An Update on the Model Clinical Trials Agreement– A perspective from ACAHO-CHA (Phase III step 1)

Presentation to Clinical Trials Ontario
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Presentation Overview

1. Meet ‘Newly Merged ACAHO-CHA’
2. Where did the mCTA come from? (Phase I)
3. What did we learn when we pilot tested it? (Phase II)
4. What are we doing about the test results? (Phase III.1)
5. Where are we now & what’s next?

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Meet newly merged ACAHO-CHA…

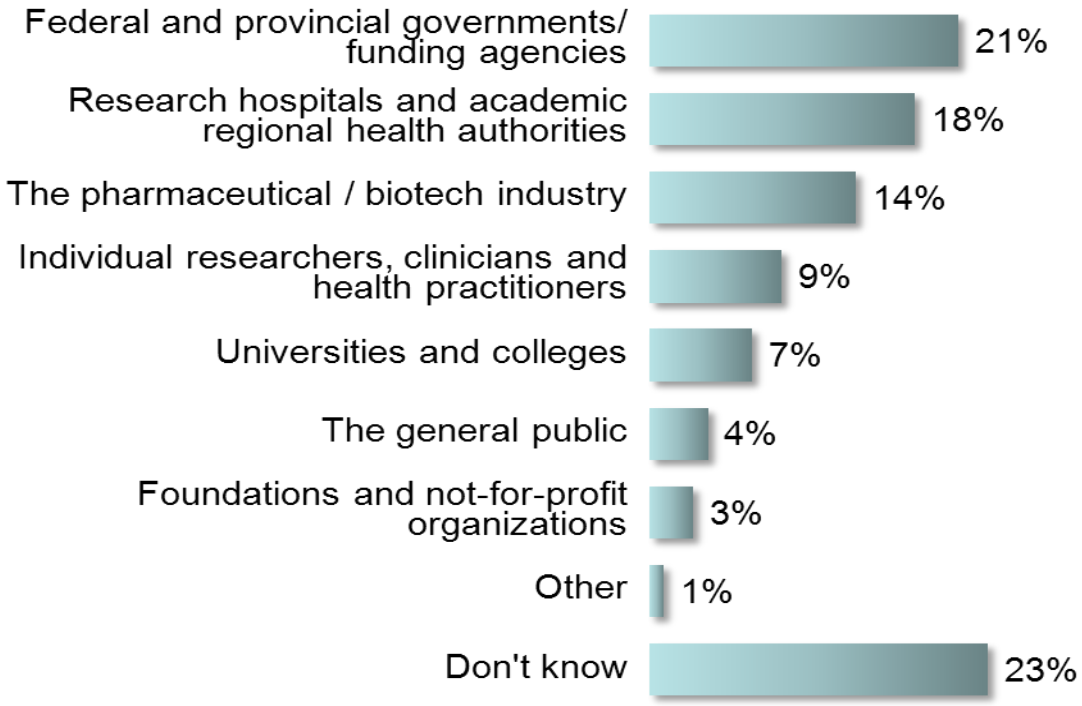
The national voice of healthcare organizations, including research hospitals, academic regional health authorities & their research institutes.

Vision Statement: To improve the health of Canadians through evidence, innovation, and infrastructure.

Mission Statement: To advance a health care system that provides Canadians with world-leading health services.

Responsible for Introducing New Innovation into Canadian Health Care System

Source: Health Care in Canada Survey, 2013-2014



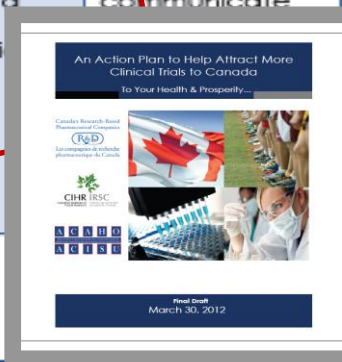
QK1: Which one health care stakeholder do you think is currently most responsible for introducing new innovation into the health care system in Canada? (n=1000)

POLLARA

Vision: Canada a premier country for industry led C.T.s

Goals: (1) help improve negative trend, (2) improve business operations, (3) position positively for future.

Strategy 1: Establish short & longer term implementation capacity for this action plan & coordination of other CT improvement activities		**Strategy 2: Improve business operations through better cost, quality, and speed of clinical trial start up times.**		**Strategy 3: Shape a positive future business environment & signal Canada's interest globally with information& incentives.**	
Recommendation	**Details**	**Recommendation**	**Details**	**Recommendation**	**Details**
Recommendation 1. Establish an implementation headquarters & resources to implement action plan & to coordinate existing clinical trial improvement activity.	Coordination & implementation focus & resource are required for this plan as is coordination of existing CT initiatives. CIHR SPOR leadership to be approached.	Recommendation 4. Improve efficiencies of ethics reviews- common forms and metrics and advance strategic considerations like accreditation & harmonization.	Leveraging appropriate expertise, common consent & ethics application forms will be developed to reduce confusion and cost. It will begin with feasibility & option assessment. Strategic issues like accreditation also require detailing.	Recommendation 8. Optimize intellectual property protection policy & SR&ED Tax Credits	We can improve the attractiveness of Canada as an investment partner by adjusting IP and SR&ED policy.
Recommendation 2. Measure, monitor, manage and market CT performance improvements	As the intent of the plan is to attract business, results need to be measured & communicated.	Recommendation 5. Develop a database of registries to identify eligible patients & consider national recruitment strategy.	Using appropriate privacy considerations, improve recruitment by focussing on the use of registries & a national recruitment strategy.	Recommendation 9. Signal our interest globally - open a concierge (storefront) servi for investors	Beginning on a small scale, communicate
Recommendation 3. Integrate health system and research infrastructure to address issues which affect CTs because of the impact on research and healthcare.	A bold long term vision is needed for issues impacting health care & research & thereby CTs. This will enable cost containment considerations and sustainability.	Recommendation 6. Adopt common SOPs, training and certification that are already available.	Resources will be sought for broader use of N2's common SOPs, training & certification to increase trust & efficiency.		
		Recommendation 7. Improve and use the model clinical trials contract (mCTA)	Upon pilot completion, adjust the mCTA as needed & communicate use to global offices.		



Where did the mCTA come from?

- Started with “CAHO principles” & Rx&D contract review
- Phase I: Draft of mCTA by Rx&D & ACAHO members

Vogel, L. 2011. Boilerplate being tested for clinical trials. Canadian Medical Association Journal. V. 183 n. 16

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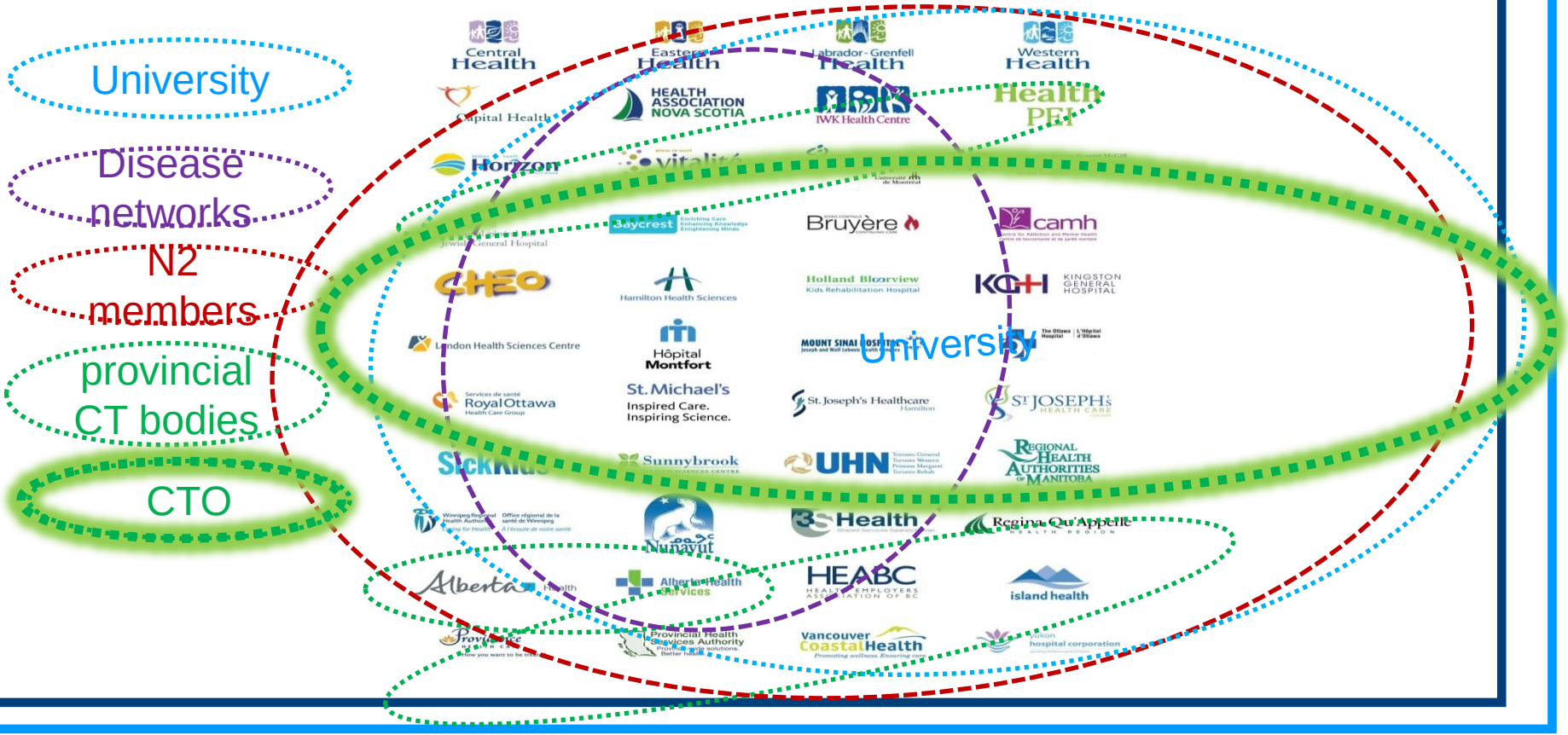
How was the mCTA pilot tested?

- Pilot methods: Sites and pharma asked to pilot test mCTA in actual negotiations, record changes, and submit them as “data”.
- Results - Industry: Serious process issues even before getting to content, such as approvals, so change in pilot methods
    - Instead of “negotiation” data, descriptive assessments
- Results - Sites: General agreement except on indemnification, limitation of liability, insurance, subject injury, governing law.
    - Surprise!? Advanced versions of mCTA in BC & QC

What did we learn mCTA & ACAHO-CHA?



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What are we doing re the pilot results? (Phase III)

Methods:

- **Step 1: Sites prepare a clean copy /clear messages**
- **Step 2: Sponsors work through process & content**
- **Step 3: Sites & sponsors reconvene**

Step 1: Quebec & BC versions of the mCTA reconciled by Ontario lawyer. Reconciled version circulated to all ACAHO members. However, feedback process led by provinces.

Clinical Trials Ontario leadership on mCTA

- 16 institutions contributed to the Ontario response to the draft national model Clinical Trial Agreement (mCTA).
- A working group was established to review the initial feedback with a view to developing a single, coordinated Ontario response
- The draft Ontario response to the mCTA with consensus changes was circulated to Ontario institutions for final comment prior to submission to ACAHO

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Options discussed for moving forward…

- Option 1: Aim to stop at province specific versions of mCTA, articulating key messages at a national level.
- Option 2: Aim to put in each province's needs and preferences and focus on the best way to present it.
- Option 3: Aim for agreement on discretionary items leaving province specific inserts for legislative items.

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What are ACAHO-CHA's next steps?…

- Finalize a single document with provincial specifications.
- Move the project under the leadership of the Canadian Clinical Trials Coordinating Centre (CCTCC).
- Re-engage industry and broader array of stakeholders as necessary while keeping provincial ties.
- Re-evaluate appropriateness of step 2 and 3 and proceed or regroup.

Thank you to the very large number of contributors….

Presentation to Clinical Trials Ontario
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