TABLE OF CONTENTS

| Executive Summary 1 |
| Ontario: A Clinical Trials Powerhouse 5 |
| Clinical Trials: The Ontario Advantage 13 |
| Showcasing Ontario’s Clinical Trials Excellence 23 |
| Ontario’s Clinical Scientists: Leaders in Virtually Every Field 43 |
| Appendices 55 |
| Key Contacts 59 |

Acknowledgment: The Ministry of Research and Innovation gratefully acknowledges the Market Intelligence Team at MaRS Discovery District for their assistance with research and content development for this publication.
“All of this (Ontario expertise) sends a clear signal to drug and pharmaceutical companies ... Groups in Canada are well-organized, have done world-class trials that have changed the way medicine is practised, and have substantial expertise. Come.”

– Dr. Salim Yusuf, MD DPhil, Professor of Medicine (Cardiology) and Clinical Epidemiology & Biostatistics, McMaster University

        Director of the Population Health Research Institute, McMaster University and Hamilton Health Sciences
EXECUTIVE SUMMARY

THE PACE OF MEDICAL DISCOVERY IS ACCELERATING, increasing the pressure on life sciences researchers to complete clinical trials quickly, efficiently and with the high quality data that regulators demand.

In Ontario, life sciences leaders continue to break new ground every day. They are finding the solutions needed to answer some of the world’s most elusive medical questions. The province’s vibrant life sciences sector, through clinical trials, is helping healthcare leaders bring life-saving solutions to global markets. These solutions provide positive patient outcomes, affordable medicines, shorter hospital stays and high quality jobs.

In fact, Ontario has long been a destination of choice for major international clinical trials sponsored by:

- multi-national pharmaceutical companies
- publicly funded research institutions and universities, and
- small/medium life science and medical device companies.

QUICK FACTS

- More than 5,200 clinical trials are underway in Ontario at any given time.
- From 2004-2008, the number of oncology trials in Ontario ranged from 450-550, involving between 5,000-6,000 patients.
- In 2009 alone, pharmaceutical companies spent $280 million on clinical trials in the province.

Ontario conducts Phase I-IV clinical trials in research areas such as:

- cancer (all types)
- general pathology
- nervous system diseases
- heart and blood diseases
- urinary tract, sexual organs and pregnancy conditions
- digestive system diseases
- immune system diseases, and
- mental health.

Our trials put patient safety first and address every aspect of patient care. We deliver treatment trials (that test new treatments or drugs), diagnostic trials (that test better ways to detect disease), prevention trials (that explore new ways to prevent disease), and quality of life trials (that improve quality of life for individuals with chronic disease).

As a result, the province has become a magnet for clinical research. Our record of accomplishments goes back a century and includes advancements in virtually every area of healthcare. The life-saving solutions developed here in Ontario are tested for global markets using our recognized clinical trials expertise and resources.
In 2010, Ontario launched a $161 million Life Sciences Commercialization Strategy. The main goals of this Strategy are:

→ To build on Ontario’s capacity for achieving world firsts in health-related research.

→ To create new opportunities for partnerships with international companies and other innovative jurisdictions.

The Strategy includes a commitment of $17 million to establish a province-wide coordinating framework for clinical trials that will streamline ethics reviews and administrative processes for our province’s multi-centre clinical trials.

Ontario continues to invest significantly in modernizing its clinical trials framework. The result: increased patient recruitment, reduced trial start-up times and a stronger value proposition for investors.

Thunder Bay Regional Research Institute scientist, Dr. Alla Reznik, and Founding Scientific Director, Dr. John Rowlands, are developing new PET imaging detectors with higher sensitivity and increased resolution.

BREAKING NEW GROUND:
ONTARIO’S RECORD OF WORLD-CHANGING TRIALS

Here are just a few highlights of Ontario’s ground-breaking innovations in clinical trials:

→ In 1986, a landmark study called the North America Symptomatic Carotid Endarterectomy Trial (NASCET) was led by Dr. Henry Barnett, scientific director of Robarts Research Institute. This was a multi-centre, randomized, controlled trial of nearly 3,000 patients from more than 100 international sites. It defined the role of carotid endarterectomy in stroke prevention. Dr. Barnett’s work with Aspirin as a preventative therapy for heart attack and stroke remains one the most important developments in 20th-century medicine.

→ From 1993-1995, the international HOPE study (Heart Outcomes Prevention Evaluation) was led by McMaster University researchers. The trial evaluated the effects of ramipril and vitamin E in high-risk cardiovascular disease patients. Ramipril significantly lowered the risk of major cardiovascular outcomes by 25-30 per cent in a broad range of high-risk middle-aged and elderly people with diabetes mellitus. Many physicians now prescribe ramipril for patients with diabetes or congestive heart failure.

→ The 2007 BART study (Blood Conservation using Antifibrinolytics in a Randomized Trial) has changed clinical trials practice around the world. It was one of the largest heart surgery trials ever conducted, involving more than 2,970 high-risk cardiac surgery patients from 19 Canadian centres. The study was centrally administered by the Ottawa Hospital Research Institute.

Thunder Bay Regional Research Institute scientist, Dr. Alla Reznik, and Founding Scientific Director, Dr. John Rowlands, are developing new PET imaging detectors with higher sensitivity and increased resolution.
THE ONTARIO ADVANTAGE

Why innovate in Ontario? For close to a century, our researchers have been at the forefront of major breakthroughs in nearly every area of medicine.

Ontario is where insulin was discovered. It’s where the pacemaker was developed. It’s where the first successful lung transplant was performed.

It’s also where a system for automatic and inexpensive DNA sequencing was developed. It’s where L-DOPA for the treatment of Parkinson’s disease originated. It’s where a synthetic bone substitute was created.

It’s no accident that so many life-changing discoveries have taken place here. In Ontario, life science and pharmaceutical firms can take advantage of:

→ A globally competitive testing environment. Major international medical authorities recognize the validity of data from Ontario clinical trials. We have well-established clinical trials networks and contract research organizations highly experienced in managing clinical trials across Canada and around the world. Staff are trained in Good Clinical Practices (GCP) and our workforce is one of the best educated in the world. In fact, 61 per cent of Ontario’s workforce has completed post-secondary education, the highest percentage among G7 nations.

→ World-class clinical research talent. Ontario’s researchers are recognized for their expertise in designing and managing complex clinical trials. Our legacy of biomedical discovery inspires and attracts the world’s best researchers. It is grounded in Ontario’s unique collaborative research environment.

→ Access to our public healthcare system and diverse patient populations. Ontario offers resources that help healthcare leaders accelerate their clinical trials. The province has a centrally managed public healthcare system. This makes it easy to access a population of more than 13 million that is demographically and ethnically diverse, a critical advantage that can accelerate understanding of the trial drug’s impact on different population subgroups. This enables more efficient drug development and helps ensure safe and effective medical products for a broader range of users.

→ Highly competitive costs and generous R&D tax incentives. Clinical trials costs here are 8 per cent below costs in San Diego and 11 per cent below Boston, for example. Also, the province has established a number of funding programs. Ontario’s R&D tax credits are considered to be among the most generous in the industrialized world.

→ Strong government support for clinical trials. We are constantly working to improve both funding support and service delivery. Our 2010 Life Sciences Commercialization Strategy committed an additional $17 million for clinical trials-related initiatives.

Just as importantly, Ontario offers a highly efficient regulatory ethics review process overseen by Health Canada. It takes just 30 days to review Phase I to Phase III protocols, and seven days to review Phase I bioequivalence trials.

In the future, a new province-wide coordinating framework will streamline ethics reviews and administrative procedures for all multi-centre clinical trials conducted in Ontario. This streamlined framework is built on the success of the Ontario Cancer Research Ethics Board (OCREB), founded in 2003. OCREB coordinates the research ethics review process for multi-centre cancer trials using a unique centralized ethics review model. This approach reduces duplication, shortens study start-up time and provides the highest quality of review.

In short, we have the people and the resources that today’s leaders in life sciences need to efficiently test their promising innovations. Ontario is ready to welcome your organization and support your clinical trial research.

LEARN MORE NOW

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Web: www.ontario.ca/innovation
E-mail: Info4@ontario.ca
ONTARIO: A CLINICAL TRIALS POWERHOUSE
A History Of World Firsts

1922
First clinical use of insulin for diabetes –
Dr. Frederick Banting and Charles Best
University of Toronto

1935
First to use heparin as a blood thinner –
Dr. Gordon Murray
University of Toronto

1946
First artificial kidney in North America –
Dr. Gordon Murray
Toronto General Hospital

1950
First regulated cardiac pacemaker –
Dr. John Hopps and Dr. Bill Bigelow
Toronto General Hospital

1961
First to discover blood-forming stem cells for bone marrow transplants –
Dr. Ernest McCulloch and Dr. James Till
Ontario Cancer Institute/Princess Margaret Hospital

1978
First clinical trial of aspirin to prevent stroke –
Dr. Jack Hirsh
Hamilton Health Sciences Centre

1983
First successful single lung transplant –
Dr. Joel Cooper
Toronto General Hospital

1989
First to discover gene responsible for cystic fibrosis –
Dr. Lap-Chee Tsui
Hospital for Sick Children

1991
First high-frequency ultrasound microimaging scanner –
Dr. Stuart Foster
Sunnybrook Hospital

1995
First to identify Alzheimer’s gene –
Dr. Peter St George-Hyslop
University of Toronto

1997
First to discover leukemia cancer stem cell –
Dr. John Dick
University of Toronto

2006
First to discover the trigger of Type 1 diabetes –
Dr. Michael Salter
The Hospital for Sick Children, Toronto

2009
First to develop virus-free induced pluripotent stem cells –
Dr. Andras Nagy
Mount Sinai Hospital

2010
First to use stem cells to give sight to blind mice –
Dr. Derek van der Kooy and Research Team
University of Toronto/McEwen Centre for Regenerative Medicine

2010
First biosynthetic cornea transplant –
Dr. May Griffith and Dr. Per Fagerholm
Ottawa Hospital Research Institute, Ottawa/Linköping University, Sweden
A Continuing Tradition Of Medical Breakthroughs

Ontario’s history of world firsts in life science achievements began in 1922, when Dr. Frederick Banting and medical student Charles Best discovered the clinical use of insulin as a treatment for diabetes. Since then, Ontario has recorded one medical research ‘first’ after another. The province has built a respected life sciences industry where multi-nationals and home-grown companies have established themselves as proven leaders in innovation. Multi-national pharmaceutical companies invest more than $280 million a year in clinical trials in Ontario.

Ontario laboratories continue to generate new breakthroughs in cardiology, oncology, neurology, stem cells and regenerative medicine, imaging, ophthalmology, infectious diseases and other areas. This tradition of biomedical discovery inspires and attracts the world’s best researchers. It is grounded in Ontario’s unique collaborative research environment.

Ontario is one of North America’s largest biomedical clusters. The province offers one of those rare global locations where leading-edge medical research converges with international business expertise and advanced manufacturing capabilities. Ontario is home to global giants, including:

→ Pfizer
→ GlaxoSmithKline
→ Sanofi Pasteur
→ Astra Zeneca
→ Eli Lilly, and
→ GE Healthcare.

It’s also where world-leading companies like Nordion, Apotex and Trudell Medical International got their start and continue to thrive.

Quick Facts

- Ontario’s life sciences industry employs more than 40,000 people in more than 900 companies. Revenues top $14 billion a year. 6, 7, 8, 9, 10, 11
- Ontario’s 25 research hospitals employ 10,000 researchers. They conduct $850 million in research each year.12
- The private sector invests almost $700 million yearly in applied health research, including clinical trials.13

Smaller life science and medical device companies also actively collaborate with Ontario’s publicly funded research institutions. Our research institutes and universities sponsor trials as well, with funding from Canada’s federal and provincial governments, as well as from the U.S. National Institutes of Health.
A MICROCHIP THAT DETECTS CANCER

In 2009, University of Toronto researchers created a portable device with a microchip that can accurately diagnose cancer. It was heralded as a landmark medical advance. Prior diagnostic procedures often took days. The chip delivers results in just 30 minutes. It detects the type and severity of cancer by sensing the signature biomarkers that indicate the presence of cancer at the cellular level.

The research team, led by Drs. Shana Kelley and Ted Sargent, tested its innovation on prostate cancer and head and neck cancer models. The discovery offers a faster, more cost-effective technology to rapidly diagnose cancers and other infectious diseases. It could also provide more targeted treatments for patients.¹⁴
Supporting Research With Targeted Funding Programs

To help ensure that Ontario continues to recruit and retain star scientists, the province has established a number of funding programs. Currently, Ontario invests more than $500 million annually in basic and translational life sciences R&D. Programs include:

➔ **The Ontario Research Fund.** This $730 million program supports the operational and capital costs of doing innovative research in Ontario.

➔ **The Early Researcher Awards.** This award provides up to $100,000 to help promising and recently appointed Ontario researchers build their research teams.

➔ **The Post-Doctoral Fellowship program.** This program provides two-year fellowships worth $100,000 to outstanding scientists at Ontario’s research institutions.

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**ATTRACTION THE WORLD’S TOP RESEARCHERS**

One of the world’s foremost neuroscientists, Dr. Adrian Owen holds Canada’s Excellence Research Chair in Cognitive Neuroscience and Imaging. He is addressing one of the most challenging topics in clinical medicine: residual brain function in patients who are non-responsive after suffering a severe brain injury.

In 2011, Dr. Owen brought his remarkable research program – and his entire research team – from Cambridge University in the United Kingdom to the University of Western Ontario. Why Ontario?

“This is the place to be for advanced neuroscience research,” Dr. Owen says. “The opportunity to work closely with world-class colleagues, with the best equipment available, and to have patients nearby that my work can help, drew me to Ontario. Being located here will make it easier for me to achieve my research objectives – and to push the envelope even further.”
Ontario helps companies take breakthroughs from the laboratory to the marketplace. The province offers a number of programs to turn research into profitable products and technologies. These include:

- **The Ontario Emerging Technologies Fund.** This $250 million fund aims to drive start-up investments in high-potential firms, including life science companies. In response to tightening credit markets, the fund co-invests up to $50 million each year, as a partner, with qualified venture capital funds and private sector investors.

- **The Ontario Venture Capital Fund.** This $205 million fund focuses on attracting investments in high-growth companies with the goal of bringing exciting new discoveries to market faster.

- **The Ontario Market Readiness Program.** This $46 million program provides high-potential innovative companies in Ontario with early-stage financial support and management expertise to help them get off the ground, and attract investment from other sources.

- **The Investment Accelerator Life Sciences Fund.** A special $7 million fund was created to help accelerate the growth of life sciences companies established in Ontario. The fund invests up to $1 million in companies that have the potential to be global leaders in their field and provide sustainable economic benefits to Ontario.

To further unlock the tremendous commercialization potential in the province, the government recently created the Ontario Network of Excellence (ONE). ONE provides one-stop access to Ontario programs and resources that will help innovators to succeed in the global marketplace. This includes access to industry-research partnerships, commercialization expertise and investment capital.

www.oneinnovation.ca

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www.oneinnovation.ca

Quick Facts:

- ONE includes close to 150 organizations and more than 1,100 commercialization experts, investors and business and community leaders from across Ontario.

- From 2007-2010, ONE helped leverage more than $530 million in private investment and more than $144 million in public investment.

Situated in the heart of Toronto’s Discovery District, MaRS is a member of the Ontario Network of Excellence (ONE) and helps entrepreneurs bring innovative ideas to the marketplace.
A Sophisticated Public Research Infrastructure

Ontario’s life sciences industry encompasses a super-cluster of more than 60 publicly funded research facilities that spans from Windsor to Ottawa, and as far north as Thunder Bay. The Toronto area alone, for example, is now the fourth largest biomedical research complex in North America.15

Ontario research facilities are internationally recognized for their expertise in specialized fields of health research. They have a history of collaboration with the private sector. Among them are the:

- Princess Margaret Hospital
- Hospital for Sick Children
- Ottawa Heart Institute
- London Health Sciences Centre, and
- Population Health Research Institute.

Quick Facts

- More than a million square feet and $1 billion in new research facilities have been completed in Ontario since 2005.16
- Over the next 12 years, the province will add another three million square feet of research space.

Sector Snapshots

- Pharmaceuticals
  - Sales of $7.5 billion17
  - More than 13,000 employees18, 19
  - Includes global giants GlaxoSmithKline, Sanofi Pasteur, Teva, and Canadian-based Apotex

- Medical and Assistive Devices
  - Sales of $4 billion20
  - 20,000 employees21, 22
  - 700 companies, including global giants such as GE Healthcare, Baxter, Agfa Healthcare and Canadian-based Nordion and Trudell Medical International

- Biotech
  - Sales of $2.8 billion23
  - 3,500 employees24
  - More than 90 companies25

- Contract Services (Research/Manufacturing/Clinical Trials)
  - 5,000+ employees26
  - 75+ companies,27 including leaders such as Kendle, Patheon and Canadian-based Therapure Biopharma, Nucro-Technics and Gamma-Dynacare
CLINICAL TRIALS: THE ONTARIO ADVANTAGE
1. A globally competitive testing environment.
2. World-class clinical research talent.
3. Access to our public healthcare system and diverse patient population.
4. Highly competitive cost structures and generous R&D tax incentives.
5. Strong government support for clinical trials.

### Table 1: Ontario: Clinical Trials By Sponsor Type 2005-2009

- Private industry: 53%
- University/research institutes: 37%
- National institutes of health: 5%
- Others: 5%

Source: clinicaltrials.gov

### Table 2: Toronto: A Major Clinical Trials Centre 2005-2009

<table>
<thead>
<tr>
<th>Location</th>
<th>Number of Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston, MA</td>
<td>6,161</td>
</tr>
<tr>
<td>Toronto, ON</td>
<td>3,711</td>
</tr>
<tr>
<td>San Diego, CA</td>
<td>3,701</td>
</tr>
<tr>
<td>Chicago, IL</td>
<td>1,526</td>
</tr>
<tr>
<td>Frankfurt</td>
<td>1,163</td>
</tr>
<tr>
<td>Tokyo</td>
<td>1,021</td>
</tr>
<tr>
<td>London, U.K.</td>
<td>563</td>
</tr>
</tbody>
</table>

Source: clinicaltrials.gov
Ontario offers unique demographics for designing and conducting clinical trials. The province is home to an ethnically diverse population of more than 13 million people.

This is critical for clinical trial research as an ethnically diverse patient group accelerates understanding of the trial drug’s impact on different population subgroups. This enables more efficient drug development and helps ensure safe and effective medical products for a broader range of users.

Another advantage is that Ontario shares North American practices in terms of medicine, regulatory frameworks, culture and language, as well as common time zones. This paves the way for successful project partnerships with U.S. firms.

At the same time, our cultural, scientific and trade ties with Europe and Asia provide a strong foundation for multi-centre international research collaborations.

Sanofi Pasteur’s Canadian Clinical Research Unit

Sanofi Pasteur is the world’s largest vaccine developer and producer. Helping to keep it at the leading edge is its Toronto-based Clinical Research Unit – one of the largest research units within the multi-national company. Sanofi Pasteur Limited researches, develops and manufactures vaccines in Ontario for global distribution. The company invests approximately $100 million yearly in Canadian vaccine R&D.
Ontario’s researchers are recognized for their ability to handle complex and ground-breaking trials. Our internationally recognized investigators are studying:

- viruses that kill cancer cells
- new diagnostics and therapies in neuroscience
- autoimmunity and other therapies related to diabetes, and
- high impact cardiovascular interventions, and much more.

To learn more about Ontario researchers, please see page 43 of this report.

The province continues to attract and develop world-class clinicians and researchers. For example:

- As part of its Clinical Research Initiative, the Canadian Institutes of Health Research (CIHR) aims to further strengthen Canadian clinical research by training more clinician-investigators to design and direct international trials. CIHR has launched a Randomized Controlled Trial Mentoring Program and a Strategy for Patient-Oriented Research to train and mentor future leaders in clinical research. It has also partnered with the Canada Foundation for Innovation to support clinical infrastructure, high quality research, research personnel, training and research programs in clinical research.28
BREAKING NEW GROUND: PREVENTING VASCULAR DISEASE IN HIGH-RISK PATIENTS

Ontario cardiovascular researchers have directly contributed to clinical trials leading to a new understanding of cardiovascular disease. Significant among these are:

‡ The INTERHEART study. This major Canadian-led global study identified nine risk factors for myocardial infarction (heart attack). These factors are the same in almost every geographic region and racial/ethnic group worldwide and are consistent in men and women.

‡ The RE-LY study (Randomized Evaluation of Long-Term Anticoagulant Therapy). This landmark study on stroke prevention in atrial fibrillation (AF) patients compared the standard anti-coagulant therapy, warfarin, to a new treatment, dabigatran. Dabigatran reduced the risk of stroke and major bleeding by 34 per cent in AF patients, compared to warfarin.

Both studies were led by researchers at the Population Health Research Institute, a joint institute of McMaster University and Hamilton Health Sciences.
In addition to biomedical expertise, Ontario offers resources for healthcare leaders that contribute to the speed, efficiency and effectiveness of their clinical trials. These include:

- **A centrally managed public healthcare system.**
  This facilitates patient recruitment and tracking and includes a large multi-cultural component. Ontario offers broad genetic heterogeneity, as well as opportunities for examining clinical outcomes over a variety of unique populations.

- **A new province-wide coordinating framework for clinical trials.** The mandate of the new framework is to:
  - increase patient recruitment and promote the social value of Ontario clinical trials
  - streamline ethics reviews and administrative procedures for all multi-centre clinical trials conducted in Ontario and,
  - support best practices in clinical trial management.

- **Well-established contract research organizations (CROs).**
  These companies offer a wealth of experience and expertise in managing clinical trials across Canada and around the world.

- **Strong networks of high quality clinical trial sites.**
  Staff at these sites are trained in Good Clinical Practices (GCP) and common standards of care. This makes it easier for multi-site data integration.

- **A highly efficient regulatory review process through Health Canada.** It takes just 30 days to review Phase I to Phase III protocols, and seven days to review Phase I bioequivalence trials.

**Access To Our Public Healthcare System**

Below: A family enjoys cycling along an Ottawa pathway. One of Ontario’s youngest cities, half of Ottawa’s population is under the age of 38. The advanced technology sector is among the city’s top employers.
As the chart on this page shows, management costs for clinical trials are lower here than in the U.S., the U.K., Germany or Japan. Institutional overhead costs in Ontario are also highly competitive, as are labour costs. This is especially true for research investigators and nurses with GCP training.

Other cost advantages include:

→ The costs for routine diagnostic procedures such as blood chemistry are often covered by our public healthcare system. This helps to offset the fees for diagnostic and therapeutic interventions such as MRI scans.

→ Ontario’s R&D tax incentive program is widely recognized as one of the most generous in the world. In fact, $100 spent on R&D can be reduced to an after-tax cost of $56, or less than $38 for small businesses.

→ A broader range of costs qualify for deductions in Ontario than in many other jurisdictions. Tax credits can be carried back for three years or forward for 20 years.

### Table 3: Lower Clinical Trials Management Costs

<table>
<thead>
<tr>
<th>Location</th>
<th>ON</th>
<th>U.S.</th>
<th>U.S. Cities Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toronto, ON</td>
<td>91.4</td>
<td>93.6</td>
<td>95.8</td>
</tr>
<tr>
<td>Raleigh, NC</td>
<td>93.6</td>
<td>97.9</td>
<td>98.7</td>
</tr>
<tr>
<td>Chicago, IL</td>
<td>97.9</td>
<td>98.7</td>
<td>98.7</td>
</tr>
<tr>
<td>Philadelphia, PA</td>
<td>99.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>San Diego, CA</td>
<td>99.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>London, U.K.</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average for U.S. cities</td>
<td>100</td>
<td>102.2</td>
<td>102.2</td>
</tr>
<tr>
<td>Boston, MA</td>
<td>102.2</td>
<td>118.7</td>
<td>118.7</td>
</tr>
<tr>
<td>Tokyo</td>
<td></td>
<td>121.7</td>
<td>121.7</td>
</tr>
<tr>
<td>Frankfurt</td>
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<td></td>
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</tbody>
</table>

Source: KPMG Competitive Alternatives 2010
Overall Business Costs Index, U.S. Cities Average = 100
In 2010, Ontario introduced a Life Sciences Commercialization Strategy that provides $17 million to enhance its framework for clinical trials. The strategy has two main goals:

1. To accelerate the growth of existing enterprises in Ontario’s bio-medical cluster.
2. To attract new companies by capitalizing on the province’s world-class research capacity, talent and collaborative spirit.

Through this strategy, Ontario aims to attract and nurture great scientific minds and increase collaboration among academia, industry and government. It will also speed the commercialization of research breakthroughs and improve financing for innovative companies, particularly at the early stage.

As part of this strategy, we are now implementing a new province-wide clinical trials coordinating framework. This will enable Ontario researchers to increase efficiency while maintaining the highest standards of ethical review to protect patient rights, safety and well-being. By streamlining ethics reviews and other administrative processes, our coordinating framework will:

- minimize overlap
- maximize effectiveness, and
- shorten trial start-up times.

This new initiative continues Ontario’s tradition of supporting the interests of patients – including those in ongoing long-term trials. It will advance clinical research in the province and maintain a competitive environment for clinical trials. Under this new framework, Ontario will offer:

- a single point of entry for industry sponsored multi-centre trials, and
- standardized administrative processes, including the use of common contracts, for multi-centre clinical trials.
“When global healthcare companies and organizations need to assess the effects of advances on clinically important outcomes, they increasingly count on Ontario’s internationally recognized biomedical expertise, well-established network and research excellence to design, run and analyze international clinical trials.”

Dr. Hertzel Gerstein
Population Health Institute Chair in Diabetes Research, and Chair, Diabetes and Cardiovascular Diseases
SHOWCASING ONTARIO’S
CLINICAL TRIALS EXCELLENCE
Ontario’s World-Renowned Centres of Excellence

More than 5,200 clinical trials are underway in Ontario at any given time. These include trials for treatment of allergies, cardiovascular disease, cancer, imaging, inflammatory bowel disease, urology, rheumatology, organ transplants and a host of others. The following is just a sampling of some of Ontario’s world-renowned centres for clinical trials and research.

Cardiovascular

After cancer, cardiovascular disease is the leading cause of death in Canada. Ontario is uniquely positioned to change the way cardiovascular disease is diagnosed and treated. The province offers all the elements required for world-class clinical trials: unparalleled research expertise in diagnostic imaging, a collaborative research environment and a focus on technology development.

Canadian Network and Centre for Trials Internationally (CANneCTIN), Hamilton

CANneCTIN aims to improve the prevention and treatment of heart disease and diabetes. It is a national clinical research network funded by the Canadian Institutes of Health Research and the Canada Foundation for Innovation Clinical Research Initiative. It is jointly led by Dr. Salim Yusuf, from the Population Health Research Institute (PHRI), and Dr. John Cairns, from the University of British Columbia. To learn more about Dr. Yusuf’s research in Ontario, please see page 45 of this report.

CANneCTIN brings together investigators from across Canada with a wide range of expertise and research achievement in cardiovascular disease and diabetes. They work collaboratively toward major discoveries that are likely beyond the capacity of an individual centre. CANneCTIN comprises a coordinating centre located at PHRI, a collaborative network of over 200 hospitals and clinics in every Canadian province, and an affiliated international network of over 1,500 centres.

Quick Facts

- Over the past 15 years, PHRI researchers have led cardiovascular clinical trials at more than 1,500 sites in 83 countries.
- These studies have involved more than 500,000 patients.

CANneCTIN’s goals:

- Increase capacity and scope of Canadian-led high impact cardiovascular and diabetes clinical trials, registries and epidemiological studies.
- Foster research partnerships between Canadian and international investigators.
- Educate the next generation of Canadian cardiovascular and diabetes clinical trial leaders.
- Develop an effective knowledge translation program and collaborate with experts to determine effective dissemination and behaviour change strategies.

Population Health Research Institute (PHRI)

McMaster University, Hamilton

PHRI is the largest academic cardiovascular research group in Canada. The Institute has conducted more than 50 global trials and epidemiological studies involving over 500,000 patients in more than 1,500 centres in 83 countries. Research areas include the causes and prevention of cardiovascular disease, diabetes, obesity and societal influences on health, vascular complications during surgery, and stroke.

World-renowned PHRI researchers include:

- Dr. Hertzel Gerstein: principal or joint investigator of the REWIND study of cardiovascular (CV) prevention in type 2 diabetes, the DREAM study of diabetes prevention in high-risk individuals and the ORIGIN study of CV prevention in people with dysglycemia. To learn more about Dr. Gerstein’s clinical trial studies, see page 44.
- Dr. Koon Teo: principal investigator of numerous clinical trials related to cardiovascular events. These include the COURAGE Trial, the FAMILY Study and the PURE Study. See page 45 to learn more about Dr. Teo’s clinical research.
Dr. Salim Yusuf: principal investigator for the INTERHEART study funded by the World Health Organization. This study explores risk factors for heart disease among 25,000 people in 55 countries. To learn more about the work of Dr. Yusuf, please see page 45 of this report.

**Applied Health Research Centre (AHRC) St. Michael’s Hospital, Toronto**

AHRC is a state-of-the-art, full-service academic and clinical research coordination centre. Its core expertise is in providing operational support for Phase II through Phase IV multi-centre clinical trials across a range of therapeutic areas. Since its launch in 2009, AHRC has initiated 40 clinical studies involving more than 6,000 patients and has secured more than $20 million in financial support.

At AHRC, academic researchers, commercial investigators, government and not-for-profit research networks collectively provide:

- project management and trial operations support (including site, safety, finance, contracts management)
- industry leading data management system (with an in-house Medidata RAVE™ deployment), and
- specialty expertise in health economics, knowledge translation and qualitative research.

AHRC is now managing a major clinical trial for Factor VIIa, a powerful blood-clotting agent, originally developed to treat haemophiliacs. Researchers are investigating its ability to stop bleeding in the brain of stroke patients. The study is funded by the Canadian Institutes of Health Research and is led by leading stroke researcher, Dr. David Gladstone. To learn more about Dr. Gladstone’s research, please read his profile on page 49.

AHRC provided the logistics and expertise to plan, support, execute and manage this trial at multiple sites across Canada.

**BREAKING NEW GROUND: TESTING A NEW TREATMENT FOR STROKE PATIENTS**

The AHRC is the Canadian lead on a major industry-sponsored international non-randomized study of patients with coronary artery disease – a common and debilitating cardiovascular condition. The AHRC was involved in enrolling over 1,200 patients in 3 months. That’s a record time for a project of this magnitude.

This project is sponsored by Servier Canada Inc, the Canadian affiliate of The Servier Research Group, a French research organization.

The Applied Health Research Centre (AHRC) is located within the Li Ka Shing Knowledge Institute at St. Michael’s Hospital in downtown Toronto. Researchers work in sophisticated laboratories and front-line clinical settings to explore the basic dynamics of disease and the best ways to improve patient outcomes.
CONTACT LENSES

There are more than 140 million contact lens wearers in the world and about four billion people who require refractive correction. Ontario’s internationally acclaimed researchers perform clinical research investigating the ocular response to contact lenses and other forms of vision correction.

Centre for Contact Lens Research, School of Optometry, University of Waterloo, Waterloo

This centre is unique in Canada, and one of only two such centres in the world dedicated to contact lens research. Established in 1988, it has developed into a world-leading research centre of excellence with a focus on contact lenses. The Centre also offers strong expertise in ocular and visual response to other refractive correcting procedures.

The Centre conducts Phase I, II or IV clinical trials in south-western Ontario involving 15 to 200 research participants. Researchers work closely with industry partners such as CIBA VISION Corporation, Johnson and Johnson Vision Care and other industry giants to perform clinical research on the physiology of the anterior eye and the ocular response to contact lens materials and care systems. Research also focuses on the performance of specialty contact lens designs, contact lens comfort, in-eye lens performance, dry eye symptoms and ocular surface sensitivity.

DIABETES

Diabetes is one of the most pervasive diseases of the 21st century. Care and treatment now represent nearly one billion dollars in healthcare costs in Ontario and as much as $200 billion in the U.S. Ontario researchers have been at the centre of most of the world’s largest diabetes-related clinical trials in recent years.

JDRF Canadian Clinical Trial Network (CCTN) for Type 1 Diabetes
University of Waterloo, Waterloo, McMaster University, Hamilton

CCTN was established in 2010 through a partnership between The Juvenile Diabetes Research Foundation (JDRF) of Canada and the Federal Economic Development Agency for Southern Ontario (FedDev). It is now developing several high-profile clinical trials in association with leading diabetes researchers at partner universities and medical centres in Southern Ontario.

The $30 million network provides funding, planning and operational support for investigator-initiated clinical trials and has a flexible partnership model that encourages collaboration between academic, industry, government and non-profit sectors. This collaborative and streamlined network provides ‘one-stop shopping’ to explore innovation in all phases of the disease.

The goal: to position Southern Ontario as an international hub for diabetes translational research, innovation, and commercialization of new therapeutics and enabling technologies.

Researchers are now targeting a wide range of research areas:
→ autoimmunity
→ beta cell replacement/regeneration
→ complications therapies, and
→ glucose control.

This broad focus will allow early access to innovative therapeutics and technologies through clinical trials, as well as faster adoption of new treatment standards.

Population Health Research Institute (PHRI)
McMaster University, Hamilton

PHRI research programs also explore the causes, treatment and prevention of diabetes. The Institute’s leading researcher, Dr. Hertzel Gerstein, has led many clinical trials on the treatment of diabetics. Among these are the HOPE, ACCORD, DREAM, ORIGIN and TIDE trials.

BREAKING NEW GROUND: DEVELOPING THE WORLD’S FIRST ARTIFICIAL PANCREAS

A key area of interest for the Canadian Clinical Trial Network is the development of an artificial pancreas. This new device will revolutionize diabetes care and dramatically improve the lives of people with any form of diabetes. It will significantly reduce the risk of devastating complications, including kidney disease, heart attacks and stroke, amputations, blindness and severe hypoglycaemia.

The new device integrates two currently available technologies – the continuous glucose monitor and the insulin pump – with control algorithms that provide the right amount of insulin in response to the body’s real-time needs.
Advances in diagnostic imaging are helping doctors and radiologists identify malignant tumours, cardiac issues and neurological diseases earlier and more accurately than ever before. In Ontario, we have a unique concentration of expertise across all imaging modalities. The province’s major imaging R&D clusters include:

- the Biomedical Imaging Research Centre (London)
- the Sunnybrook Health Sciences Centre (Toronto), and
- McMaster University (Hamilton).

These centres have the largest concentration of imaging scientists in North America, with a team of more than 300 in London alone.

The newly established Centre for Imaging Technology Commercialization (CImTeC) provides greater opportunity for the Canadian medical imaging sector to:

- establish and sustain world leadership in innovation and technological development, and
- provide benefits to the economy and healthcare system.

The Centre was awarded $13.3 million by the federal government’s Centres of Excellence for Commercialization and Research program. An additional $14.3 million was provided by other sources, including the Government of Ontario. This program supports successful research partnerships between universities, industry, not-for-profit organizations and government. It helps its members to address barriers in the path of commercialization of medical imaging technologies.

CImTeC will help small and medium-sized enterprises capture more of this market. It will bring together Canadian researchers and technical experts in medical imaging and provide them with greater access to resources and infrastructure. This concentration will accelerate research and development in the medical imaging sector.

Dr. Aaron Fenster, Director for CImTeC, expects the Centre to change the landscape of medical imaging. To learn more about Dr. Fenster’s work, please see page 46 of this report.
Ontario is the largest hub of clinical trial activity in Canada, and the third-largest biomedical research centre in North America. Major provincial hubs include Ottawa, Kingston, Toronto, Hamilton, London, Kitchener-Waterloo and Thunder Bay. At any given time, more than 5,200 clinical trials are underway across the province.

Below are examples of the clinical trials research centres found across Ontario.

**ALLERGIES**

Kingston General Hospital, Kingston
→ Environment Exposure Unit
→ www.eeu.on.ca

**CARDIOVASCULAR**

Canadian Network And Centre For Trials Internationally Hamilton
→ www.cannectin.ca

Population Health Research Institute McMaster University, Hamilton
→ www.phri.ca

Applied Health Research Centre St. Michael’s Hospital, Toronto
→ www.stmichaelshospital.com/research/ahrc

**CONTACT LENSES**

Centre For Contact Lens Research School Of Optometry, University Of Waterloo, Waterloo
→ www.contactlensupdate.com

**DIABETES**

Juvenile Diabetes Research Foundation
Canadian Clinical Trial Network For Type 1 Diabetes
University Of Waterloo, Waterloo
McMaster University, Hamilton
→ www.jdfc.ca

**IMAGING**

Centre For Imaging Technology Commercialization The University Of Western Ontario, London
→ www.robarts.ca

Sunnybrook Research Institute, Toronto
→ www.sunnybrook.ca/research

The Biomedical Imaging Research Centre The University Of Western Ontario, London
→ www.birc.ca

Robarts Research Institute The University Of Western Ontario, London
→ www.robarts.ca

Lawson Health Research Institute, London
→ www.lawsonresearch.com

The Centre For Probe Development And Commercialization, Hamilton
→ www.imagingprobes.ca
Sunnybrook Research Institute (SRI)
Toronto

SRI has one of the strongest research programs in medical imaging worldwide, with a focus on cancer, cardiology and neurosciences. More than 200 researchers conduct research in 150,000 square feet of state-of-the-art facilities. SRI is funded by the Canadian government and the province of Ontario.

At SRI, high-potential research ideas are translated from the bench, developed, tested and delivered to the bedside. SRI is a leader in clinical trials for therapeutics in oncology and the evaluation of new imaging systems.

Led by Dr. Martin Yaffe, SRI researchers have contributed greatly to the science and technology of digital mammography. They helped to lead the landmark DMIST (Digital Mammographic Imaging Screening Trial) study of 50,000 women in the U.S. and Canada to test and prove the clinical value of this new method for breast cancer detection. In addition, they led a practice-changing study demonstrating the value of MRI for detecting breast cancer in high-risk women. To learn more about Dr. Yaffe’s work, please see page 48 of this report.

SRI is also home to The Centre for Research in Image-Guided Therapeutics, the only one of its kind in the world. It houses preclinical, clinical, image processing, device development and image-processing laboratories, including a GMP (Good Manufacturing Practice) facility. SRI has also launched several highly successful imaging spin-off companies including Visualsonics and Sentinelle.

Top: Lois Westwood and Dr. David Gladstone. After a stroke in 2009, Westwood received a clot-busting drug at Sunnybrook that enabled full recovery. Centre: Sunnybrook’s M-wing expansion will house the Centre for Research in Image-Guided Therapeutics, a world first. Below: Drs. Yuexi Huang, Kullervo Hynynen and Junho Song assemble a magnetic resonance imaging-guided focused ultrasound device, developed by Sunnybrook Research Institute.
Dr. Michael Kovacs, Director of the Nordal Cyclotron & PET Radiochemistry Facilities at Lawson Health Research Institute, uses external manipulator arms to handle radioactive isotopes within lead-lined hot cells.

The Biomedical Imaging Research Centre (BIRC)  
University of Western Ontario, London

BIRC is focused on the discovery and development of innovative imaging techniques and instrumentation to improve the understanding, diagnosis and treatment of human diseases.

Biomedical imaging research in London is now a highly integrated program covering all major imaging modalities and biomedical applications. BIRC integrates biomedical imaging research at three centres:

1. **Robarts Research Institute.** Robarts is a centre of academic excellence for clinical research in most major diseases. Here, Dr. Ting-Yim Lee developed CT scanner technology to help doctors immediately track blood flow to the brain after a stroke.

2. **Lawson Health Research Institute.** The Institute offers expertise in major disease areas for Phase I - Phase IV trials. Lawson initiates approximately 600 new clinical trials each year and has demonstrated its ability to transfer technology from the laboratory to the commercial world. As of 2009, it held some 110 patents, with over 80 per cent generating revenue.

3. **University of Western Ontario.** Over the past five years, Cognitive Neuroscience and Imaging research at Western has attracted more than $24 million in funding. From 2001-2010, the Centre recruited more than 30 new neuroscience researchers, including world-renowned pioneer Dr. Adrian Owen. To learn more about Dr. Owen’s research, please see page 50 of this report.

The newly established Centre for Imaging Technology Commercialization (CImTeC) is also integrated with BIRC.

**The Centre for Probe Development and Commercialization (CPDC), Hamilton**

The Centre’s core mandate is to advance the next generation of molecular imaging probes – chemical compounds that provide a non-invasive means to diagnose disease at its earliest stage. These probes are used in conjunction with medical imaging scanners, such as MRI, CT, ultrasound and nuclear imaging, to allow non-invasive disease detection. The Centre is the world’s first facility focusing on this area of research.

Government investment in molecular imaging probe R&D has led to exciting and innovative Canadian discoveries in the field. The Centre will help to move these innovative probes and tools from university labs to hospitals and clinics.

The Centre receives federal investment through the Networks of Centres of Excellence program. The CPDC is also supported by national and international partners.

Dr. John Valliant, is the Centre’s Scientific Director and CEO. He is internationally recognized for his work in radiopharmaceutical chemistry. To learn more about Dr. Valliant's work, please see page 47 of this report.

Scientists at the Centre for Probe Development and Commercialization work to identify molecular markers for some of most pervasive cancers, and develop new probes that can offer personalized diagnosis and treatment.
INFLAMMATORY BOWEL DISEASE (IBD)

Canada has one of the highest incidences of IBD in the world. In 2008, costs covered by the healthcare system were estimated at $753 million. This includes expenses such as hospitalization, surgery, medication and physician visits. The wider cost to individuals, their families and society at large is estimated at $1.8 billion yearly. Ontario provides access to world leaders in gastroenterology research, as well as a large number of specialists treating the large patient pool in the province.

Robarts Research Institute
The University of Western Ontario, London

When Robarts Research Institute was established in 1986, its first study was the landmark North America Symptomatic Carotid Endarterectomy Trial (NASCET). This multi-centre, randomized, controlled trial involved nearly 3,000 patients at 106 centres in 13 countries. The study spanned more than a decade. It defined the role of carotid endarterectomy for the prevention of stroke and changed the management of patients with carotid stenosis, worldwide.

Today, Robarts Clinical Trials is recognized for its unique capabilities in designing and conducting IBD disease trials. A clinical trial led by Dr. Brian Feagan has transformed clinical practice for IBD. The study found methotrexate to be an effective therapy and maintenance drug for chronically active Crohn’s disease. Dr. Feagan is also the professional investigator of the REACT (Randomized Evaluation of an Algorithm for Crohn’s Treatment) study sponsored by Abbott Healthcare. This multi-national study involves 40 gastroenterology practices in Canada and Belgium. Study results could lead to new and more effective treatments for Crohn’s disease.
ONCOLOGY

Despite improvements in the detection and treatment of cancer, there’s still an urgent need for therapies that are innovative, efficient, less costly – and which result in fewer adverse side-effects. Ontario has a critical mass of leading researchers in cancer biology, therapeutics, imaging and ‘-omic’ technologies. They conduct ground-breaking translational research and are international leaders in trials testing personalized medicine paradigms.

National Cancer Institute of Canada Clinical Trials Group
Queen’s University, Kingston

The National Cancer Institute of Canada (NCIC) Clinical Trials Group (CTG) is a cooperative oncology group that brings researchers together from across the country. Its primary mission is to:

- assess the effectiveness of interventions to prevent cancer, and
- improve the care of patients who develop cancer.

CTG carries out clinical trials in cancer therapy, supportive care and prevention across Canada and internationally. Studies span the full spectrum, from Phase I testing of new agents, to large Phase III randomized controlled trials.

Between 1980 and 2009, the NCIC CTG conducted:

- more than 245 Phase III programs involving more than 57,555 patients and,
- more than 175 Phase I and Phase II studies including more than 4,160 patients.

More than 90 member institutions across Canada enrol patients in CTG studies. These members range in size from major cancer centres to community hospitals. More than 1,000 physicians, research nurses, data managers and pharmacists participate in the local administration of these trials.

Ontario Clinical Oncology Group
McMaster University, Hamilton

This group is one of the largest academic-based clinical trials organizations in Canada. It combines the clinical expertise of Hamilton Health Sciences, a premier teaching hospital, with the academic leadership of McMaster, a highly respected university. Together, they provide resources and services to design, conduct and analyze clinical trials.

The specific goals of the Group are to determine:

- how new anti-cancer agents and procedures can best be incorporated into clinical practice
- the optimal method of employing existing therapies in clinical practice
- the most cost-effective therapy where treatments offer equal efficacy, and
- the efficacy of supportive care interventions.

The Group specializes in the development, coordination and promotion of Phase I, II and III trials. These include clinical trials for cancers of the breast, brain, head and neck, ovary, prostate, lung, colon, brain metastases and pre-malignant conditions for the lung and cervix. Trials have ranged in size from 20 to several thousand patients in clinical centres worldwide.
Ontario Institute for Cancer Research (OICR)
Toronto

OICR is an independent, not-for-profit corporation funded by the Government of Ontario and other sources. Since its launch in 2005, Ontario has invested $380 million in the Institute.

Researchers pursue multi-disciplinary research in cancer prevention, early detection, diagnosis and treatment. They collaborate across institutions to investigate the major research questions of our time. For example, Dr. Tom Hudson, the Institute’s President and Scientific Director, is studying genome variation that affects the progress of a cancer. To learn more about Dr. Hudson’s research, please see page 51 of this report. OICR invests more than $150 million each year in translational research to move new discoveries from the bench to practical applications for patients.

The Institute is also working to develop personalized medicine for cancer patients. Key to this effort is the development of reliable biomarkers, which requires strong collaborative multi-disciplinary and translational research capabilities. Investments here include:

- A $22 million initiative to support the coordination of imaging platforms, technology pipelines and research across several institutions, led by Drs. Aaron Fenster and Martin Yaffe. To learn more about their research, please see pages 46 and 48 of this report.
- A coordinated initiative to develop molecular imaging probes, led by Dr. John Valliant. To learn more about Dr. Valliant’s work, please see page 47 of this report.

*Top: Scientists analyze the purity of samples. Below: Dr. Thomas Hudson, co-founder of the International Cancer Genome Consortium (ICGC), and President and Scientific Director of the OICR, believes in the benefits of working as a large consortium in the fight against cancer. Ontario researchers at OICR and other research institutions share a history of collaboration.*
International Cancer Genome Consortium (ICGC) Toronto

Ontario is currently coordinating a global effort to investigate the links between genetics and cancer. The province is investing $40 million over 10 years in the International Cancer Genome Consortium, through the Ontario Institute for Cancer Research (OICR). Dr. Tom Hudson, President and Scientific Director of OICR, was instrumental in the creation of the Consortium.

Its goal: to coordinate a global effort to unlock the genome of the 50 most common cancer tumours that plague humanity.

This project will generate 25,000 times more data than the Human Genome Project. Funding organizations in Asia, Australia, Europe and North America have already committed funds for 38 project teams to study more than 16,000 tumour genes.

Not only has Ontario been chosen as the world headquarters of this global effort, one of the largest scientific projects in history, it has also been tasked to serve as the global data centre. In essence, the province will create the largest health informatics database in history. This information will lead to better ways of diagnosing, treating and preventing cancer, a disease that strikes almost 13 million people a year worldwide.

Ontario Cancer Research Ethics Board (OCREB) Toronto

OCREB streamlines the research ethics review process for multi-centre oncology trials. It uses a unique centralized ethics review model that minimizes the administrative workload for ethics reviews. Based on a single ethics approval from the OCREB, study sponsors can initiate a multi-centre cancer clinical trial rapidly, at all participating centres within Ontario.

OCREB is independent of researchers and organizations sponsoring and conducting research. It may approve, reject, propose changes to, put on hold or terminate research at its sole discretion. The review process is supported by a group of oncologists, nurses, ethicists and pharmacists who are extremely knowledgeable in the area of current cancer research.

Ontario’s new province-wide clinical trials coordinating framework builds on the success of OCREB. For multi-centre trials, the new framework will:

- include a central Ontario clinical trials office to coordinate reviews for participating research ethics boards
- act as a single point of entry for industry sponsors, and
- standardize administrative processes.
In 2009, Ontario launched the first High Impact Clinical Trial (HICT) program in the world. It is a joint program of the Ontario Institute for Cancer Research and Cancer Care Ontario. It is designed to:

- support hypothesis-driven translational research in clinical trials, and
- facilitate the evaluation of personalized medicine strategies and interventions.

HICT clinical trials will change how we prevent, diagnose, monitor and treat cancer in patients. The program engages both industry and academic clinical trial sponsors. Studies will focus on the areas of experimental therapeutics, bio-specimen-based diagnostics and biomarker evaluations.

International leaders with expertise and knowledge in translational research, experimental therapeutics, molecular pathology, pharmacology, medical imaging and biostatistics are on the HICT Science Advisory Board.

Current research includes projects that:

- characterize circulating tumour cells and evaluate agent effects on circulating tumour cells
- develop ways to assess and evaluate agent effects on cancer stem cells
- incorporate imaging modalities to predict therapeutic activity
- develop a platform for real-time targeted patient genotyping, and
- evaluate a novel clinical trial design to efficiently screen for anti-tumour activity of two targeted agents in rare tumour settings.
Princess Margaret Hospital Drug Development Program

Toronto

Clinical and research staff at Princess Margaret Hospital (PMH) include many of the world’s leading experts in oncology. The hospital’s Drug Development Program focuses on Phase I and Phase II clinical trials for innovative cancer drugs. There is a strong emphasis on pharmacokinetics and correlative studies.

The Program’s collaborative and multi-disciplinary approach supports the rapid completion of high quality studies. These trials take place primarily within 10 priority disease sites: colorectal, pancreas, renal, bladder, prostate, small cell and non-small cell lung, ovary, cervix and head and neck. The goal is to determine:

- mechanism of action of anti-cancer drugs
- mechanism of drug resistance
- molecular factors predicating for response and resistance and,
- tumour microvasculature and angiogenesis.

Program leaders Drs. Malcolm Moore, Amit Oza and Lillian Siu have developed a model program for the clinical and translational development of new anti-cancer drugs. To learn more about their research, please see pages 52 and 53 of this report.

A further component of the Program is the PMH Phase II Consortium. To date, this Consortium has enrolled more than 1,200 patients in more than 60 trials in 17 study sites throughout Canada and the United States. Its focus is to improve access to new National Cancer Institute anti-cancer drugs.

Thunder Bay Regional Research Institute

Thunder Bay

The Thunder Bay Regional Research Institute is an independent, not-for-profit research centre located in northwestern Ontario. The Institute’s scientists and clinicians collaborate with academic and industry partners to advance new standards of excellence in clinical investigation of novel molecular imaging-based diagnostics, and bring advanced diagnostic technology to patients.

Globally, molecular imaging and molecular medicine are driving rapid improvements in cancer, cardiac and neurosciences care. Key to the Institute’s success in these areas is an ongoing partnership with the Thunder Bay Regional Health Sciences Centre. The Centre ranks among Canada’s leading academic health sciences centres. It has led successful clinical trials in cancer for 25 years.

Now, through a new Translational Research Program, all clinical trials at the Centre are partnered with the Institute. Their ground-breaking clinical trial research focuses on cancer, cardiology and molecular imaging.

The Institute has attracted world-class experts, scientists, and clinician-scientists, guided by Founding Scientific Director Dr. John A. Rowlands. To learn more about Dr. Rowlands’ research, please see page 47 of this report.
Research into diseases is vital to the health of Canada’s children. Some of the emerging issues include chronic disease, childhood obesity, diabetes, asthma, injury, mental health disorders and socioeconomic gaps in health. Ontario researchers are leaders in the global effort to advance children’s health.

The Hospital for Sick Children (SickKids) Toronto

SickKids is recognized as one of the world’s foremost pediatric healthcare institutions. It is Canada’s leading centre dedicated to advancing children’s health through the integration of care, research and education.

At Canada’s largest pediatric academic health sciences centre, and one of North America’s largest hospital-based research centres, the Hospital For Sick Children (SickKids) is world-admired for family-centred and compassionate care, scientific and clinical advancement, and preparing the next generation of leaders in child health.

SickKids’ commitment to improving the health of children is demonstrated by its legacy of historical milestones and important research discoveries. These include:

→ **Discovery of one of the genetic variations responsible for kidney failure in diabetics.** SickKids scientists discovered that variations in the gene SOD1 are linked to diabetic nephropathy (kidney failure). This finding could lead to new treatments to prevent the development of diabetes-related complications.

→ **Detection of frequent structural changes of chromosomes in autism.** A Canadian team led by SickKids scientists discovered numerous chromosomal regions containing autism spectrum disorder (ASD)-susceptibility genes. Additionally, a new region was identified on chromosome 16 which confers risk of ASD in one per cent of families.

→ **Link found between iron-deficiency anemia and stroke in young children.** Researchers at SickKids and U of T found that previously healthy toddlers who have a stroke are 10 times more likely to have iron-deficiency anemia than otherwise healthy children of this age group.

Scheduled to open in 2013, SickKids’ new Research & Learning Tower will bring together researchers from different scientific disciplines and a variety of clinical perspectives to accelerate future discoveries and their application to child health.
RHEUMATOLOGY

Ontario researchers continue to work with pharmaceutical companies and other clinical research organizations to test novel therapies for arthritis and other rheumatic diseases. These diseases are among the most common chronic health conditions in Canada. In 2007, arthritis affected an estimated 4.5 million people in Canada. This number is expected to climb to 6.4 million by 2026.

**Canadian Rheumatology Research Consortium Toronto**

This Consortium facilitates the conduct of rheumatology clinical research across Canada. It acts as a single point of contact to reach a national network of Canadian academic and community trial centres. The Consortium also collaborates with international partners at sites all over the world. It works to help clinicians, researchers, industry participants and sponsors with all aspects of clinical trial management. Services include:

- trial design
- site selection
- centralized budget and contract negotiations, and
- trial evaluation, analysis and follow-up.

It is a one-stop shop for all rheumatology studies, with experts available at all stages of research, from pre-clinical studies through to Phase III and Phase IV post-marketing studies. Launched in 2003, it has grown from focusing on rheumatoid arthritis to adding ankylosing spondylitis, psoriatic arthritis, osteoarthritis and lupus to its areas of expertise.

Top: Dr. Michael Kovacs, Director of the Nordal Cyclotron & PET Radiochemistry Facilities, Lawson Health Research Institute, makes adjustments on the cyclotron target filler panel. **Below**: Cameron McAlpine, a Medical Sciences graduate, McMaster University, is pipetting samples in an ice box for a study investigating links between diabetes and cardiovascular diseases.
MULTI–DISCIPLINARY RESEARCH

Centre for Addiction and Mental Health (CAMH)
Toronto

CAMH scientists employ their world-leading expertise to create personalized approaches for treating mental health and addiction disorders. Current studies showcase the wide range and multi-disciplinary nature of the Centre’s research. For example, CAMH is:

→ Participating in the largest randomized controlled clinical trial for adult outpatients with anorexia nervosa. This study, led by Dr. Allan Kaplan, assesses the medication olanzapine and includes analysis of genes that predict response to the drug. To learn more about Dr. Kaplan’s work, please see page 49 of this report.

→ Serving as a field trial site for the 5th Edition of the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders – the only centre outside of the United States and one of only seven overall.

→ Demonstrating that mindfulness-based cognitive therapy, using meditation, is effective in preventing depression relapse. Neuroimaging studies are underway to further investigate this approach.

→ Using PET scans and natural health products to balance brain levels of certain chemicals and nutrients in new mothers.

→ Using virtual reality environments and MRI scans to measure motivation in schizophrenia patients attempting everyday tasks.

→ Investigating new treatments to help people stop smoking.

→ Using genetic testing to determine which medications will be effective for which patients.

The Centre for Addiction and Mental Health is home to Canada’s only positron emission tomography (PET) facility fully dedicated to mental health and addiction research and is one of the few in the world.

Ottawa Hospital Research Institute
Ottawa

The Ottawa Hospital Research Institute (OHRI) is a major centre for clinical research. Several thousand patients participate in 1,500 active clinical trials here at any given time. More than 60 per cent of these trials are sponsored by private healthcare companies.

OHRI researchers have achieved unique success in translating their discoveries into new therapies and better healthcare. They have developed:

→ viruses that selectively destroy cancer cells
→ stem cell therapies for heart and lung disease, and
→ bio-engineered corneas for debilitating blindness and the world’s first biosynthetic cornea implant.

In 2008, Drs. Dean Fergusson and Paul Hébert completed the largest heart surgery clinical trial at that time; the results changed standard heart surgery practice around the world. To learn more about Dr. Fergusson’s work, please see page 44 of this report.

Other OHRI research includes:

→ the discovery of proteins that cleave DNA, and
→ the link between type 1 diabetes and the reaction of the gut immune system to certain foods.
BREAKING NEW GROUND: NEW HOPE FOR THE BLIND

At Ottawa Hospital Research Institute, Dr. May Griffith, along with Swedish collaborators, achieved a world first in cornea transplants. They successfully showed that biosynthetic corneas can help to regenerate and repair damaged eye tissue and improve vision in humans. The results from an early clinical trial with 10 patients appeared in the August 25, 2010 issue of *Science Translational Medicine*. The Institute made this groundbreaking study possible by acting as a catalyst between industry (FibroGen Inc., San Francisco) and government agencies from Canada and Sweden for project funding and support.

"With further research, this approach could help restore sight to millions of people who are waiting for a donated human cornea for transplantation," says Dr. May Griffith.

University Health Network (UHN)

**Toronto**

UHN is a research hospital network that is home to the largest hospital-based research program in Canada. The Network consists of the Toronto General, Toronto Western and Princess Margaret Hospitals. Its major research areas include:

- transplantation
- cardiology
- neurosciences
- oncology, and
- surgical innovation
- infectious diseases.
- genomic medicine

Clinical research is an important focus at UHN. The Network has a rich history of research innovation leading to global impact and exemplary patient care. To date, it has hosted more than 2,200 clinical trials and studies. For example, Dr. Sharon Walmsley, Director, Clinical Research Program, has participated in pivotal HIV trials on antiretroviral agents. To learn more about her research, please see page 46 of this report.

In fact, the Princess Margaret Hospital is the only site outside of the United States that holds a Phase I grant and Phase II contract for adult cancers with the U.S. National Cancer Institute [LG1]. It was also recently selected as the only non-U.S. member of the Cancer Immunotherapy Trials Network to conduct Phase I and II trials in cancer immunotherapy.

UHN is also home to Ozmosis Research Inc., an academic, not-for-profit Ontario enterprise. Ozmosis offers the full services of a clinical trials management company, with significant expertise in oncology and drug development.
ONTARIO’S CLINICAL SCIENTISTS: LEADERS IN VIRTUALLY EVERY FIELD
Ontario’s researchers include many pioneers and leaders in their respective fields. Their groundbreaking discoveries are helping Canada and the world to better understand today’s most pressing medical and scientific challenges. The following is a list of some of the leading researchers at work in Ontario’s world-renowned clinical trials and medical research.

CARDIOVASCULAR

DEAN FERGUSSON, MHA, PhD
Senior Scientist and Director, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa
dafergusson@ohri.ca

Research focus and interests
- Methodology and ethics of clinical trials and systematic reviews
- Transfusion medicine: transfusion alternatives and the effectiveness of blood products

Research summary
Dr. Dean Fergusson is co-founder and Director of the Ottawa Methods Centre at the Ottawa Hospital Research Institute. The Centre provides advice and clinical research mentoring services to the Ottawa Hospital.

Dr. Fergusson is a principal investigator on a number of large, peer-reviewed clinical trials in transfusion medicine. These include:
- The BART study (Blood Conservation using Antifibrinolytics: Randomized Trial in High-Risk Cardiac Surgery)
- The Age of Red Blood Cells in Premature Infants (ARIPi)
- The Age of Blood Evaluation (ABLE).

Anyone undergoing heart surgery today is likely to be affected by Dr. Fergusson’s groundbreaking research. His 2007 BART study revolutionized standard practice around the world. The results of his clinical research have saved thousands of lives.

Dr. Fergusson collaborates widely with researchers in diverse research areas, including:
- transfusion medicine
- kidney disease
- lung disease
- urology, and
- perinatology
- thrombosis.

His research interests also include the methodology and ethics of clinical trials and systematic reviews. He has been widely recognized for his contributions to medical research. Dr. Fergusson has authored more than 225 articles, abstracts, and book chapters.

HERTZEL C. GERSTEIN, MD, MSC, FRCPC
Director, Endocrinology and Metabolism, McMaster University, Hamilton
Deputy Director, Population Health Research Institute, Hamilton
gerstein@mcmaster.ca

Research focus and interests
- Using population health approaches to reduce the burden of diabetes in society and to prevent new diabetes
- Measuring the burden of diabetes in Canada
- Using epidemiologic approaches to study the relationship between dysglycemia, diabetes and cardiovascular disease
- Exploring the emerging role of albuminuria as an important risk factor for both kidney and heart disease in the population
- Running clinical trials for diabetes prevention and therapy

Research summary
Dr. Hertzel Gerstein holds the McMaster-Sanofi-Aventis Population Health Institute Chair in Diabetes Research. He has been at the centre of most of the world’s largest diabetes-related clinical trials in recent years. His current roles include:
- International principal investigator of the REWIND trial of cardiovascular prevention in type 2 diabetes
- Joint international principal investigator of the ORIGIN study (Outcome Reduction with an Initial Glargine Intervention) of cardiovascular prevention in people with dysglycemia
- Joint international principal investigator of the ACCORD follow-up study (Action to Control Cardiovascular Risk in Diabetes) called ACCORDION.
Other major international clinical research trials in which Dr. Gerstein has played or is continuing to play a major leadership role include the HOPE, MICRO HOPE, DREAM, TIDE, RECREATE, ELIXA and CANVAS trials. His role of principal investigator or joint principal investigator continues Ontario’s century-old tradition of diabetes discovery.

Dr. Gerstein’s research is funded by the U.S. National Institutes of Health, the Canadian Institutes of Health Research, Health Canada and the Canadian Diabetes Association. In addition to his research, Dr. Gerstein is the founding director of Diabetes Hamilton. This public program helps people with diabetes to best manage their disease.

KOON TEO, MBBCH, PhD, LRCP, MRCP, FRCP
Professor of Medicine, Department of Cardiology, McMaster University, Hamilton
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Research focus and interests

- Clinical trials and epidemiology studies of cardiovascular diseases

Research summary

Dr. Teo is a principal investigator of major clinical trials and epidemiology studies, including:

- The FAMILY study (Family Atherosclerosis Monitoring In earLY life). The study will track 859 families, including 901 babies, over a 10-year period, to observe how the first decade of life can influence the development of obesity, atherosclerosis and other risk factors for cardiovascular disease (CVD). Results of the FAMILY study will advance understanding of the fetal and early childhood determinants for CVD development.

- The COURAGE study (Clinical Outcomes Utilizing Revascularization and Aggressive drug Evaluation). Dr. Teo is the Canadian principal investigator of this joint Canadian-U.S. study. It involved 2,287 patients with myocardial ischemia and significant coronary artery disease. The trial was conducted at 50 U.S. and Canadian centres. Study results reinforced existing clinical practice guidelines and have had a large impact on clinical practice.

The PURE study (Prospective Urban Rural Epidemiology). This multi-national study involved more than 140,000 subjects from 17 countries. The study examined the impact of societal influences on human lifestyle behaviours, cardiovascular risk factors, and incidence of chronic non-communicable diseases in low-, middle- and high-income countries.

SALIM YUSUF, MD, DPHIL, MRCP
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Research focus and interests

- Societal, biologic and genetic determinants of population health in developing populations
- Societal and biologic determinants of diseases and evaluation of therapies in humans, with special focus on cardiovascular diseases, obesity, and diabetes

Research summary

Salim Yusuf is a world-renowned researcher in cardiovascular diseases and prevention. He has participated in studies in more than 66 countries and is responsible for many discoveries that are used in clinical practice worldwide.

Dr. Yusuf developed the concept of “large, simple trials” and meta-analysis while studying at Oxford University. Throughout his career, he has put these concepts to work. His research and clinical trials have established new medical practices and benefited millions of people around the world. These concepts are now widely accepted and have influenced research in several fields of medicine.
HIV

SHARON WALMSLEY, MD, MSc, FRCP
director, clinical research program
University Health Network, Toronto General Hospital Division, Toronto
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Research focus and interests

→ HIV infection
→ Antiretroviral resistance
→ Antiretroviral therapy
→ Management of HIV-infected women

Research summary

Dr. Sharon Walmsley has participated in a number of clinical trials involving:

→ Therapy of human immunodeficiency virus infection, including nucleosides, non-nucleosides, protease inhibitors, fusion inhibitors and integrase inhibitors.

→ Management of complications of HIV therapy, including lipid abnormalities and lipodystrophy.

Dr. Walmsley and her research team lead national and international multi-centre trials, sponsored by industry. She and her team also design and enrol patients in national trials as part of the Canadian HIV Trials Network.

As a clinical epidemiologist, Dr. Walmsley has participated in pivotal trials of antiretroviral agents both for treatment naïve and treatment experienced patients and has been published widely in the field. She also has a strong interest in the management of HIV-infected women. She is currently co-investigator of a multi-centre trial evaluating the response of women and girls with HIV to the human papilloma virus vaccine.

Her current work also studies co-infection between HIV and other viral infections including hepatitis C, hepatitis B and herpes simplex virus. These studies include:

→ Impact of HAART therapy (Highly Active Anti-Retroviral Therapy) on the outcomes of hepatitis C and liver disease

→ Durability of the immune response to the hepatitis B vaccine in persons living with HIV, and

→ Role of herpes simplex virus in accelerating the course of HIV disease.

Dr. Walmsley is currently the National Chair of the Scientific Steering Committee and Co-director of the Clinical Management Core of the Canadian HIV Trials Network.

IMAGING

AARON FENSTER, PhD
Director, Biomedical Imaging Research Centre (BIRC)
Director & Scientist, Imaging Research Laboratories, Robarts Research Institute, The University of Western Ontario, London
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Research focus and interests

→ 3D ultrasound-guided breast biopsy
→ 3D ultrasound-guided & robotically aided prostate brachytherapy
→ Ultrasound-guided vascular imaging

Research summary

Dr. Fenster’s current research includes an ultrasound-guided breast biopsy project to develop a 3D biopsy instrument involving an advanced imaging approach and sophisticated real-time image guidance. This will allow a suspicious breast lesion, identified through traditional mammogram screening, to be located during the biopsy procedure. The biopsy can consequently be taken accurately, swiftly and with minimal discomfort.

Dr. Fenster is also leading a project to overcome current limitations to brachytherapy procedures by developing a dynamic prostate brachytherapy approach that allows real time adjustments to the procedure during surgery.

Another of Dr. Fenster’s current projects is the development of 3D ultrasound technology for imaging carotid arteries and providing information on the progression or regression of carotid plaques. This technology has already been validated and is being used in multiple clinical trials investigating management approaches of patients at risk for stroke.

Dr. Fenster also co-leads the Imaging Pipeline platform at the Ontario Institute of Cancer Research with Dr. Martin Yaffe. This project supports the early diagnosis of cancer and the development of imaging techniques for cancer screening, cancer stem cell research and clinical trials.
JOHN A. ROWLANDS, Ph.D, FCCPM  
Founding Scientific Director, Thunder Bay Regional Research Institute, Thunder Bay  
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Research focus and interests

- Cancer imaging
- PET imaging
- Cardiac imaging

Research summary

Medical imaging and physics have been a common thread in the professional experience and international stature of Dr. Rowlands. His most significant recent contribution is a novel optical detector for Positron Emission Tomography (PET). This stems from his research into the fundamental x-ray imaging properties of amorphous selenium.

Dr. Rowlands has championed the use of amorphous selenium as an x-ray detector for over 15 years. This is now used in commercial medical imagers from four major imaging companies.

Dr. Rowlands has received peer-reviewed funding from:

- National Institutes of Health (U.S.)
- U.S. Army
- Medical Research Council of Canada
- Natural Sciences and Engineering Research Council of Canada
- National Cancer Institute of Canada.

His awards include the 1995 University Industry Synergy Award for Best Practices in Research and Development, NSERC and Conference Board of Canada in the area of flat panel imager development.

Other projects that Dr. Rowlands guides include a novel approach to incisionless surgery to treat cancer tumours deep in the body. This treatment is made possible using high-intensity focused ultrasound with MRI.

Dr. Rowlands has authored 35 peer-reviewed papers, 17 book chapters and conference proceedings papers and 26 abstracts resulting in 4 patents (2 issued, 2 pending).

JOHN VALLIANT, Ph.D  
Scientific Director and CEO, The Centre for Probe Development and Commercialization (CPDC)  
McMaster University, Hamilton  
valliant@mcmaster.ca

Research focus and interests

- Molecular imaging probe development
- Isotope research
- Radiopharmaceutical chemistry
- Radiolabeling methods and compound discovery strategies

Research summary

Dr. Valliant is internationally recognized for his work in radiopharmaceutical chemistry. His current research focuses on developing new radiolabeling methods and compound discovery strategies to create clinically relevant molecular imaging probes and therapeutic radiopharmaceuticals.

Dr. Valliant is working closely with leading academic institutions from around the world and multi-national and emerging companies, including:

- Pfizer Inc.
- GE Healthcare, and
- Molecular Insight Pharmaceuticals Inc.

Their work focuses on health-related industrial research and development.

Dr. Valliant currently has five patents or patent applications under review. He has also published numerous papers in refereed journals and conference proceedings. His work has been presented at more than 100 scientific conferences the world over.

Based on his research accomplishments, dedication to teaching and efforts to foster the commercialization of imaging research, in 2010 Dr. Valliant was selected one of Canada’s Top 40 under 40.
MARTIN YAFFE, PhD
Senior Scientist, Sunnybrook Research Institute, Toronto
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Research focus and interests
→ Digital imaging for medical diagnosis

Research summary
Dr. Yaffe’s research is directed toward development and improvement of imaging techniques for the detection, diagnosis, and treatment of cancer. He has a special focus on breast cancer. His research team is interested in methods for analyzing image patterns to predict breast cancer risk, study the causes of breast cancer and help develop preventive measures.

Dr. Yaffe’s research includes:
→ development of ultra high resolution digital x-ray detectors
→ design, fabrication and evaluation of high resolution solid state imaging sensors for digital mammography
→ development of image processing strategies to improve the quality of diagnostic images, and
→ research on breast density and its role in breast cancer etiology and detection.

His investigation of new applications includes:
→ 3D imaging (tomosynthesis)
→ contrast-enhanced imaging methods
→ a system for 3D imaging of breast histology to help improve the accuracy of breast surgery, and
→ quantitative imaging analysis for risk prediction and the use of computer-aided detection.

Dr. Yaffe has authored over 180 peer-reviewed publications.

BRIAN FEAGAN, MD
Director, Robarts Clinical Trials, Robarts Research Institute, London
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Research focus and interests
→ Therapy for Inflammatory Bowel Disease (IBD)

Research summary
Dr. Feagan is Professor of Medicine, Epidemiology, and Biostatistics at the University of Western Ontario in London, Ontario. He is also a specialist in internal medicine with training in clinical epidemiology and gastroenterology.

At Western, his research interests focus on the design and implementation of randomized controlled trials of therapy for IBD. He has been the principal investigator on numerous multi-centre trials that evaluate new treatments for the disease.

Dr. Feagan is also investigating the application of cluster randomization in the evaluation of health policies. This methodology is well-suited to the assessment of the effectiveness of treatment programs, such as a care path for disease management.

Throughout his career, he has published more than 120 peer-reviewed articles. He is currently a reviewer for the New England Journal of Medicine, Gastroenterology and the American Journal of Gastroenterology.
MENTAL HEALTH

ALLAN KAPLAN, MSC, MD, FRCP C
Chief of Clinical Research and Director of Research Training, Centre for Addiction and Mental Health (CAMH), Toronto
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Research focus and interests

→ Psychobiology of anorexia nervosa and bulimia nervosa
→ Medical complications of anorexia nervosa and bulimia nervosa
→ Neuroendocrinology of anorexia nervosa and bulimia nervosa

Research summary

Dr. Allan Kaplan has focused his research on the psychobiology of anorexia nervosa (AN) and bulimia nervosa (BN). This includes:

→ the medical complications of AN and BN, and
→ the neuroendocrinology of these disorders, including neurotransmitter abnormalities in both the serotonergic and dopaminergic systems.

Dr. Kaplan has also developed and rigorously evaluated innovative treatments, such as day hospitalization and community-based treatments for eating disorders. He has also:

→ examined predictors of outcome in AN and BN
→ conducted randomized controlled trials evaluating relapse prevention strategies for AN using cognitive behaviour therapy and fluoxetine, and
→ focused on innovative pharmacologic approaches to AN and on the genetics of both AN and BN.

This includes conducting research as part of a large multi-site consortium evaluating the genetics of AN and BN using linkage analyses, candidate gene analyses and genome wide association studies.

In collaboration with other investigators at CAMH, Dr. Kaplan’s research has examined genetic factors in weight regulation and caloric intake in obese and non-obese binge eaters.

NEUROSCIENCE

DAVID GLADSTONE, MD, PhD, FRCP C
Director, Regional Stroke Prevention Clinic, Sunnybrook Health Sciences Centre
Scientist, Sunnybrook Research Institute, Toronto
david.gladstone@sunnybrook.ca

Research focus and interests

→ Emergency stroke management
→ Intracerebral hemorrhage
→ Stroke prevention
→ Atrial fibrillation
→ Transient ischemic attacks
→ Stroke recovery and rehabilitation
→ Clinical trials and outcomes research

Research summary

Dr. Gladstone conducts clinically relevant research that can be immediately applied to patient care. He is the principal investigator of a number of studies, including:

→ The EMBRACE study. This is a national multi-centre randomized trial to improve early detection of paroxysmal atrial fibrillation in patients with cryptogenic strokes.
→ The SPOTLIGHT study. This randomized trial is to study an innovative image-guided emergency treatment protocol for patients with hemorrhagic stroke.

Dr. Gladstone has directed projects for the Registry of the Canadian Stroke Network to evaluate quality of care, safety issues and practice gaps in stroke management. He is actively engaged in medical education, sharing his research knowledge and experience at local, regional, national and international meetings that promote best practices in stroke diagnosis, treatment and prevention. He also delivers continuing education lectures to healthcare professionals, researchers and the public.
**DR. ADRIAN OWEN, PHD**

Canada Excellence Research Chair in Cognitive Neuroscience and Imaging  
The University of Western Ontario, London  
adrian.owen@uwo.ca

**Research focus and interests**

- Residual brain function in patients who are non-responsive after suffering a severe brain injury

**Research summary**

Dr. Adrian Owen is one of the world’s foremost neuroscientists. In 2011, he brought his remarkable research program – and his entire research team – from Cambridge University to the University of Western Ontario.

Dr. Owen has pioneered a new way to communicate with patients who are non-responsive after suffering a severe brain injury. This work could lead to new treatments to help unconscious patients regain brain function.

More than 500 patients, distributed across five centres, are currently enrolled in clinical trials managed by Dr. Owen. In one study, Dr. Owen and his partners are developing methods to improve the diagnosis and assess issues relating to prognosis after serious brain injury. Study results will help develop a standardized international protocol.

Dr. Owen is also investigating:

- the roles of medication and genotype in the cognitive profile of patient’s with Parkinson’s disease
- new theoretical models and use of functional neuroimaging (fMRI) approaches to detect and measure activity in brain-injured patients who appear to be entirely vegetative, and
- new brain-computer interfaces that will allow these patients to communicate with the outside world and will expand their choices for therapy.

These pioneering techniques offer a new window into the consciousness of some brain-injured patients.

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**MICHAEL SALTER, MD, PHD**

Canada Research Chair, Neuroplasticity and Pain  
Head of the Program in Neurosciences & Mental Health,  
The Hospital for Sick Children, Toronto  
Professor of Physiology, University of Toronto  
michael.salter@sickkids.ca

**Research focus and interests**

- Neurotransmitter receptors/signal transduction
- Purine receptors
- Post-translational modification of ion channels
- Spinal cord physiology
- Neuron-glia signalling
- Neuroimmune interactions
- Pain/nociception
- Excitotoxicity/neurodegeneration

**Research summary**

Dr. Michael Salter is one of Ontario’s leading pain researchers, exploring the genesis of pain at the molecular level. His work is opening new doors to our understanding of cell-to-cell communication within the body’s nervous system. His discoveries offer new hope of relief for millions of chronic pain sufferers around the world.

Dr. Salter conducts fundamental studies on the cellular, molecular and genetic mechanisms of chronic pain. In addition, he has a broad interest in neuroscience and has conducted pioneering work relevant to learning and memory, stroke-induced neuron death, epilepsy and schizophrenia.

Dr. Salter has received numerous awards for his research and has launched two start-up biotech companies. He is founding scientist and vice president of NoNO Inc., which is developing novel therapeutic agents for the treatment of stroke, neurodegeneration, neurotrauma and pain.
ONCOLOGY

JOHN C. BELL, PhD
Senior Scientist, Ottawa Hospital Research Institute, Centre for Innovative Cancer Therapeutics
Program Leader, Immuno- and Bio-Therapeutics, Ontario Institute for Cancer Research, Toronto
jbell@ohri.ca

Research focus and interests

- Oncolytic viruses
- Cell-based cancer therapeutics

Research summary

Dr. Bell’s lab has shown that a variety of viruses selectively replicate in and kill cancer cell lines while leaving healthy parts of the body intact. Dr. Bell and his colleagues have developed a number of oncolytic viruses that preferentially grow in and kill tumour cells, without the side effects of traditional cancer therapies. Viruses are able to infect cells, replicate, induce cell death, release viral particles and spread through human tissues, making them an ideal weapon against cancer.

Dr. Bell is now taking this research from ‘bench to bedside.’ He is working with an industrial partner to develop therapeutic viruses for cancer treatment. Phase I and Phase II clinical trials on cancer patients at the Ottawa Hospital show great promise. Results demonstrate the viruses’ ability to selectively target and destroy cancer cells in humans.

Jennerex, a private, clinical-stage biotherapeutics company, is sponsoring Dr. Bell and his colleagues to conduct Phase III trials of the therapeutic viruses in multiple international locations. These trials have demonstrated the viruses’ medical potential.

As a Senior Scientist at the Centre and Professor of Medicine at the University of Ottawa, Dr. Bell has published nearly 100 research papers and filed 16 patents.

TOM HUDSON, MD
President and Scientific Director, Ontario Institute for Cancer Research (OICR), Toronto
tom.hudson@oicr.on.ca

Research focus and interests

- Cancer genomics
- Human genetic diseases

Research summary

- Founder and Scientific Director, Public Population Project in Genomics (P3G)
- Founding member, International Haplotype Map Consortium
- Founding member, International Cancer Genome Consortium
- Director of the McGill University and Genome Quebec Innovation Centre
- Assistant-Director of the Whitehead/MIT Center for Genome Research.

Under Dr. Tom Hudson’s leadership at the OICR, multi-disciplinary teams translate research discoveries into interventions for better prevention, detection, diagnosis and treatment of cancer. Dr. Hudson is internationally renowned for his work in genomics and human genome variation. He is a leader in the development and applications of robotic systems and DNA-chip based methodologies for genome research.

Dr. Hudson’s interests in human genetic diseases focus on the dissection of complex genetic diseases. Disease projects in Dr. Hudson’s laboratory have included:

- the search for genes predisposing to lupus
- inflammatory bowel disease
- coronary artery disease
- asthma
- diabetes, and
- colon cancer.

The laboratory also used DNA-chip technology to characterize breast and ovarian cancer.

At OICR, Dr. Hudson is studying genome variation that affects cancer predisposition, progression and response to therapy. His main project focuses on the genetic architecture of loci associated with risk to colorectal cancer.
MALCOLM MOORE, MD  
Director of the Drug Development Program, Ontario Cancer Institute/Princess Margaret Hospital, Toronto  
malcolm.moore@uhn.on.ca

Research focus and interests
- Development and testing of new cancer therapies
- Therapeutic interventions for pancreatic cancer
- Genetic changes related to human diseases

Research summary
Dr. Moore’s work involves the evaluation and early clinical testing of novel agents for gastrointestinal and genitourinary cancer therapy. He is a principal investigator for many Phase I, II and III trials. He has developed several chemotherapy drugs, including gemcitabine and erlotinib for pancreatic cancer.

Dr. Moore’s current research focus is pancreatic cancer and developing therapeutic approaches based upon the genetic changes in diseased individuals. He directs the Drug Development Program at Princess Margaret Hospital. His research includes the development and use of pharmacokinetic and pharmacodynamic assays for use in Phase I and II studies of new drugs.

The Drug Development Program includes the largest Phase I program in Canada with studies supported by agencies such as:
- the National Cancer Institute (United States)
- National Cancer Institute of Canada
- the pharmaceutical industry, and
- a National Institutes of Health (NIH) grant to support Phase II drug development of novel anti-cancer agents.

Dr. Moore has authored more than 180 peer-reviewed publications and has given more than 150 lectures worldwide.

AMIT OZA, BSc (LON), MBBS (LON), MD (LON), FRCP, FRCPC  
Senior Staff Physician, Princess Margaret Hospital, Toronto  
amit.oza@uhn.on.ca

Research focus and interests
- Development, assessment and validation of novel therapeutic strategies for cancer
- Clinical and translational research in gynecological malignancies

Research summary
Dr. Amit Oza has been the principal investigator and co-investigator in Phase I, II and III trials for gynecological cancer and advanced colorectal malignancies. His research interests are the development, assessment and validation of novel therapeutic strategies for cancer, including molecular targeted therapies.

He is currently Co-Director of the Robert and Maggie Bras and Family Drug Development Program at Princess Margaret Hospital. This is the largest new drug development program in Canada. It is also the only centre outside the United States to have a contract with the National Institutes of Health for Early Phase Therapeutic studies.

Dr. Oza also established and is CEO of Ozmosis Research. Ozmosis is a not-for-profit social enterprise company that runs and manages clinical trials across Canada. He has authored or co-authored numerous publications in major peer-reviewed journals.
FRANCES SHEPHERD, MD, FRCP  
Chair, The National Cancer Institute of Canada Clinical Trials Group Lung Cancer Site  
Princess Margaret Hospital, Toronto  
frances.shepherd@uhn.on.ca  

Research focus and interests  
→ Clinical trials for lung cancer  

Research summary  
Dr. Shepherd has been recognized for her many contributions in the field of lung cancer research, most notably her longstanding international leadership in the development of innovative therapies. Dr. Shepherd has designed and led more than 100 clinical trials over the past three decades. Her studies have changed treatment and outcomes for lung cancer patients at a global level. She sits on numerous national and international lung cancer advisory boards. She also chairs and/or sits on several data and safety monitoring boards for international lung cancer trials.  

In 2001, she was named the Scott Taylor Chair in Lung Cancer Research, becoming the first holder of this esteemed research position. Dr. Shepherd also served as Chair of the Lung Cancer Site Committee of the National Cancer Institute of Canada Clinical Trials Group for almost 20 years. She was President of the International Association for the Study of Lung Cancer from 2003 to 2005.  

Dr. Shepherd has authored or co-authored more than 380 peer-reviewed publications and 35 book chapters. In recognition of her contributions to cancer research and treatment, she received the Order of Ontario in 2007.

LILLIAN SIU, FRCP, MD  
Staff physician, Department of Medical Oncology and Hematology  
Princess Margaret Hospital, Toronto  
lillian.siu@uhn.on.ca  

Research focus and interests  
→ Developmental therapeutics and Phase I clinical trials of novel agents  
→ Head and neck malignancies  

Research summary  
Dr. Lillian Siu is the Associate Director of the Drug Development Program and Director of the Phase I Clinical Trials Program at Princess Margaret Hospital. She is the principal investigator of a Phase I Cooperative Award ($3.4 million U.S. from 2008-2013), sponsored by the National Cancer Institute (NCI) in the United States. The goal is to expedite the access to and evaluation of novel anti-cancer agents.  

In addition, Dr. Siu is principal investigator of many Phase I, II and III trials supported by NCI U.S., the National Cancer Institute of Canada and the pharmaceutical industry. Dr. Siu has received many national and international awards, including the Michael C. Christian Award in Oncology Drug Development from the NCI U.S. in 2010. She has published more than 110 peer-reviewed manuscripts.
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PHOTO CREDITS AND COURTESIES

Dr. Ahmed Mamai using an LC MS/MS instrument to analyze chemicals [Page 1]
Dr. Alla Reznick and Dr. John A. Rowlands [Page 2]

Mount Sinai Hospital research lab [Page 5]
Insulin artifact image [Page 6]
Dr. Gordon Murray [Page 6]
First artificial kidney made in North America, Dr. Gordon Murray [Page 6]
First regulated cardiac pacemaker [Page 6]
Dr. J. Till and Dr. E. McCulloch [Page 6]
Dr. Joel Cooper [Page 6]
Dr. Stuart Foster, Sunnybrook Research Institute [Page 6]
PET scans [Page 6]

Acute myeloid leukemia (AML) [Page 6]

Dr. Michael Salter [Page 6]
Dr. Andras Nagy [Page 6]
Dr. Derek van der Kooy [Page 6]
Dr. May Griffith [Page 6]
Sanofi Pasteur clinical scientist [Page 7]
Leslie L. Dan Pharmacy Building [Page 8]
Drs. Shana Kelley and Ted Sargent [Page 8]
Dr. Adrian Owen [Page 9, top right]
Brian Li, researcher, Sunnybrook Research Institute [Page 9, bottom left]
The MaRS Centre, Discovery District [Page 10]
Princess Margaret Hospital [Page 11]
City of Toronto green skyline [Page 12]
Kingston City Hall [Page 13]
Chemotherapy nurse and patient, Princess Margaret Hospital [Page 15]
Toronto site of Sanofi Pasteur [Page 15]
A Sanofi Pasteur lab technologist [Page 15]
The Advanced Technology and Academic Centre, Lakehead University, Thunder Bay campus [Page 16]
Michael G. DeGroote Centre for Learning & Discovery [Page 17]
Family cycling in Ottawa [Page 18]
Toronto’s financial district at night [Page 19]

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Thunder Bay Regional Research Institute/Thunder Bay Regional Health Sciences Centre
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Ontario Ministry of Economic Development and Trade
Ontario’s Life Sciences Commercialization Strategy [Page 20]
Dr. Hertzel Gerstein [Page 21]
Eli Lilly researchers [Page 21, top right]
Researchers at Lawson Health Research Institute [Page 21, bottom right]
Mount Sinai Hospital clinical researcher [Page 21, centre right]
Sunnybrook Health Sciences Centre, Bayview Campus [Page 22]
St. Michael’s Hospital, Applied Health Research Centre [Page 25]
Clinical researcher [Page 27]
Brain image produced by Siemens 3T Tim Trio MRI scanner [Page 27]
Dr. David Gladstone and patient, Sunnybrook Research Institute [Page 30, top right]
Concept of Sunnybrook’s M-wing expansion [Page 30, centre right]
MRI-guided focus ultrasound device assembly [Page 30, bottom left]
Nordal Cyclotron & PET Radiochemistry facilities [Page 31, top left]
Team of scientists identifying molecular markers [Page 31, bottom left]
Robarts Research Institute [Page 32, top right]
27.5 tonne Varian/Siemens 7 Telsa (7T) functional magnetic resonance imaging system [Page 32, bottom right]
Radiation therapy at Juravinski Cancer Centre [Page 33]
Scientists using a mass spectrometer [Page 34, top right]
Dr. Tom Hudson [Page 34, bottom right]
Technician in a genomics laboratory [Page 35]
Quality Control technologist [Page 35]
Medicinal chemist purifying compounds [Page 36]
Plasmid DNA constructs [Page 36]
Chemo therapy nurse and patient, Princess Margaret Hospital [Page 37]
The Hospital for Sick Children [Page 38]
Nordal Cyclotron Core Facility [Page 39]
McMaster University medical sciences graduate student [Page 39]
Positron emission tomography (PET) facility [Page 40]
Ottawa Hospital paramedic and emergency physician [Page 40]
Dr. Shaf Keshavjee, Toronto General Hospital [Page 41]
Dr. May Griffith and artificial cornea [Page 41]
Charles Best and Dr. Frederick Banting, circa 1924 [Page 42]
Dr. John Dick [Page 43]
Dr. Tom Hudson [Page 51]
St. Michael’s Hospital aerial view [Page 54]
A patient receives a PET scan with a Glucovision® probe [Page 55]
Microscope slides [Page 59]
ENDNOTES

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For guidance in setting up clinical trials research programs in Ontario contact the Ministry of Research and Innovation.

Access to Capital and Business Development Branch Manager, Life Sciences Programs Unit
Tel: 416-212-5448/1-866-446-5216
Email: Info4@ontario.ca

BEFORE STARTING A TRIAL

Sponsors must submit a Clinical Trial Application and receive Health Canada approval before initiating a trial in Canada. This applies to Phase I through III clinical trials only.

Health Canada hosts consultation meetings where sponsors can present relevant data, discuss concerns, resolve potential issues and receive guidance related to the proposed trial. To learn more, visit the Health Canada website: www.hc-sc.gc.ca

For more information on the Ministry of Research and Innovation, please visit us at:

Web: www.ontario.ca/innovation
Web: www.ontario.ca/mri-publications
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For a list of international phone numbers, visit:
Web: www.investinontario.com/contactus

The content of this publication is for general information purposes only. It is not intended to be an exhaustive presentation of Ontario’s clinical trials assets. Rather, it is a sampling of the capabilities and opportunities in clinical research you will find across the province of Ontario.