

CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES'

Report to Canadians

A COMMITMENT TO INNOVATION, DISCOVERY, QUALITY AND SAFETY

*Partners for research, healthcare and community
The innovative pharmaceutical sector creates real value in collaboration*

Vaccines: A Success Story

*Insights Into Safety:
Canada's innovative pharmaceutical companies put safety first*



A MESSAGE FROM RX&D PRESIDENT RUSSELL WILLIAMS

AT RX&D WE RECOGNIZE AND VALUE THE ROLE WE PLAY IN IMPROVING THE LIVES OF PATIENTS. ALL INTERACTIONS ARE ETHICAL AND CONDUCTED WITH RESPECT AND INTEGRITY, AND WE ADHERE TO THE PRINCIPLES AND LETTER OF OUR CODE OF ETHICAL PRACTICES. WE WORK TIRELESSLY TO FURTHER OUR MEMBERS' INTERESTS OF: BECOMING AN AUTHENTIC, SOLUTION-DRIVEN PARTNER THROUGH EFFECTIVE ALLIANCES, POLICY AND LEADERSHIP; IMPROVING THE ACCESS AND REGULATORY ENVIRONMENT IN CANADA; AND ADVOCATING FOR A GLOBALLY COMPETITIVE INTELLECTUAL PROPERTY REGIME. WE CONDUCT OURSELVES IN A MANNER THAT OFFERS PRO-ACTIVE SOLUTIONS TO ADDRESS CANADIAN HEALTHCARE CHALLENGES.



The innovative pharmaceutical industry recognizes that Canadians expect companies to be accountable for their conduct. Rx&D's Code of Ethical Practices provides a mechanism for its members to establish and maintain an ethical culture through a committed, self-regulated approach.

Rx&D's Guiding Principles and requirements of the Code set out strict standards for the activities of all member company employees.

canadapharma.org/commitment-to-ethics



"We work with remarkable organizations, healthcare professionals, patients, governments, academia, and the private sector, and we all have the same goal: we want to make Canada better."

RUSSELL WILLIAMS
President, Rx&D

Canada's Research-Based Pharmaceutical Companies (Rx&D) is the community of more than 50 innovative companies committed to the discovery and development of new medicines and vaccines. As the national voice of our industry, Rx&D advocates for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of Canadians.

We are the men and women who do research, who make important discoveries and who help make innovative medicines available to the people who need them. We are also the men and women who sit in doctor's offices, hear difficult news about our own health, and make life-changing decisions on how to deal with illness. We are the men and women who know that prevention goes a long way, that healthcare is a team effort and that safety is paramount.

We work with remarkable organizations, healthcare professionals, patients, governments, academia, and the private sector, and we all share the same goal: we want to make Canada better.

I wanted to share examples of these partnerships and help Canadians have a better understanding of our industry and the role that we play in this country.

Through this publication, we hope to let you know who we are, why we do what we do, how we do it, and how passionate we are about helping Canadians live longer, and better. We also hope Canadians will learn something new by reading this. An informed patient is an empowered patient.

As we celebrate 100 years as an association and 100 years of Canadian innovation, we have a lot to be proud of. Every year, we invest more than \$1 billion in life science R&D, generating \$3 billion annually for the Canadian economy. Discovering and developing new medicines and vaccines helps save Canadian lives and makes Canadian communities stronger. The discovery of innovative medicines and vaccines creates jobs and contributes to the economy and to the sustainability of our healthcare system. Most importantly, innovative medicines save lives.

As I look back on the last 100 years and the tremendous advances in healthcare that have transcended, I cannot help but wonder: what will the next 100 years bring?

Russell Williams
President
Canada's Research-Based
Pharmaceutical Companies (Rx&D)

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LIVING LONGER, STRONGER, & HEALTHIER

**IN LESS THAN A CENTURY, CANADIANS HAVE ADDED
MORE THAN 20 YEARS TO THEIR LIFESPAN.**

That is not an accident. It is partly the result of years of investment and innovation, developing new and better healthcare practices, discovering cures and more effective treatments that not only help Canadians live longer lives, but ensure those extra years are fulfilling and productive. A cornerstone of this innovation is the development of medicines and vaccines that help people recover faster, avoid illness and stay healthy. This, in turn, has generated measurable savings across the healthcare spectrum by keeping people out of hospitals and avoiding costly, often invasive procedures.

“Innovative medicines treat disease and improve health, and they can generate important savings elsewhere in the health system,” says Mark Lievonon, President of Sanofi Pasteur Limited and Chair for the Board of Directors for Canada’s Research-Based Pharmaceutical Companies (Rx&D). “That’s not to mention that healthy people make for a more productive workforce. The benefits of innovative medicines to health and to society in general are well documented.”

THE VALUE OF INNOVATIVE MEDICINES:
WHAT IS IT AND HOW DO WE MEASURE IT?

The value of innovative medicines to the healthcare system is substantial. A ground-breaking 2012 study by Frank R. Lichtenberg from Columbia University found that life expectancy was significantly higher in countries that had access to, and used, newer medications. An earlier study by Dr. Lichtenberg concluded that investing in innovative medications saves money elsewhere in the healthcare system by a significant margin. For every \$1 spent on new medications, non-medication expenses dropped by more than \$7.

But it's not just Dr. Lichtenberg who sees the value in developing new medications.

A 2013 study published by the Conference Board of Canada examined the health and economic benefits associated with pharmaceutical spending in Ontario from 2007 to 2012. The research concluded that spending \$1.22 billion generated offsetting health and societal benefits of nearly \$2.44 billion — a 2:1 benefit-to-cost ratio that increases over time. Some of the benefits included reduced demand for hospital services and increased productivity in the workplace.

All healthcare expenses must be carefully assessed in accordance with their value and in the context of the total healthcare budget. A 2013 study published by Canadian Health Policy Institute (CHPI) using data from the Patented Medicine Prices Review Board (PMPRB) and the Canadian Institute for Health Information (CIHI) calculated that total direct spending on patented medicines accounted for \$12.8 billion, or 6.2 per cent of the \$205.9 billion spent on all (public plus private) healthcare in 2012. The CHPI study also estimated that total provincial/territorial government spending on patented prescribed drugs in public drug plans was approximately \$4.7 billion, or 3.5 per cent of the \$134.7 billion total spent by provincial/territorial governments for healthcare in 2012.

Full value for investments into innovative medicines and vaccines must include consideration for the safety and clinical effectiveness for patients, patients and caregivers' quality of life, cost, value-added services (such as patient adherence initiatives), the capacity to address urgent public health threats as well as benefits to society like improved individual and workforce productivity.

MAKING SURE VALUE IS RECEIVED
AT THE PATIENT LEVEL

The basic and clinical research that goes into the discovery and development of a new medicine takes, on average, ten years. New medicines then undergo complex regulatory reviews before they are approved for use in Canada which take, on average, two years to complete. But just because a medicine or vaccine is approved does not mean that Canadians have access to it.

Canadians are often surprised to hear that Canada actually ranks 23rd out of 32 OECD nations in terms of access to medicines it provides to patients.

Canada has a unique healthcare system. Its publicly funded healthcare system sees ten provincial and three territorial health insurance plans which aims to provide access to universal coverage for medically necessary hospital and physician services. The provinces and territories administer and deliver most of Canada's healthcare services. Governments assess and list medicines, which are then covered for patients through provincial formularies. Medicines approved in Canada that go beyond these provincial listings may be covered through private insurance plans. Across the country, access to medicines varies based on one's location and the level of their private insurance coverage, if they have it.

Through the Pan-Canadian Pharmaceutical Alliance (PCPA), Canadian governments have recognized this challenge and are trying to address it. The PCPA's public stated objectives include: driving best prices and value for medicines; increasing access to treatment options for patients; improving the consistency of drug listing decisions across the country; and drive efficiency in processes. So far, the PCPA has only focussed on the simple economies of pricing negotiations and they have not developed metrics to be accountable to Canadians on how they are achieving the objectives Canadian patients are most concerned about – timely access and consistency of access to needed medicines across the country. Rx&D stands ready to partner with the PCPA to achieve all of its objectives.

"We all should consider the overall value of innovative medicines as we build public policy," said Russell Williams, President, Rx&D. "The appropriate use of innovative medicines and vaccines is a key enabler to health system sustainability. We believe

that governments will be even more productive and effective when they engage our industry as a healthcare partner."

Addressing these policy restrictions and encouraging more investment in the research and development of new medicines will enable Canada to make greater strides in helping people live longer, healthier lives — giving them more time to contribute to our communities and spend time with their families.

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—
RUSSELL WILLIAMS
President, Rx&D



At only 33 years old, and with no family history or risk factors, Michelle was shocked when she got the diagnosis from her doctor. The suspicious lump she had found in the spring of 2014 was stage IV breast cancer. A loving wife, proud mother to two-year-old Taylor and a communications manager at AstraZeneca Canada, Michelle had little choice but to face this challenge with determination, a bit of humour and a steely resolve to beat it. "My decade with AstraZeneca has certainly made me familiar with the cancer treatments that are available, but that work became very personal when my oncologist told me two astrazeneca medications would be part of my treatment plan," mMichelle says. In the months since her diagnosis, Michelle's family, friends and colleagues say she has become a true inspiration and a daily reminder why the work done by canada's innovative pharmaceutical companies matters.

NEW
MEDICINES
MAKE A
DIFFERENCE

EVERY DAY, MILLIONS OF CANADIANS ARE TAKING SOME SORT OF MEDICATION TO HELP THEM LIVE NORMAL, PRODUCTIVE LIVES. FOR EXAMPLE:

The use of innovative pharmaceuticals has reduced the number of HIV/AIDS-related deaths in Canada by 66 per cent for males and 43 per cent for females.

In 2002, the average annual cost of the antidepressant venlafaxine was \$255, less than the cost to employers for one day of missed work.

Innovative medications have greatly reduced the mortality rate for cardiovascular disease, which has dropped 56 per cent over the past 50 years.

Leukemia used to be a death sentence for children; advancements in medication have helped four out of every five children live at least five years after diagnosis.

Better education and improved medications have drastically reduced the number of hospitalizations due to asthma, from roughly 250 per 100,000 people in 1987 to less than 150 today.

AN IDEA WORTH HOLDING ON TO

INNOVATION IS THE FOUNDATION OF CANADA’S RESEARCH-BASED PHARMACEUTICAL INDUSTRY.

Researchers across the country are working hard to discover and develop tomorrow’s cures, pain relievers and vaccines. Canada is competing with nations around the world to attract the investments that support the ground-breaking research and the clinical trials that lead to breakthrough medications.

“I define innovation as the successful implementation of new ideas,” said Senator Kelvin Ogilvie. “Pharmaceutical innovation is critical to dealing with ever increasingly sophisticated threats to health, especially from bacteria and viruses. When this innovation occurs within Canada, economic benefits are significant and go beyond the important health benefits. The benefits include the support for further Canadian research and provision of on-site knowledge in dealing with medical problems.”

When it comes to bringing new medicines and vaccines to market here at home, Canada’s biggest challenge is its ability to compete for R&D investments globally. The country boasts world-class science, researchers and infrastructure, but needs world-class public policy. Canada has taken some great steps towards global competitiveness – most recently with the intellectual property improvements included in the Comprehensive Economic and Trade Agreement (CETA) with the European Union. Specifically, the enshrinement of 8 years of protection for clinical trial data, the restoration of some balance to the patent

linkage system by providing an effective appeal right for innovators, and the provision of up to 2 years of patent time lost due in the long development, testing and regulatory processes necessary to bring new innovative medicines to Canadians. However, there is still much work to do to transform Canada into an ideal destination for R&D investments.

“It is important that Canada have a policy environment that drives discovery and research,” said Russell Williams, President of Canada’s Research-Based Pharmaceutical Companies (Rx&D). “A competitive intellectual property regime is vital to bringing new dollars to Canada to support research and development. It can take 15 years and costs roughly \$1 billion to take a new medicine from discovery to market, and we need to make sure Canada is in a position to attract investments.”

Over the years, Canada has been a fertile ground for the discovery of new medications and treatments. Perhaps the most renowned is insulin, but new discoveries continue into some of the world’s most challenging health concerns.

Just over the past 20 years, Canadian researchers have made great strides. Dr. Peter St. George-Hyslop from the University of Toronto has had encouraging test results from an experimental vaccine for Alzheimer’s disease used on mice. We are closer to an HIV vaccine than we have ever been, and a new anti-malaria agent was discovered by Dr. Lakshmi Kotra from the University Health Network in Toronto. Significant strides have

been made in cancer care, whether using stem cells in innovative treatments or experimenting with immune-biology, which uses the body’s own immune system to attack cancerous cells.

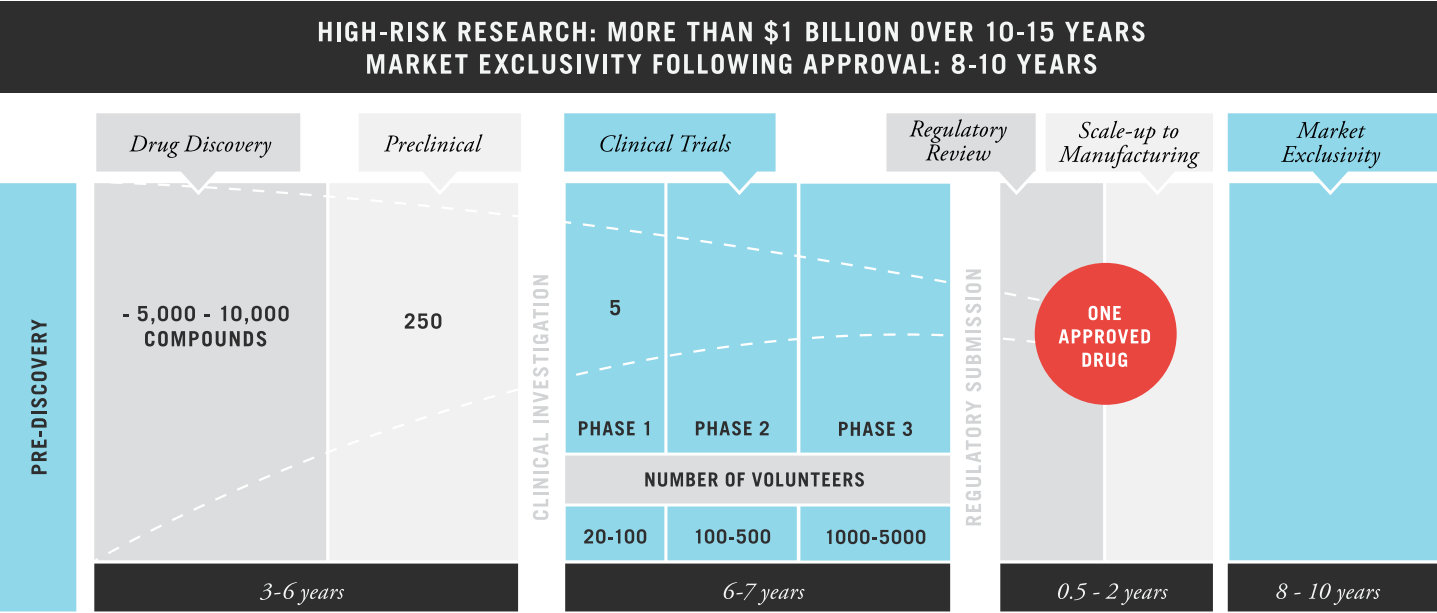
“We strongly support the robust protections of intellectual property contained in the Comprehensive Economic and Trade Agreement (CETA). We believe that cal research regarding all mental illness, but in particular concerning depression, bipolar disorder and PTSD, will increase; and new treatments, including new pharmaceutical therapies, will be discovered. New treatments will help Canadians suffering from mental illness and boost the research and development side of Canada’s life sciences sector, benefiting local economies and providing employment to more Canadians.”

—
PHIL UPSHALL
*National Executive Director,
Mood Disorders Society of Canada*

THE SANOFI PASTEUR INSULIN BOTTLE IS MEMORIALIZED ON THE BACK OF CANADA’S \$100 BILL, WHICH IS ITSELF A NICE TRIBUTE TO MEDICAL RESEARCH IN THIS COUNTRY.



DRUG DISCOVERY & DEVELOPMENT PROCESS:



INSIGHTS INTO SAFETY

CANADA’S INNOVATIVE PHARMACEUTICAL COMPANIES PUT SAFETY FIRST

Researchers work on medicines and vaccines that heal and prevent illness and ensure that the benefits of these medications far outweigh any risks.

The World Health Organization estimates that 50 per cent of patients do not take their medications when and how they are supposed to. Like Canada’s Research-Based Pharmaceutical Companies (Rx&D), it has established safe medication use as a global priority.

“Our responsibility for patient safety goes well beyond ensuring our medications don’t have debilitating side effects,” says Sylvia Hyland of the Institute for Safe Medication Practices. “We have taken extensive efforts to empower patients and help them take more control over their treatments and health.”

Knowledge is the Best Medicine (KiBM) is a program designed to help Canadians take control of their health while working with their healthcare teams to keep track of

their medications and use them safely. This contributes to reducing medication errors and non-adherence, thus easing pressure on the healthcare system. The entire healthcare community has a common interest in ensuring patient safety.

That’s why Rx&D, the Canadian Nurses Association, the Canadian Pharmacists Association, the Canadian Medical Association, the Institute for Safe Medication Practices Canada, the Victorian Order of Nurses and the Best Medicines

Coalition have joined together to support development of the KiBM patient tools.

“We work in partnership with health care providers, hospitals, governments, patients, and insurers to promote patient safety and appropriate use of medicines, and it’s important to us that we do so,” says Russell Williams, President of Rx&D. “Medications must be used properly, and our members are actively involved in ensuring Canadians are informed on any risks associated with a particular medicine.”

EMPOWERING PATIENTS WITH TECHNOLOGY: MyMedRec

With an easy-to-use interface that puts medication and immunization information at a person’s fingertips, MyMedRec is helping Canadians take better control of their healthcare.

Available for iPhone, Android devices and BlackBerry10, MyMedRec is a free app that empowers people to use their smartphones as a tool to better manage a wide range of information that will help them — and their healthcare professionals — administer their medications safely and appropriately.

Available globally, MyMedRec was developed by seven of Canada’s leading healthcare organizations — Canada’s Research-Based Pharmaceutical Companies (Rx&D), the Canadian Nurses Association, the Canadian Pharmacists Association, the Canadian Medical Association, the Institute for Safe Medication Practices Canada, the Victorian Order of Nurses

and the Best Medicines Coalition — to ensure patients and their healthcare teams have all the information they need, when they need it.

It includes features such as refill and dose reminders, storing of medication histories and multiple patient profiles, email and picture capabilities, as well as contact information of prescribers and pharmacies. It can also record clinical outcomes such as blood pressure and cholesterol, set dose reminders and share information with clinicians via email.



VACCINES: A SUCCESS STORY

Vaccines have been hailed as the greatest public health innovation in modern history. By preventing illness, and in some cases eradicating certain diseases in Canada, vaccines have saved billions of dollars for the Canadian healthcare system, and countless lives by preventing illnesses that at one time had been debilitating — or even fatal.

Vaccination is the most effective medical intervention ever introduced and, together with clean water and sanitation, it has eliminated a large part of the infectious diseases that once killed millions of people. The Public Health Agency of Canada estimates that vaccination has saved more lives in Canada over the past 50 years than any other health intervention.

Vaccines are the cornerstone of public health, protecting communities from diseases that used to run rampant through the population. Just a century ago, infectious diseases were the leading cause of death worldwide. Today in Canada, fewer than five per cent of all deaths are related to infectious diseases, the result of widespread use of vaccines. In 1980 the World Health Organization declared that smallpox had been eradicated from the world through vaccinations, and Canada was declared polio-free in 1994. Other infectious diseases that have been all but wiped out in Canada as a result of immunization include diphtheria, CRS, rubella and tetanus.

Vaccination is also a cost-effective intervention. By keeping people healthy and out of hospital, it can be easy to forget the savings as result of immunization. But it has been estimated that since the polio vaccine was made available in 1955, it has saved Canadian healthcare an estimated \$33 billion and has made the disease history in Canada. The rotavirus vaccine keeps 4,300 people from going to the hospital annually, saving roughly \$30 million every year. Remarkably, vaccines represent only approximately 0.26 per cent of healthcare spending in Canada.

These are significant numbers, and the good news is that work on new vaccines continues. Collaboration between Canada's innovative pharmaceutical companies and academic researchers is breaking new ground on more potential game changers.

Dr. Chil-Yong Kang at the University of Western Ontario in London led a team that has developed a preventive vaccine for HIV. The experimental vaccine is in currently in phase two and three clinical trials, and is showing promise to be the world's first vaccine for a deadly virus that has killed 25 million people worldwide, including 25,000 Canadians, since it emerged in the 1980s.

A synthetic vaccine has proven highly effective against meningococcal meningitis. Effective for babies as young as two months but providing protection for people of all ages, the vaccine known as NeisVac-C was developed by Dr. Harry Jennings, an immunologist with Canada's National Research Council in Ottawa.

Other vaccines at various stages of development in Canada promise to treat several types of aggressive cancers, including brain, cervical, colorectal and pancreatic cancers. Vaccines are safe, effective, and continue to help us prevent disease.

DID YOU KNOW?

VACCINES ARE AMONG THE SAFEST TOOLS OF MODERN MEDICINE. IN CANADA, SERIOUS SIDE EFFECTS OCCUR VERY RARELY — LESS THAN ONCE IN EVERY ONE MILLION DOSES OF VACCINE. IF THEY DO HAPPEN — THEY CAN BE TREATED QUICKLY AND EFFECTIVELY. THE DANGERS OF VACCINE-PREVENTABLE DISEASES ARE MUCH GREATER THAN THE RISKS OF A SERIOUS REACTION TO A VACCINE.

Source: Public Health Agency Of Canada

1914

2014

1914
1st Public Health Vaccines
& Sera Produced in Canada



1921
Discovery of Insulin



1925
Discovery of
Parathyroid Hormone



1930
Development of
Pabulum

1928
First Canadian
Manufacturer of
Vitamin D

1938
First Studies to Validate
the Tuberculosis Vaccine



1944
First Electrophoresis
of Proteins

1953
Clinical Trial
of Chlorpromazine

1959
Development of
Vinblastine for
Chemotherapy

1961
Discovery of Calcitonin

1965
Discovery of First
Cancer Tumor Antigen

1968
Development of
Rh Immunoglobulin

1970
First Clinical Trials
of Cyclosporin

1967
Preventing Childhood
Poisonings: First Child
Safety Caps

1969
Vitamin D in Milk

1972
Discovery of Herapin
for Blood Clots

1977
Discovery of
Prolactin

1974
Identification of
P-glycoprotein

1978
Aspirin for
Stroke Prevention

1980
Development of
Ganciclovir

1981
Discovery of Atrial
Natriuretic Peptide

1983
Discovery of
T-Cell Receptor

1985
Discovery of SH2
Protein Domain

1989
Cystic Fibrosis
Gene Identified



1993
Apolipoprotein E4 and
Alzheimer's Disease

1989
3TC Joins the Fight
Against Hep B and HIV

1993
Site-directed
Mutagenesis

1991
Clinical Trials
of STC

1995
Identification of
Early-Onset
Alzheimer's Genes

1995
Co-Discovery of
Photodynamic Drug
Vertporfin



2000
First Vaccine to
Prevent Alzheimer's
in Mice

1997
Nanocrystalline Silver
Wound Dressings

1996
New Treatment Method
for Retinoblastoma



2007
Discover of New
Anti-Malaria Agent

2002
First Infant
Meningitis Vaccine

2006
Reducing the Symptoms
of Alzheimer's: Scyllo-Inositol

2004
World's First Use of
Palladium 'Seeds'



2011
First HIV
Prevention Vaccine



2013
Targeting Cancer
Stem Cells

2013
New Micro-Tissue Model

PATIENTS, INDUSTRY WORKING TOGETHER TO CONTINUOUSLY IMPROVE HEALTHCARE

NO SINGLE PERSON OR ORGANIZATION HAS SOLE RESPONSIBILITY FOR CANADIAN HEALTHCARE.

The system works because all stakeholders — patients, healthcare professionals, governments, private payers and supporting industries — work together for the betterment of all.

“These are vital relationships that put the needs of patients first, providing them with the most appropriate care,” said John Helou, President of Pfizer Canada Inc. and Incoming Chair of the Board of Directors for Canada’s Research-Based Pharmaceutical Companies (Rx&D). “Together, we can work on ensuring Canadians have access to the medicines they need, that they are used safely, and that we relieve pressure on the overall healthcare system.”

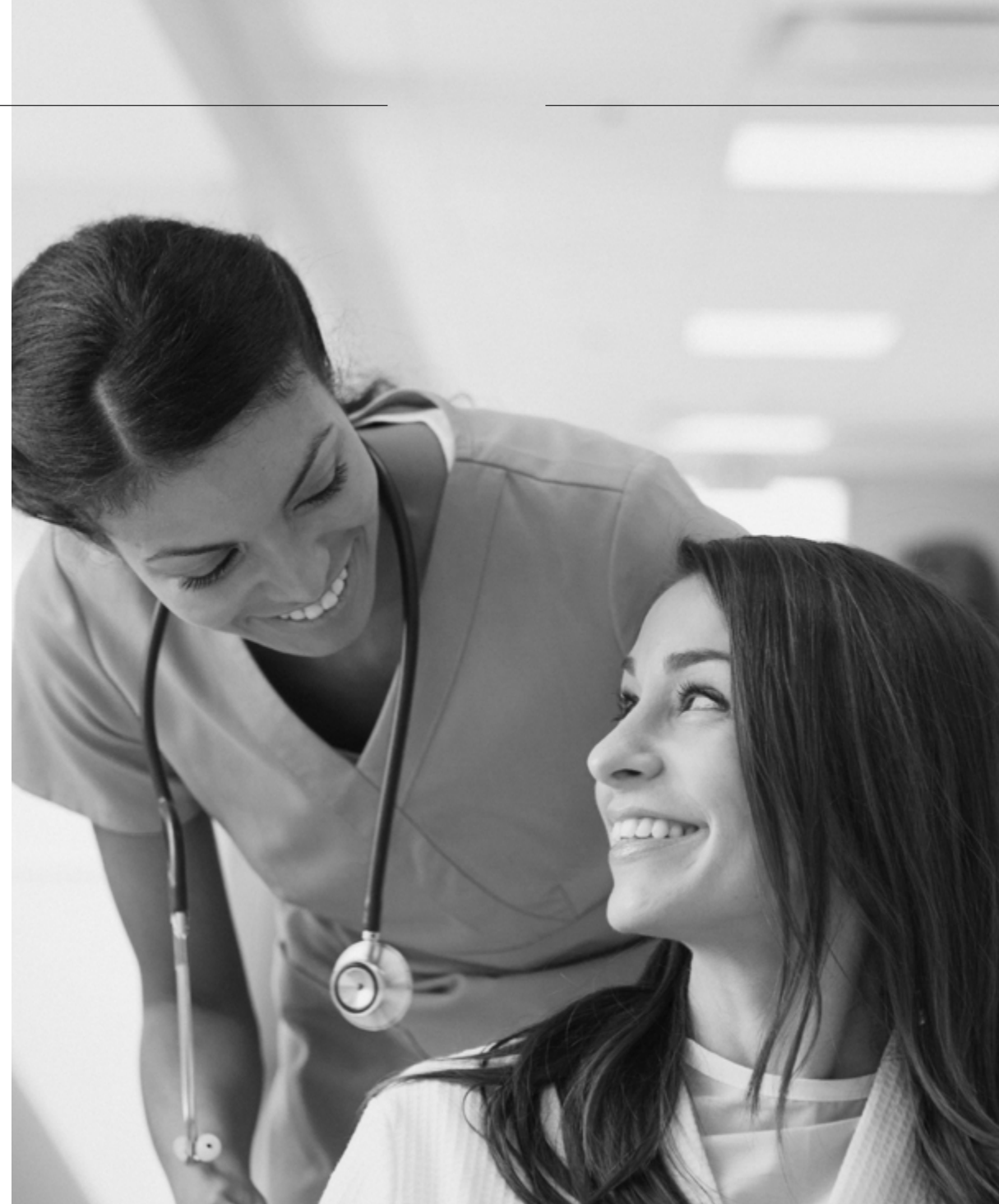
Canada’s innovative pharmaceutical companies are important partners in this group, in part because of their unwavering commitment to follow a mandatory Code of Ethical Practices as a condition of their membership in Rx&D. Since 1988, Canada’s Research-Based Pharmaceutical Companies’ (Rx&D) Code of Ethical Practices has been the foundation of the

industry’s commitment to relationships based on trust, openness and transparency. This has earned Rx&D and its members international recognition as world leaders in ethical practices. Since its creation, the Code has been constantly modernized to incorporate ethical issues facing the industry and its stakeholders.

Rx&D also helped create the Consensus Framework for Ethical Collaboration, an initiative of the International Federation of Pharmaceutical Manufacturers and Associations. The Framework brings together patient groups, doctors, nurses and the pharmaceutical industry to provide resources and guidance to promote transparency, respect, trust and clear and independent information about health treatments.

“Working together as trusted partners is vital to improving the health of Canadians,” says Gail Attara, Chair, Best Medicines Coalition and President, GI Society. “Our collective work is built upon a shared commitment to ethical practices. Excellent

healthcare is ethical healthcare that empowers patients to play an active role in managing their own health and making informed decisions about treatments and care.”



The National Research Council of Canada (NRC) and KalGene Pharmaceuticals recently announced an agreement to co-develop a new treatment against aggressive brain cancers. By combining their research, NRC and KalGene are targeting glioblastomas, which are severe brain tumours associated with a median patient survival of about 15 months.

Health Science North and its affiliate, the Advanced Medical Research Institute of Canada, have received a \$100,000 grant to conduct research into personalized medicine, which uses a patient’s individual DNA to diagnose and treat their illnesses. Roche Canada is supporting the work of the hospital and the Advanced Medical Research Institute of Canada, in what is being called the new frontier of medicine, where drugs and treatments are targeted at individuals rather than illnesses or diseases as a whole.

McGill University announced the creation of the Albert Boehringer (1st) Chair in Pharmacoeconomics, made possible through a \$3 million gift from Boehringer Ingelheim (Canada) Ltd. Bridging the disciplines of pharmacology and epidemiology, pharmacoeconomics examines the use and effect of medicines to assess their benefits and possible adverse effects for defined populations. Establishing a Chair is an opportunity for McGill to support students and fellows as they pursue research leading to improved treatments for diseases.

Servier Canada and the Research Centre of the Centre hospitalier de l’université de Montréal (CHUM) are collaborating on the OPTI-THERA program, an avant-garde diagnostic platform that will combine genetic factors, biomarkers, and clinical signs to accurately treat patients or allow earlier detection. The program focuses on the renal complications of diabetes.

DRIVING VALUE AS A HEALTHCARE SYSTEM TEAM

Through Value Demonstrating Initiatives (VDI), industry, government and/or other stakeholders work together to identify and deliver practical, scalable and independently verified approaches to healthcare delivery. VDIs can improve patient outcomes and demonstrate the value of medicines.

In partnership, five Rx&D members, the Rx&D Health Research Foundation (HRF), Vitalité Health Network, Horizon Health Network and the New Brunswick Department of Health created and implemented Diabetes Clinical Order Sets (DCOS). This two-year, \$250,000 project will improve glycemic management and improve outcomes for hospitalized seniors with diabetes, eventually across New Brunswick’s hospitals by ending the use of sliding scales for determining insulin therapy and enable the adoption of a basal (overnight fasting and between-meals) and nutritional insulin regimen, based on individualized treatments and a collaborative model of care. Evidence shows the sliding scale approach in which regular insulin is given only in response to particularly high blood glucose levels can lead to erratic glucose control resulting in patient risk and longer hospital stays. The goal of the project is generate evidence to inform clinical practice to reduce complications and shorten hospital stays.

To improve the health outcomes of chronic obstructive pulmonary disease (COPD) patients, who are at high risk of hospitalization, four Rx&D member companies, Rx&D, the Rx&D HRF, the Ontario Ministry of Health and Long-Term Care and the Ontario Lung Association have formed a two-year partnership. The project will focus on measuring a variety of interventions – including appropriate pharmacotherapy, clinical and quality of life improvements – and their impact on improving patient outcomes, leveraging the provincial HealthLinks model and driving health system and resource allocation efficiencies. Three Local Health Integration Networks will participate and patients will be enrolled in early 2015.

A partnership between five Rx&D members, the Rx&D HRF, the British Columbia Ministry of Health, the University of British Columbia’s Personalized Medicine Initiative PMI, GenomeBC and others is evaluating the use of pharmacogenomic markers to improve prescribing, adherence and health outcomes in primary care settings with a focus on seniors currently taking multiple medications. The goal of the project is to demonstrate how personalized healthcare, or using genomic markers, can decrease healthcare costs and improve health outcomes for patients by reducing unnecessary adverse events, reducing mortality and improving quality of life.

CODE OF ETHICAL PRACTICES HELPS PROTECT PATIENTS

Over 20 years ago, Canada’s Research-Based Pharmaceutical Companies created the Code of Ethical Practices, which helps ensure interactions between doctors and pharmaceutical companies are done to the highest ethical standard. It is a tangible demonstration of the innovative pharmaceutical industry’s commitment to relationships based on trust, openness and transparency.

The Code, which is constantly reviewed, upgraded, improved and strengthened, explicitly prohibits gifts or other inducements to healthcare professionals and other stakeholders, and mandates that all interactions between Rx&D member companies and healthcare professionals be conducted in an ethical and professional manner.

THE GUIDING PRINCIPLES OF THE CODE ARE:

The health and well-being of patients and all Canadians is the first priority of the innovative pharmaceutical industry.

The independence and integrity of stakeholders, in terms of their operations, policies and activities, should be assured.

All interactions with stakeholders should be conducted in a manner that avoids any real or perceived conflict of interest.

Joint activities should be based on mutual respect and trust, with the parameters of such ventures clearly delineated.

Members should encourage stakeholders to obtain funding for their operations and activities from multiple sources.

Members should maintain transparent funding relationships with all stakeholder partners, and require their stakeholder partners to do likewise.

Clear lines of communications should be established at an early stage of any undertaking between members and stakeholders.

CANADA PUTTING THE FOCUS ON CLINICAL TRIALS

CLINICAL TRIALS ARE REQUIRED TO BRING SAFE, INNOVATIVE AND EFFECTIVE DRUGS, VACCINES AND DEVICES TO MARKET. THEY OFFER HIGHLY CONTROLLED SETTINGS TO TEST NEW DISCOVERIES ON HUMANS.

In addition to the opportunity they represent for future therapeutics, they also can provide hope to Canadians as they represent access to new, potentially life-saving medications and therapies. In Canada, research-based pharmaceutical companies invest \$750 million annually into clinical trials, representing a major contribution to life sciences R&D spending in Canada. In turn, clinical trials give Canadians tailored care that meets their needs by using family history and details about individual habits and lifestyle to create personalized therapies and treatments and therapies. They also allow Canadian healthcare professionals and hospitals to introduce innovative new therapies.

However, clinical trials face some challenges in Canada both domestically and from international competition. Canada benefits from a first-rate reputation for clinical research in Canada and the pharmaceutical industry is working with its partners in innovation to ensure Canada remains attractive for global investments in R&D.

In an effort to address these and other challenges, a Clinical Trials Action Plan and Canadian Clinical Trials Coordinating Centre (CCTCC) were created as a result of the Summit on Clinical Trials in Canada, to re-establish Canada as a preferred destination for research and development. The CCTCC coordinates links and leverages interdisciplinary and inter-provincial clinical trial improvement activities.

Furthermore, through the Comprehensive Economic and Trade Agreement (CETA) negotiations, Canada is taking important steps in strengthening its intellectual property (IP) protections for life sciences to levels already in place in the other major developed countries. By harmonizing IP standards with other jurisdictions,

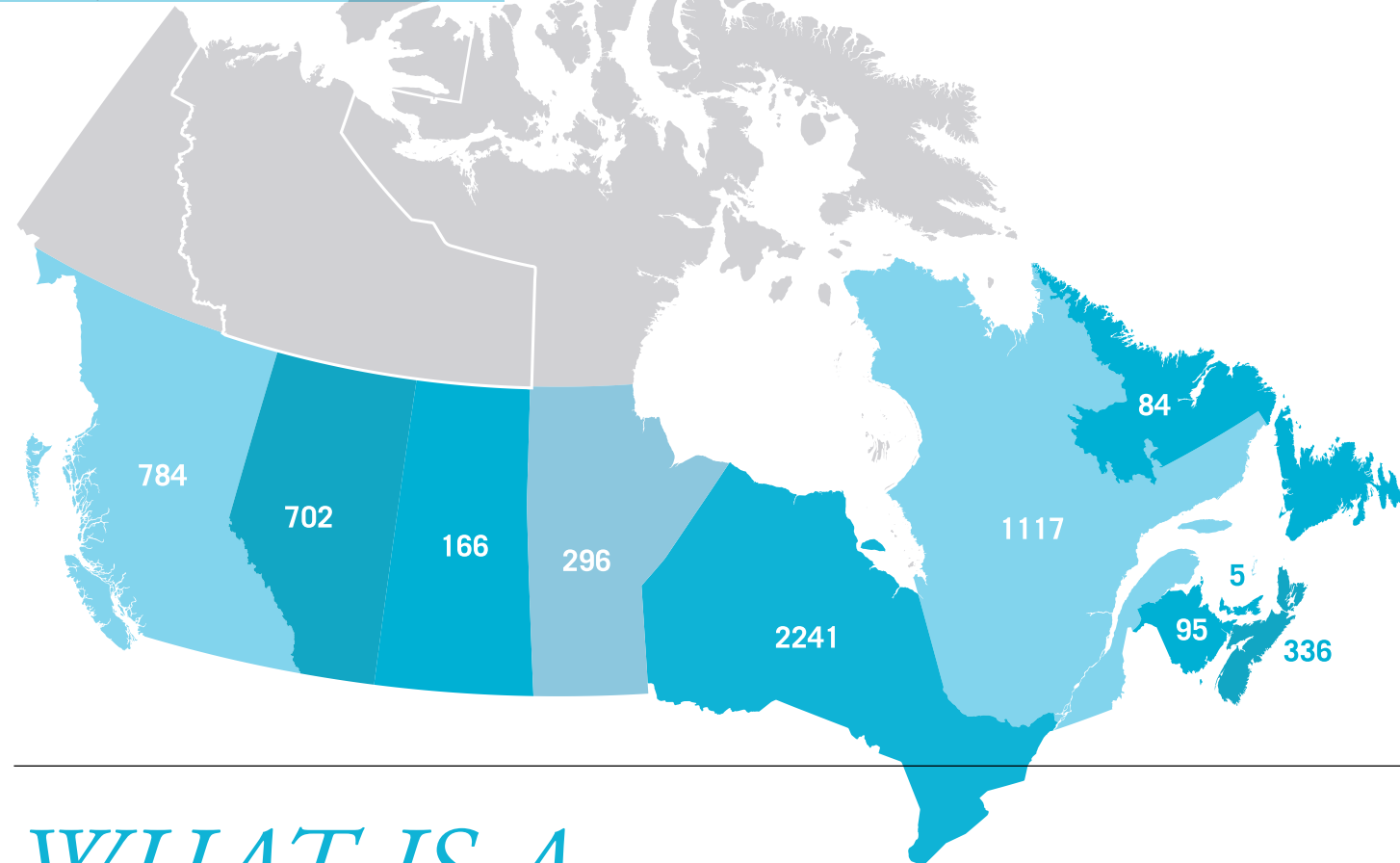
Canada will become a more attractive, secure, and sustainable place for investment. This is essential to sustaining Canada’s life sciences sector and to maximizing investment into Canadian clinical science from global sources.

“Canada is not the only country that benefits from clinical trials. Other countries compete with us and those that that provide the best comparative return on investment for increasingly scarce research dollars win contracts; when this happens, Canadians lose,” said Belinda Vandersluis, Director of Implementation, Canadian Clinical Trials Coordinating Centre (CCTCC). “We need to work together to ensure that Canada – and most importantly Canadians – win on this front.”

One recommendation of the Action Plan was to create the Canadian Clinical Trials Asset Map, a unique, robust, searchable web-based database designed to communicate Canada’s clinical research strengths to all stakeholders, including clinical trial sponsors. The Asset Map will help showcase Canada’s capability to conduct clinical trials and help re-position Canada as an attractive clinical trials destination globally.

“The innovative pharmaceutical industry plays a critical role in the discovery and development of medicines and vaccines that improve and save human lives. It is our goal, through this partnership, to build Canada’s as a leader in clinical research for the benefit of all Canadians,” said Russell Williams, President, Canada’s Research-Based Pharmaceutical Companies (Rx&D).

THE NUMBER OF ACTIVE CLINICAL TRIALS IN CANADA, DISTRIBUTED BY PROVINCE



WHAT IS A CLINICAL TRIAL ANYWAY?

A clinical trial is an investigation in which a medication, treatment or device is given to research participants to learn about how well it works, its safety and its side effects.

We learn more about new medications, treatments and devices and whether they improve health through carefully conducted clinical trials. In Canada, clinical trials are conducted with oversight from Health Canada and a research ethics board.

WHY CLINICAL TRIALS?

- To see if a new medication, treatment or device is safe and effective for people to use.
- To compare two or more existing medications, treatments or devices to determine which is better.
- To study new ways to use standard (approved) medications, treatments or devices.
- To learn how best to use medications, treatments or devices in a different populations, such as the elderly or children.

WHAT'S IN IT FOR ME?

You may gain access to new medications, treatments or devices, which may be beneficial to your health. You may receive care specific to the clinical trial, which may include additional testing and/or more frequent follow up with medical staff for the condition being studied. You will help others by contributing to medical research and treatment advances. You may have the opportunity to gain additional knowledge about your own medical condition. There are different benefits and risks with each clinical trial. Please discuss with your family, friends and doctor before you participate.

Source: N2 Canada's Alliance for Excellence in Clinical Research

FROM BEAKERS TO BRICKS

Innovative pharmaceutical industry active partner in community-minded initiatives

While they are well known for developing ground-breaking medications that help Canadians live longer and healthier lives, Canada's Research-Based Pharmaceutical Companies (Rx&D) are also active partners in community-minded initiatives that build stronger communities.

Rx&D member companies annually donate an estimated \$80 million to charities and non-profit organizations, collaborating with hundreds of organizations, patient support groups and community efforts to build better, stronger communities across Canada.

The innovative pharmaceutical industry has demonstrated that it cares for Canadians throughout their lives, which extends to end of life care. Living Lessons®, a partnership between the Canadian Hospice Palliative Care Association, hospice palliative care organizations and The GlaxoSmithKline Foundation, helps raise awareness of and support for hospice palliative care services to help enhance the quality of end-of-life care.

In 2013, compassionate care and special access programs for medications from Rx&D members added up to \$178 million. Patient assistance programs provide patients with information, support and access to innovative medicines to best manage their health and well-being. They are intended to improve adherence

to treatment and assist patients to access the medication that is best for them.

Rx&D members also actively encourage and support the next generation of healthcare practitioners, scientists and researchers by sponsoring academic scholarships in Canadian universities, as well as provide support for scholarships to organizations like the Canadian Nurses Foundation.

And just recently, Rx&D piloted a project to implement a national community service week for the association and its members. By partnering with Habitat for Humanity, Rx&D partly funded and staffed the building of four new homes in Vancouver, Calgary, Montreal & Halifax. Nearly twenty pharmaceutical companies were represented.

"Canadians who work in the pharmaceutical sector are not only community-minded themselves, but they are members of and often beneficiaries of the many community-based organizations we support," says Martine Elias, Director, Patient Engagement Strategy at Janssen Inc. "We feel a great sense of pride in working for companies that think beyond their corporate walls, for companies that care for the communities in which they operate."

LENDING A HELPING HAND



In partnership with Habitat for Humanity, Rx&D and its member companies participated in the building of four new homes in Vancouver, Calgary, Montreal & Halifax.

When a family is struck with the devastating news a loved one has been struck by cancer, they turn organizations like Willow to get them through an incredibly difficult and trying time.

Willow Breast & Hereditary Cancer Support provides confidential support through the strength, compassion and understanding that comes with hard-earned knowledge — but it wouldn't be able to reach as many people as it does without strategic partnerships like it has with Canada's Research-Based Pharmaceutical Companies (Rx&D).

Like many organizations, Willow relies on industry partnerships for funding and in-kind support to deliver information and programs that empower people with breast cancer to take charge of their health and make informed decisions. As a trusted source of information, Willow is often called on by patients who wish to learn more about treatment options, side effects and other questions regarding medication. The support Willow provides facilitates adherence to treatment plans and often compliments patient assistance services provided by pharmaceutical companies.

"Community partnerships are essential to the work of Willow and other patient support organizations," says Jeffrey Beach, CEO of Willow. "Working together with industry has allowed Willow to reach broader audiences, connect with more patients and families and provide better support and information, for people across the spectrum of breast cancer, from those at risk, to those in active treatment, survivorship, people living with advanced breast cancer and those facing end of life."

We've seen it on the news and we've read about it: developing nations are often faced with widespread health crises and it is often difficult – sometimes impossible – for patients to get access to the medicines that they desperately need.

GLOBAL COMPASSION

And the problem isn't just about getting medicines on the ground. Infrastructure, education, and access to clean water are major hurdles to overcome.

HOW CANADA AND THE INNOVATIVE
PHARMACEUTICAL INDUSTRY ARE PART OF
THE SOLUTION IN THE DEVELOPING WORLD



Through a series of multinational affiliations and partnerships, research-based pharmaceutical companies are active in a global compassion movement that is supporting 220 aid programs in 160 countries.

The participation varies, from donations of dollars and supplies to strategic partnerships that encourage the growth of domestic pharmaceutical industries.

- In response to the disastrous Ebola outbreak in West Africa this year, Medicago Inc. is part of the ongoing Canadian and International effort, working with partners to develop and possibly produce antibodies to combat the disease.
- Earlier this year Janssen, the pharmaceutical companies of Johnson & Johnson launched a collaborative initiative called New Horizons Advancing Pediatric HIV Treatment. At the core of this is a drug donation program to expand access to the company’s approved HIV medicines for children and adolescents failing HIV treatment in sub-Saharan Africa. The number of HIV-infected children receiving antiretroviral therapy is still extremely low—a mere 24% [1]. Together with our partners including the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), the goal is accelerate access to treatment for children and adolescents infected with HIV.
- Merck for Mothers is a 10 year, \$500 million initiative to reduce maternal mortality worldwide. The focus is the two leading causes of death – postpartum hemorrhage and preeclampsia – and on family planning, a powerful prevention tool to save women’s lives. Merck for Mothers leverages Merck’s scientific and business expertise to support sustainable solutions. In 2014, Gilead Sciences expanded its partnerships with multiple generic drug manufacturers to produce high-quality, low-cost Gilead HIV medicines for the developing world. Currently, 19 manufacturers in India, China and South Africa hold Gilead HIV licenses, and today 6.7 million people living with HIV in low- and middle-income countries are receiving Gilead-based regimens – more than half of all people on antiretroviral treatment in the developing world. In addition, Gilead has entered licensing agreements with seven Indian companies to expand access to its hepatitis C medicines in 91 countries that together account for more than 100 million infected with the hepatitis C virus.
- The Pfizer Foundation has announced \$2 million in grant funding for pilot programs to improve immunization coverage in Africa. The programs will focus on ‘last-mile’ interventions to reach underserved populations living in Ethiopia, Malawi, Rwanda, Uganda and Zambia. The grants will focus on building the capacity of healthcare systems within the five countries to ensure that efficient and sustainable vaccine supplies are available to reach children who need access to vaccines.

In May of 2014, Rx&D participated in Prime Minister Stephen Harper’s Maternal, Newborn and Child Health Summit in Toronto. The Summit, “Saving Every Woman, Every Child,” brought together domestic and international leaders from government, NGOs, and the private sector to renew the global commitment to fund and implement programs that will reduce the burden of disease, improve nutrition and strengthen health systems in the developing world. Rx&D Board Chair and Sanofi Pasteur President Mark Lievonen participated in a panel entitled “Saving Lives Through Immunization.” He spoke of the increasing number of lives saved by improving vaccination rates in the developing world. Since 1990, there has been a 43 per cent drop in the number of deaths of children under the age of five. This international effort is helping save 14,000 children every day from premature death, due to measures like vaccinations against polio, measles and malaria.



Ever wonder where Canadian doctors get the essential medicines and medical supplies they need to do volunteer medical missions to the developing world?

For more than two decades they have been turning to Health Partners International of Canada (HPIC). HPIC is a not-for-profit relief and development organization that delivers health and hope to the world’s most vulnerable people. Our mission is to increase access to medicine and improve health in the developing world.

Rx&D helped kick-start HPIC’s mission into action in 1990. The association rallied Canada’s research-based pharmaceutical companies to send emergency medical relief through HPIC to Iran following a devastating earthquake.

Since that first project, Rx&D and its members have continued to work through HPIC to respond to dozens of emergencies, to support Canadian doctors and mission teams, and to provide bulk shipments in response to the needs of hospitals and clinics in the developing world.

In 2015, HPIC will be marking its 25th anniversary; 25 years built on the support of partners like founding donor Rx&D, as well as its member companies.

These 25 years have amounted to HPIC delivering more than \$450 million in essential medicines and medical supplies to over 100 countries.

GLEN SHEPHERD
PRESIDENT AND CEO OF HEALTH PARTNERS
INTERNATIONAL OF CANADA
([HTTP://WWW.HPICANADA.CA](http://www.hpicanada.ca))



HEALTH RESEARCH IN ACTION

EVERYONE BENEFITS WHEN PEOPLE ARE HEALTHY.

That’s what Canada’s Health Research Foundation (HRF) has known for 50 years. Founded in 1964 by Canada’s Research-Based Pharmaceutical Companies (Rx&D), the HRF makes significant annual investments in research and innovation. When research leads to better health outcome, it also means that Canadians can live full, productive lives. Their families, friends and communities benefit. As does Canada’s healthcare system.

Through its programs, the HRF invests in partnership-driven applied research projects that aim to improve healthcare sustainability, recognizing the importance of public and private partnerships in creating innovative solutions to improve the health of Canadians. The foundation also funds interdisciplinary research, which integrates knowledge from multiple disciplines to address a problem that goes beyond a single area of research. These collaborations enhance the ability to find

better treatments for patients and increase the ability of these treatments to be effectively translated into practice. Finally, working with the Canadian Institutes of Health Research, the HRF funds research focused on patients themselves, looking at short and longer term impacts on patients including patient experience, safety, and quality of life.

“We are truly very appreciative of the funding from HRF. This funding is allowing us to conduct research on how to best improve access to treatment for depression and anxiety using the Internet. Depression and anxiety are highly prevalent, disabling conditions that are often under treated. Without funding, it is very difficult to develop and research innovative novel treatments that can overcome barriers to treatment and improve the healthcare delivery system,” said Heather D. Hadjistavropoulos who received funding from the Foundation for the work she is doing on therapist-assisted Internet-Cognitive Behaviour Therapy (ICBT) at the University of Regina.

Recognizing excellence and pivotal contributions to health science is a part of the process to drive cutting-edge research. That’s why the HRF has awarded its medal of honour to remarkable individuals whose research or contributions to public policies supportive of research and development in Canada have achieved international recognition.

“Over the last 50 years, the HRF has adapted its research programs to respond to the health needs of Canadians. Putting the health of Canadians first will continue to drive our research investments, our partnerships and our focus to ensure we all live healthier lives,” said Mel Cappe, newly appointed Chair of the HRF and Professor in the School of Public Policy and Governance at the University of Toronto.



THANKS IN PART TO HRF FUNDING, HEATHER D. HADJISTAVROPOULOS’ RESEARCH IS HELPING PATIENTS OVERCOME DEPRESSION AND ANXIETY.

A LOOK AT SOME OF THE PAST RECIPIENTS OF THE HRF MEDAL OF HONOUR

Dr. Julio Montaner, for his life changing contributions to the field of HIV/AIDS including development of Highly Active Antiretroviral and Treatment as Prevention Therapies

The Honourable Kelvin K. Ogilvie, for the invention of the “Gene Machine” and Ganciclovir as well as his contribution to public policies supportive of health research in Canada

Dr. Charles M. Scriver and Mr. Arnold Steinberg, for ensuring the addition of Vitamin D to milk in Quebec and in establishing a Metabolic Food Distribution centre

The Right Honourable Brian Mulroney, for his contribution to the Canadian healthcare system

Dr. Bernard Belleau for the discovery of 3TC

Dr. Lap-Chee Tsui and Dr. Jack Riordan, for the discovery of the defective gene causing cystic fibrosis

Dr. Edward C. Kendall, for the discovery of cortisone

Dr. Charles H. Best, for the co-discovery of insulin

Sir Alexander Fleming, for the discovery of penicillin



“One
sometimes
finds
what
one
is not
looking for.”

SIR ALEXANDER FLEMING



MY LIFE
is to be active

MY MEDICINE
is my hope



My name is
Gerard Genest
I'm from Montreal
and I am cured
of Hepatitis C

I was born with hemophilia and have received many blood transfusions. As a child, I was still able to play hockey and continued being active into my adult years. My life changed forever when I contracted Hepatitis C from a blood transfusion at the age of 32. Doctors kept me alive long enough to try a new medicine through a compassionate care program. After living with the virus for 25 years, I was cured after 24 weeks. I was able to return to my family and to my life. Research saved my life.

www.canadapharma.org/hope

Rx&D MEMBER COMPANIES

Abbott Laboratories, Limited	JSS Medical Research Inc.
AbbVie Corporation	Janssen Inc.
Actelion Pharmaceutiques Canada	KalGene Pharmaceuticals Inc.
Almirall Ltd. (Canada)	Les Laboratoires BNK Canada inc.
Amgen Canada Inc.	LEO Pharma Inc.
Astellas Pharma Canada, Inc.	Lundbeck Canada Inc.
AstraZeneca Canada Inc.	Medicago
Bayer Inc.	Merck Canada Inc.
BioContact Quebec	NeuroImage Inc.
Boehringer Ingelheim (Canada) Ltd.	Novartis Pharmaceuticals Canada Inc.
Bristol-Myers Squibb Canada	Novo Nordisk Canada Inc.
Brunel Canada Ltd.	Nucro-Technics Incorporated
Ceapro Inc.	NutraSource Diagnostics Inc.
Charles River Laboratories	Otsuka Canada Pharmaceutical Inc. (OCPI)
Conundrum Solutions	Paladin Labs Inc.
Council for Continuing Pharmaceutical Education	Pfizer Canada Inc.
Dalton Pharma Services	Proteocyte Diagnostics Inc.
Eisai Limited	Purdue Pharma
Eli Lilly Canada Inc.	Ropack Inc.
EMD Serono, A division of EMD Inc.	Sanofi Canada
Endoceutics Inc.	Sanofi Pasteur Limited
Forest Laboratories Canada Inc.	Servier Canada Inc.
Genome Canada	Shire Canada Inc.
Gilead Sciences Canada, Inc.	Sunovion Pharmaceuticals Canada Inc.
GlaxoSmithKline Inc.	Takeda Canada, Inc.
GLyPharma Thérapeutique Inc.	Therapure Biopharma Inc.
Hoffmann-La Roche Limited	Theratechnologies Inc.
InterMune Canada Inc.	

