Towards Health & Prosperity…

An Update on an *Action Plan to Help Attract More Clinical Trials to Canada*

Canada's Research-Based Pharmaceutical Companies

R&D

Les compagnies de recherche pharmaceutique du Canada

CIHR IRSC

Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

ACAHO

Association of Canadian Academic Healthcare Organizations

Association canadienne des institutions de santé universitaires

ACISU

A 1st Year Communiqué on Progress Since the Clinical Trials Summit

December 2012

A Message from the Presidents

On behalf of ACAHO, CIHR, and Rx&D, it is our pleasure to provide you with an update on our progress since the 2011 Clinical Trials Summit last September. As you know, the Summit resulted in the Action Plan entitled, *"To Your Health & Prosperity, an Action Plan to Help Attract More Clinical Trials to Canada"*.

Today, less than a year from the release of the Action Plan, with thanks to activities of many organizations and individuals, we are well into its implementation.

In this Communiqué, you will find updates on progress and next steps towards the establishment of a program coordination capability for the action plan; studies on the feasibility of common application and consent forms and strategic ethics review issues; the pilot of the model clinical trial agreement; development of a national asset map; and efforts to improve tax and intellectual property policy as it pertains to clinical trials.

The progress made to advance the specific recommendations is not the only progress made on the Action Plan. Our colleagues across the provinces have allowed us to highlight some of their additional related activities in this update and in an *Addendum* on the ACAHO and Rx&D websites. Most recently, the Senate Standing Committee on Social Affairs, Science and Technology released their report on clinical trials. Their report echoes many of the recommendations in the Summit Action Plan.

It is important to recall that the Summit Action Plan is intended as a starting point focussed on the near-term contributions that can be offered by the country's academic, health care, and research organizations, the national and provincial bodies they work with, and Canada's research-based pharmaceutical companies. As progress is made, collaborative opportunities and next steps can evolve.

We hope that what you read here will be useful and encouraging. If you have questions or comments, contact information is enclosed. Finally, we look forward to continuing this journey with you – and to the human, social, scientific and economic benefits of more clinical trials for Canada. We thank you for your continued support & leadership.

Glenn G. Brimacombe
President & CEO
ACAHO

Dr. Alain Beaudet
President & CEO
CIHR

Russell Williams
President & CEO
Rx&D

Executive Summary

Towards Health and Prosperity is an update on the first year since the National Clinical Trials Summit of September 2011. In the first six months following the Summit, ACAHO, CIHR, and Rx&D worked with stakeholders to confirm the proceedings and priorities, and then drafted and consulted upon the draft Action Plan, entitled *To Your Health & Prosperity, an Action Plan to Help Attract More Clinical trials to Canada.* All of these materials are available on the ACAHO and Rx&D websites.

In the six months following the release of the Action Plan in March 2012, many activities have helped to advance the recommendations. The table below provides the 6-month update and anticipated next steps. Additional activities occuring in each province are also briefly discussed within this document.

Action Plan's Status as at September 30, 2012 & Anticipated Next Steps		
Recommendation in *To Your Health & Prosperity*	**Current Status** (March 31, 2012 to September 30, 2012)	**Next Steps & Timeline**
1: National headquarters to oversee Action Plan & to coordinate related clinical trial activities.	✓ The recommendation was presented to the National Steering Committee of the Strategy for Patient Oriented Research (SPOR) & received support in principle. ✓ CIHR developed a proposal for the establishment of an external headquarters via a competitive RFA process. ✓ Consultation on this initial proposal completed & new options are being explored with stakeholders.	✓ Work will continue to determine and secure the structure and resources needed for the headquarters. ✓ Timeline: Summer 2013 for initial inception of headquarters.
2: Metrics to evaluate & market progress on Action Plan's goals	✓ Metrics presented by Rx&D at the Summit continue to be collected. ✓ Organizations outside of CIHR, Rx&D & ACAHO also advanced issue.	✓ Dataset will be proposed from existing metrics. ✓ Timeline: once headquarters established.
3: Bold vision for health care and research ecosystems	✓ SPOR has made key announcements (see CIHR website) illustrating a forward looking vision. ✓ ACAHO and Rx&D's Federal Budget Consultation submissions provide examples of issues being pursued.	✓ As other Action Plan recommendations are completed, this will drive future summit foci and next steps considerations. ✓ Timeline: ongoing.
4: Improve ethics review efficiency, and study feasibility	✓ As part of SPOR, CIHR has struck an external Ethics Advisory Committee. ✓ Completed analysis of application	✓ The SPOR Ethics Advisory Committee will make its recommendations to the

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of common consent, application, and harmonization	& consent forms & literature review. ✓ Key informant interviews ongoing to determine recommendations for ethics review harmonization, etc.	SPOR National Steering Committee. ✓ Consultations & next steps to be determined. ✓ Timeline: Spring 2013.
5: National patient registries & recruitment plan	✓ This recommendation has yet to be pursued by ACAHO, Rx&D or CIHR.	✓ Timeline: To be pursued upon establishment of headquarters.
6: Common standard operating procedures, training & certification	✓ The Network of Networks (N2) continues to advance and support excellence, trust and efficiency in clinical research. ✓ ACAHO has drafted a discussion document to explore the concept of certification.	✓ To be pursued upon establishment of the headquarters.
7: A model clinical trials agreement (mCTA) to help streamline the negotiation process and reduce start up times	✓ Phase I of the mCTA was the draft proposed at the Summit. ✓ Phase II was the mCTA pilot which indicated: (1) sponsors experienced 3 process issues (outside of basic clause issues) that must be addressed; (2) clinical sites agree to most of the mCTA but have common areas of concern; and (3) Quebec and British Columbia have made advancements to the mCTA that can be considered nationally. Phase III follows.	✓ Step 1: Clinical trial sites will be asked to review Quebec and BC solutions to common issues and agree on modifications. ✓ Step 2: Sponsors will work with Rx&D to review a modified version and address process issues. ✓ Step 3: Sites & sponsors will reconvene. ✓ Timeline: Summer 2013 for completion of Phase III.
8: Optimized intellectual property protection & SR&ED Tax Credits	✓ Rx&D has led a campaign to help bring Canada to standards commensurate with Europe's ✓ Discussions to increase utility of the SR&ED credits continue.	✓ Partners will continue to leverage opportunities for improvements. ✓ Timeline: ongoing.
9: National Clinical Trials Asset Map	✓ A committee has been struck with members from industry, health care, government, & others. ✓ Reviewed existing disease, domain & regional asset maps. ✓ Initial scoping parameters set.	✓ A stakeholder survey will be conducted to refine database scope. ✓ Terms of use will be developed. ✓ Timeline: ongoing.

Towards Health & Prosperity…

What progress has been achieved in the year since the National Clinical Trials Summit? Do we have an Action Plan? How is it being mobilized?

This document provides an update on the year since the National Clinical Trials Summit and a six-month status report since the release of *"To Your Health & Prosperity: An Action Plan to Help Attract More Clinical Trials to Canada".* The document serves the practical purpose of keeping all stakeholders informed of efforts at the national level to address operational issues discouraging clinical trial investment in Canada. It is also intended as an expression of accountability and appreciation to the many organizations and individuals contributing to any of the Summit or Action Plan's recommendations, goals, and vision.

I. Towards an Action Plan…

The purpose of the National Clinical Trials Summit of September 2011 was to develop an Action Plan to help Canada regain its capacity to attract clinical trials. The resulting Action Plan is called *"To Your Health & Prosperity: An Action Plan to Help Attract More Clinical Trials to Canada".*

To develop the Action Plan, in the first six months after the Summit, ACAHO, Rx&D and CIHR worked with Summit participants, their members, and other stakeholders within the clinical trials community to transform the Summit feedback into a realistic, effective, feasible, and desirable plan of action. This involved the following:

- ✓ *"Towards an Action Plan: Proceedings & Implications of the National Clinical Trials Summit"* was released along with a "translation" of the feedback into 40 potential actions.
- ✓ A *"Request to the Reader"* was circulated with the proceedings to validate and prioritize the proposed action items and identify missing items.
- ✓ The resulting material allowed for the selection and framing of the 9 recommendations in *"To Your Health & Prosperity".*
- ✓ The Action Plan was released in draft for feedback. The feedback was supportive & highly instructional on how to ensure implementation success.
- ✓ The feedback to the final draft Action Plan is summarized in an appendix which is now part of the final document.

Readers will find the proceedings, Action Plan, and the Summit presentations on the ACAHO and Rx&D websites.

II. Acting According to Plan…

"To Your Health & Prosperity: An Action Plan to Help Attract More Clinical Trials to Canada" contains nine recommendations. The recommendations are specific and intended to be a starting point for addressing a number of operational issues affecting Canada's capacity to retain industry-led clinical trial investments. In this section, we review each of these nine recommendations from the perspectives of ACAHO, Rx&D and CIHR. We provide an update on the current status and the proposed next steps. A summary is available on pages 3-4.

1. A national headquarters for clinical trial improvement activities

The Action Plan's first recommendation was the establishment of a national headquarters to oversee its implementation and serve as a coordinating mechanism for regional and domain-specific clinical trial improvement activities.

Some stakeholders expressed a preference to align this headquarters under the Strategy for Patient-Oriented Research (SPOR). In May of 2012, CIHR discussed this with the National Steering Committee of SPOR. While the Steering Committee is strongly supportive of the Action Plan, determining a mechanism to support a national headquarters presents a number of challenges.

To help explore options, consideration was given to a proposal that a competitive RFA process be used to enable the rapid establishment of a headquarters outside of CIHR. The inherent risk of inadvertently creating competition where the full collaboration of all is required was recognized. Under the leadership of CIHR, organizations are now engaged in exploring additional options through which all stakeholders may be involved in a pan-Canadian solution.

In the meantime, each of the sponsors as well as many other national and provincial organizations is providing interim resources and informal support to mobilize the Action Plan. The experience of working informally with leaders across the country who care deeply about Canada's success in clinical trials, speaks volumes about the potential of what can be achieved. More information will be forthcoming in 2013.

2. Measuring, monitoring and marketing progress and performance

The second recommendation in the Action Plan is about the metrics that will help us to understand if we are achieving the goals of helping to reverse or improve the downward investment trend; improve our business landscape; and create a forward looking opportunity for the future. This is an essential consideration because simply satisfying each recommendation is necessary but not sufficient to reach the vision and mobilize its goals.

Several independent groups, including Rx&D, are already studying metrics such as speed of recruitment, patient retention, and overall costs. The original metrics presented by Rx&D at the Summit are now also being published in the peer reviewed literature. Next steps are to bring experts together so that a number of key common measures can be selected and implemented nationally. Further work on this recommendation will ensue upon establishment of the headquarters.

 # 3. A bold long-term vision for health and research

While the Action Plan's operational recommendations are considered important starting points, it was well understood that clinical trial success goes far beyond operational issues. To be truly successful, Canada needs to further build and maintain robust healthcare and research ecosystems.

Recommendation 3 of the Action Plan captured this relationship. It is a longer term issue at the heart of many organizations' strategic and advocacy efforts.

For readers interested in the types of issues and efforts that Rx&D and ACAHO have made in raising and addressing these broader issues, their respective August 2012 Pre-budget Consultation Submissions to the Federal Government for Budget 2013 will provide a suitable overview. These submissions are available through the ACAHO and Rx&D websites and through the Parliament of Canada website.

Addressing the broader issues affecting clinical research has also been at the heart of SPOR. Since September 2012, there have been important and exciting announcements on elements of SPOR programs that are now available on the CIHR website.

 # 4. Protecting people and promoting research through ethics reviews

While Canada is known for its ethical vigilance in research involving humans, many experts in the ethics review community believe that this can be maintained while improving efficiency. For this reason, Recommendation 4 in *To Your Health and Prosperity* was to explore the feasibility of common application, consent, and harmonization strategies for Canada.

It should be noted that the progress made on this recommendation is not a direct result of the Clinical Trials Summit. Rather, a CIHR SPOR Ethics Advisory Committee established in March 2012 was struck to provide advice to the SPOR National Steering Committee about streamlining multisite research ethics reviews and improving the efficiency of patient-oriented research. Rx&D and ACAHO proposed that this Committee's advice to SPOR could also be considered in response to recommendation 4 of the Action Plan.

Progress to date includes:

- ✓ CIHR has commissioned a study of Research Ethics Board application and consent forms. An expert was retained to inventory forms from across the country; interview stakeholders; assess the literature; and discuss the feasibility of a common consent and application form across Canada. The report is being finalized and next steps will be determined.

- ✓ Recognizing that application and consent forms are only part of larger harmonization issues, the Committee has undertaken a set of interviews with experts across the country on the types of harmonization initiatives undertaken and the key learnings. These interviews will allow the Committee to determine its recommendations and will provide useful information to other experts in this area.

As next steps, the Committee will complete its reports and recommendations, present them to the SPOR National Steering Committee. It may also seek further instructions and resources for broader consultation and next steps. Its reports and recommendations will be available in the Winter of 2013. In the meantime, each province is also diligently pursuing improvements in the areas of ethics reviews (see page 12).

 # 5. Patient recruitment – a national strategy & a database of registries

Recommendation 5 of the Action Plan was about patient recruitment and will be initiated in 2013. It has two components that reflect what appear to be two schools of thought on patient recruitment. In the first, it is believed that Canada needs a national patient recruitment strategy. In the second, notwithstanding privacy concerns that need to be addressed, it is believed that Canada needs a database of registries so that patients can be found against complex inclusion and eligibility criteria. Work on this file is anticipated to accelerate once the national clinical trial headquarters is established.

 # 6. Efficiency and trust with common standards, training, & certification

Recommendation 6 in the Action Plan was about adopting common standard operating procedures (SOPs) and training modules at clinical trial sites across the country. It was also about certifying organizations adopting common approaches so that search costs for investors could be reduced. Since many organizations already adopt the SOPs and training modules of the Network of Networks (N2), the recommendation also called for funding to assist N2 in expanding and/or stabilizing its capacity to assist the clinical trials community. Since the Action Plan:

- ✓ N2 has provided ACAHO, Rx&D and CIHR with a letter of support in principle for this recommendation and for the Action Plan.

- ✓ ACAHO has drafted a preliminary discussion document to initiate conversations with N2 about what a certification program might look like.

Aside from these two very preliminary items, no further work on recommendation 6 has yet been pursued by CIHR, Rx&D or ACAHO. However, N2 has continued to support excellence, trust and efficiency for clinical research operations in Canada. While recommendation 6 references N2 in the context of SOPs and training, N2 also provides a national forum for addressing many other clinical trial issues at the national level. More work on this file is anticipated once a headquarters is established.

7. Getting to Yes – a model Clinical Trial Agreement (mCTA)

Launched at the Clinical Trials Summit, the model Clinical Trial Agreement's (mCTA) progress is the essence of Recommendation 7 in the Action Plan. Recommendation 7 calls for the improvement and implementation of the template into practice. To facilitate this, CIHR led a pilot study on the mCTA that has recently ended. During this time, provincial bodies and pilot participants made outstanding efforts to advance the mCTA. The learnings to date include the following:

- ✓ Both clinical trial sites and sponsors provided helpful feedback on the process of using the mCTA and on the clauses within the contract. At least in part due to the aggressive timelines, participants in the pilot had difficulty using the mCTA as the basis of actual clinical trial agreement negotiations.

- ✓ The feedback from sponsors suggests that they experienced three types of difficulties: (1) achieving clearance from global head offices; (2) addressing change management issues at the national offices; and (3) possibly because of staff turnover issues, understanding the pilot methodology.

- ✓ The feedback from clinical trial sites suggests that most of the mCTA's clauses are acceptable, with a few exceptions. These will need to be adjusted. They included: Indemnification, Limitation of liability, Insurance, Subject Injury, and Governing Law.

- ✓ In Québec, the FQRS has made specific revisions to the mCTA so that it can be acceptable to the Québec Civil Code; its provincial regulations; and consequently to all clinical trial sites in Québec. Its revised version was submitted to the sponsors as a translated and tracked document in order to further facilitate the pan-Canadian vision for the mCTA.

- ✓ The British Columbia Clinical Research Infrastructure Network (BCCRIN) has worked with BC insurers to find language that will make the mCTA

acceptable to all of BC's clinical trial sites. The proposals of BCCRIN will also be offered to other clinical trial sites to help address relevant issues.

It is clear that implementing the mCTA in Canada is not simply an issue of amending clauses. In order for the mCTA to be successful, it must be approached from both a change management and content management perspective.

It is also clear from the number of letters that CIHR received from both the clinical trial sites and sponsors, that there is a willingness to persevere in order to make the mCTA a reality in Canada. As such, Phase III of the mCTA is proposed as follows:

- ✓ **Step 1:** Using the pilot feedback from the sites, the work of the FQRS in proposing language to make the mCTA consistent with the Civil Code, and the efforts of BCCRIN in incorporating the language of insurers, the clinical sites will propose a modified draft of the mCTA to address the limited number of concerns about the mCTA from the clinical trial site perspective.
- ✓ **Step 2**: Once a revised version, or at least clear messages, can be sent back to the sponsors, Rx&D will reconvene the sponsors in a within-sponsor and cross-sponsor conversation on both the content and the process of implementing the mCTA within their companies.
- ✓ **Step 3:** Sponsors and sites will be re-engaged in an advanced discussion of the mCTA to evaluate the next steps and then implement the mCTA.

 # 8. Maximizing incentives – intellectual property (IP) and tax policy

As per the first part of this recommendation, Rx&D has been working diligently to advance strategic issues as they pertain to life sciences intellectual property (IP) issues. This includes advocating for the Federal Government to conclude the Comprehensive Economic & Trade Agreement (CETA) with the European Union (EU) with positive IP improvements as part of the larger agreement.

Such a conclusion would help to strengthen Canada's intellectual property (IP) protections for life sciences to levels already in place in the other major developed countries. By harmonizing IP standards with the EU, Canada will become a more attractive, secure, and sustainable place for investment. This is essential to sustaining Canada's life sciences sector and to maximizing investment into Canadian clinical science from global sources.

The second part of this recommendation addresses ways to help improve the administration of Scientific Research & Experimental Development (SR&ED) tax credit such that credits are received in time to offset the costs of trials. Since the SR&ED program has become an area of focus for the Federal Government, the Summit sponsors will continue to monitor opportunities to advance this issue.

9. Communicating Canada's clinical trial assets

Recommendation 9 in the Action Plan concerns the establishment of a national clinical trials asset map that would serve as the first step towards a potential "storefront" for global sponsors. The goal is to communicate key information, enable strategic marketing, and facilitate information gathering where possible.

In a unique initiative led by Rx&D and involving members of ACAHO, CIHR, the Department of Foreign Affairs and International Trade, Industry Canada, Health Canada, N2, national and provincial clinical trials bodies, and others, a committee has been struck to develop a Clinical Trials Asset Map for Canada.

The project aims to create a one-stop and web-based tool to communicate key clinical trial asset information to both academic and commercial sponsors. It also seeks to leverage and integrate asset map experiences and initiatives already completed by region or discipline to the extent possible. To date, the Clinical Trials Asset Map committee has accomplished the following:

- ✓ Established a diverse committee membership which includes clinical sites, trial sponsors, organizing bodies, key government departments and others.
- ✓ Consulted with members of Rx&D, as a primary audience and end user, to reconfirm the required broad scope of the asset map.
- ✓ Collected and reviewed over 20 existing asset maps from across the country to assess design options and integration potential.
- ✓ Developed preliminary recommendations for database structure to maximize its effectiveness and value.

Key principles upon which the initiative is being developed include: optimizing the scope and application of the tool; ensuring technological capacity to shape and grow the asset map as stakeholder needs evolve; and considering feasibility issues for both end user and data supplier perspectives. The goal is to complete this recommendation by the Fall of 2013.

III. Foreshadowing the Future – Looking to the Provinces

In many respects, the success of a national Action Plan stands on the shoulders of experts and other stakeholders who have the capacity to implement solutions that address regional and domain specific needs while working within a meaningful pan-Canadian vision. This is the essence of Canada's capacity to maximize value in each region while integrating multiple smaller markets into a coherent national landscape that can compete with the consolidation efforts of comparator countries. In this section, our colleagues in the provinces have offered a snapshot of sample initiatives from their perspectives. More detail, acknowledgements, and contact information are available in an Addendum to this Communiqué which is available on the ACAHO and Rx&D websites. Our thanks to all who contributed.

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 ✓ 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.

Provincial Body	Examples of activity areas relevant to *To Your Health & Prosperity Action Plan* Recommendations (potential leverage points for future)
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 bring the majority of clinical research physically together which 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.

Concluding Remarks

In this update, we have described the year since the Clinical Trials Summit of September 2011 and the status of the recommendations in *To Your Health & Prosperity, an Action Plan to Help Attract More Clinical Trials to Canada* at the six month mark. We hope that what you have read in this paper is useful and reassuring of a collective commitment to the Action Plan.

If you have related questions that are not answered in this document, or ideas or comments that you would like to share, please contact any of Dr. Tina Saryeddine, Assistant Vice President Research and Policy Analysis at ACAHO [saryeddine@acaho.org]; Dr. Kenneth Hughes Vice President Scientific Affairs and Regulatory Affairs at Rx&D [khughes@canadapharma.ca]; or Mr. Geoffrey Hynes, Project Lead SPOR, CIHR [geoffrey.hynes@cihr-irsc.gc.ca].

On behalf of CIHR, Rx&D and ACAHO, we once again thank you for your support and interest in advancing the Action Plan. We believe that as we address these operational issues together, we also strengthen a collective capacity for collaboration, health, innovation and investment. We look forward to continuing the journey with you.

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)

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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
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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.