

Making the Connection

This edition of the *Catalyst* shines a spotlight on the start-up of Clinical Trials Ontario (CTO) and the significance of this initiative for a healthier and wealthier Ontario. CTO is an example of a strong partnership built around the pursuit of a common objective – streamline review processes to attract investment while maintaining the highest ethical standards. This objective directly supports CAHO's mission to translate research evidence into practice for the benefit of the healthcare system and increasing investment in healthcare research.

Several key actors have helped make CTO a reality. The Ministry of Economic Development and Innovation (MEDI) will invest \$1.5 million each year for the next three years in CTO. CAHO facilitated the formation of the Clinical Trials Stakeholder Association and advancing the proposal to create CTO. Industry has actively collaborated with government, hospitals, academia and other key stakeholders. Together we are all trying to create a more competitive environment for industry-led clinical trials in Ontario. However, the foundation for Ontario's competitiveness in clinical trials is a thriving health research enterprise.

A thriving health research enterprise provides an innovation platform capable of attracting transforming industry investment into something meaningful, producing results and outcomes Ontarians, the provincial government and the CAHO community desire. Channeling this investment requires collaboration and support and CTO is a great step in the right direction. We also need to concentrate on strategies that will ensure the sustainability and growth of a globally competitive and unique health research enterprise.

The benefits are increasingly apparent. Many CAHO members have commercialization offices that transform medical discoveries into jobs and opportunities. Our member hospitals hold a multitude of patents for world-class discoveries and most are licensing their discoveries. The CAHO community translates these findings into spin-off companies with direct contributions to Ontario's economy.

The CAHO community is committed to working with the Ontario Government to maximize these opportunities. We continue to make great progress across our community on moving research evidence into practice through our ARTIC Program – a made in Ontario innovation that is being applied across the system to improve care and reduce costs. As a result of our first CAHO ARTIC Project, a company, HandyMetrics, was created employing six people and serving over 100 hospital sites across Canada and attracting world-wide interest.

Looking ahead, CAHO, with industry and government stakeholders, will need to work in the same spirit of collaboration to put an Ontario Health Research and Innovation Strategy in place. We need to do all we can to maximize the value of Ontario's investment in health care. A strategy would coordinate and align the many moving parts of Ontario's health research enterprise, improving the efficiency of delivery of new discoveries, providing evidence for best practices, and a stronger health-based economy for Ontario – harnessing our collective innovation and directing it intelligently.

We need to work together to address some key challenges: coordination and sustainability of research funding, facilitating commercialization and developing pathways for translating research evidence into practice. The outcomes from such a strategy would include improved patient care, jobs and wealth creation, improved coordination and collaboration between stakeholders, investment and priorities.

As Ontario continues to develop a knowledge-based economy, investments in the health research enterprise play a critical role in the competitiveness of Ontario on the global stage. As our members continue to create jobs and economic value, it is important emphasize the need for these investments in research to continue to develop these commercial opportunities. Focusing on the long-term goals of the health research enterprise in Ontario allows the CAHO community to continue being critical contributors to a healthier and wealthier Ontario.

In the Spotlight

Dr. Paige is an internationally recognized leader in the area of lymphocyte development and antibody formation. He is using his knowledge of immunology to train the immune system to recognize and kill cancer cells. He earned a Ph.D. in Immunology at the Sloan-Kettering Division of Cornell University Graduate School of Medical Sciences. He was a Member of the Basel Institute for Immunology in Switzerland (1980-1987) before joining the Ontario Cancer Institute as a Senior Scientist in 1987.

In 1990, Dr. Paige became the founding Director of the Arthritis and Autoimmunity Research Centre as well as Director of Research at The Wellesley Hospital. In 1998, he returned to the Ontario Cancer Institute to assume the role of Vice-President, Research and, subsequently, he assumed his current position of Vice-President, Research, University Health Network.

A Professor in the Departments of Medical Biophysics and Immunology at the University of Toronto, Dr. Paige is an active educator in the undergraduate, graduate and postgraduate programs of the University. Dr. Paige is active in promoting public policy that supports technology innovation and commercialization in Ontario and Canada and has also founded UHN Shanghai a company based in China that provides chemistry services for drug development and serves as a link to Shanghai academic and private sector institutions.

CAHO Catalyst recently sat down with Chris and asked him to reflect on his career and the current challenges facing health research in Ontario.

1. To date, you have had a tremendous career as both a professor and a researcher. What are you most proud of in your career?

I am not sure I can give you a "most" but I find it extremely satisfying to receive the hard bound copy of a successful PhD thesis from one of my University of Toronto graduating students (17 and counting). I am also proud of the many institutional and team grants that I have had the opportunity to influence – in particular the Research Hospital Fund grant which helped us to significantly increase the research footprint at UHN - this was the combined efforts of more than 70 researchers. Finally, the fact the UHN thinks of itself as a Research Hospital – not a hospital where research happens to occur – is something that makes me very pleased, although, again, this is not a singular achievement but one supported by hundreds of our clinicians, researchers, and enlightened administrative leads.

2. What do you see as the biggest challenges in your current role?

Navigating a difficult funding environment is always a challenge – also ensuring that the return on investment is clearly depicted for our funders in government, industry, and the philanthropic community. We also have to make sure that return on investment (ROI) is understood not just in financial terms but also in the impact our innovations have on the health and well being of patients and families in Ontario and worldwide. That said, government funders of health care need to recognize that there is a cost to innovation. I believe that the health of Ontarians depends on the health of our research hospitals and their extended care networks.

3. You have been active in a number of clinical trials initiatives at both the federal and provincial level. Do you think the CAHO community can be a catalyst for creating a stronger health research enterprise for Ontario?

I strongly believe that Ontario can be a magnet for clinical trials. This will benefit Ontario patients and families by providing additional treatment options and also help build the groundwork for additional investments in the biomedical sciences. CAHO hospitals already support many internationally recognized opinion leaders in most key clinical disciplines. We are making progress in streamlining the trial approval process while maintaining the highest standards for patient safety, and I think it is now recognized that we need increased computational power designed specifically for hospital data repositories. We are also experiencing unprecedented cooperation in disseminating best practice information. So yes, I think CAHO has a very important role in creating a stronger health research enterprise for Ontario.

4. Can you share with CAHO Catalyst some of the research priorities of UHN?

We have strong commitments to the full spectrum of research – discovery, translational, clinical – and we are increasingly our emphasis on health services research. UHN is a living laboratory to pilot health innovations not only in terms of new diagnostics and treatments but also in how to deliver care in a complex environment that includes different levels of hospital and community care.

5. When you are not at UHN or the University of Toronto, what do you like to do in your spare time?

Colleen and I generally find time to charter a sailboat with a few friends in warm ocean waters. When you sail you almost always end up in a nice place, although the actual destination and arrival time depends on the strength and direction of the wind – attention to navigation keeps you off the reefs – in some ways, not too different from my day job.

CAHO News**Modernizing the clinical trials process in Ontario**

In July 2012, the inaugural meeting of [Clinical Trials Ontario \(CTO\)](#) was held marking an important milestone in the growth of a dynamic clinical trials program in Ontario. The work being undertaken by CTO will help attract investment in the health research enterprise giving Ontarians access to innovative treatments developed by the best and brightest researchers and clinicians in the health care system.

Clinical trials are required to bring safe, innovative and effective treatments to patients. Because the pace of medical discoveries is accelerating, pressure on researchers to complete clinical trials quickly and efficiently while maintaining the highest ethical standards is increasing.

Ontario is facing increased competition for industry investment in clinical trials from jurisdictions in the developing world offering generous tax and other incentives. To combat this, Ontario has committed to leveraging competitive advantages, such as employing world-class clinicians and researchers, a centralized health care system and sharing common North American practices and regulatory frameworks, to attract investment.

To get to this point, in November 2010, the Ministry of Economic Development and Innovation (MEDI) brought together a group of stakeholders to submit recommendations on how best to streamline the ethics review process for industry-sponsored multi-site clinical trials in Ontario. In 2011, CAHO played an active role in the process of developing of the Clinical Trials Stakeholders Association (CTSA), the precursor to Clinical Trials Ontario (CTO). Through the CTSA, CAHO along with key stakeholders including universities, industry and hospitals put forward a proposal for addressing the challenges of investment competitiveness while meeting the highest ethical standards. Based on the Strategic Plan developed by CTO, the Ministry of Economic Development and Innovation (MEDI) made a three-year commitment in June 2012 to invest \$1.5 million annually in the start-up of CTO to implement the CTSA recommendations.

Clinical Trials Ontario has been created to serve as a central organization to improve the speed of trials and reduce costs by moving towards a coordinated, streamlined and seamless model for multi-site clinical trials. Also, CTO is working improve patient recruitment by engaging patients and the public to recognize the benefits of clinical trials. Other developed nations have moved to a similar streamlined model and have seen an increase in their market shares.

Under the current process, when bringing forward new treatments, industry partners work with a number of different sites on a clinical trial and each site would conduct their own Research Ethics Board (REB) review. While thorough in its reviews, the numerous, and sometimes discrepant, reviews across various sites are both resource intensive and slow down the launch of a clinical trial across all sites.

A streamlined process reduces duplication and accelerates start-up times by producing one REB review and harmonizing administrative processes. This approach will also provide the highest quality of review and ensure the highest standard of patient safety while increasing patient access to investigational therapies.

Ontario is home to a diverse population that enables the development of an understanding on a drug's impact on different subgroups. As clinical trials become more complex, the challenge in finding suitable candidates for patient recruitment has grown. To combat this, Clinical Trials Ontario is looking to engage patients and the public to recognize the benefits of clinical trials to their own health and improve patient recruitment through education.

In its first year of operation, CTO has identified five core projects to focus on:

1. Developing Ontario standards for clinical trials
2. Defining the framework for streamlining research ethics reviews
3. Developing standard operating procedures for the research ethics board review system
4. Conducting an evaluation and analysis of current online administrative and application systems
5. Developing appropriate clinical trial metrics and targets to support financial sustainability

In addition, three working groups have been established to provide advice and recommendations for the five core projects. These working groups feature experts and leaders within the CAHO community and community hospitals, academia and industry. The focus of the working groups are on streamlining research ethics reviews, information technology harmonization and legal and liability issues to support the single REB review model. The working groups are expected to complete their work by early 2013.

CAHO is committed to the modernization of the clinical trial process and helping Ontario to compete aggressively for investment while maintaining the highest ethical standards. As the CTO mandate continues to evolve, the CAHO community is committed to partnering in the success of CTO in order to advance the stability of, and increased investment in, the health research enterprise, especially as CAHO member hospitals engage extensively in clinical trial partnerships. By doing this, Ontario will remain an attractive place for investment while infusing innovation and cutting-edge health research into its health care system.



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