative. Our thanks to Ms. Heather Harris, BCCRIN and Ms. Laurel Evans, University of British Columbia.

[3] More information on initiatives in Alberta is available by contacting Alberta Innovates Health Solutions. Our thanks to Ms. Linda Barrett Smith and Dr. Tammy Mah, Alberta Innovates Health Solutions for assisting us with this section.

[4] More information can be obtained from the Saskatoon Health Region, Saskatoon Centre for Patient Oriented Research. Our thanks to Mr. Gordon McKay for assisting with this section.

[5] More information can be obtained from Health Sciences Centre and St. Boniface. Our thanks to Dr. John Wilkins, Health Sciences Centre, for assisting us with this section.
[6] More information on Ontario initiatives can be obtained from Clinical Trials Ontario. Our thanks to Dr. Ron Heselgrave and Ms. Susan Marlin for assisting us with this section.
[7] More information on Quebec's clinical trial activities is available through FQRS. Our thanks to Dr. Farida Dabouz and Dr. Michel Bureau at FQRS for assisting us with this section.
[8] More information on these initiatives can be obtained through Horizon Health Network. Our thanks to Dr. Edouard Hendricks and Mr. Barry Strack for assisting with this section.
[9] More information on these initiatives can be obtained through Dalhousie, Capital Health and IWK. Our thanks to Dr. Patrick McGrath for assisting us with this section.
[10] More information on these initiatives in Newfoundland can be obtained through Eastern Health and Memorial University. Our thanks to Ms. Katherine Chubb, Dr. Proton Rahman, and Dr. Don McKay for their assistance.